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Global assessment of the severity of epilepsy (GASE) Scale in children: Validity, reliability, responsiveness

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FULL-LENGTH ORIGINAL RESEARCH

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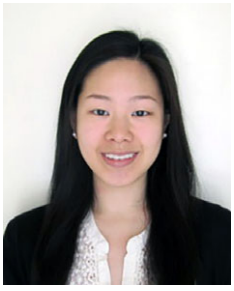

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Summary

Objective: **The Global Assessment of Severity of Epilepsy (GASE) Scale is a single-item, 7-point global rating scale designed for neurologist-report of overall severity of epilepsy in children. Building on previous preliminary evidence of its validity and reliability for research and clinical use, this study evaluated the GASE Scale's construct validity, reliability, and responsiveness to changes in severity of epilepsy.**

Methods: **Data used for the study arose from the Health-Related Quality of Life in Children with Epilepsy Study (HERQULES), a 2-year multicenter prospective cohort study (n = 374) with observations taken at baseline, and 6, 12, and 24 months after diagnosis. Construct validity and reliability were quantified using Spearman's correlation and intraclass correlation coefficient (ICC). Responsiveness was assessed using both distribution-based and anchor-based indices.**

Results: **The GASE Scale was at least moderately correlated ($r \geq 0.30$) with several key clinical aspects and most strongly correlated with frequency and intensity of seizures and interference of epilepsy or drugs with daily activities ($r > 0.30$). Total variation in GASE Scale scores explained by seven core clinical aspects of epilepsy increased over time (R^2 = 28% at baseline to R^2 = 70% at 24 months). The GASE Scale had modest test–retest reliability (ICC range: 0.52–0.64) and was responsive to changes in clinical criteria (standardized response mean range: 0.49–0.68; probability of change range: 0.69–0.75; Guyatt's responsiveness statistic range: 0.56–0.84). The GASE Scale showed potential to discriminate "stable" and "changed" patients according to select criteria and to a composite score (area under the receiver operating characteristic [ROC] curve range: 0.50–0.67).**

Significance: **Results offer additional evidence in support of the GASE Scale's validity, reliability, as well as responsiveness to changes in severity of epilepsy in children. We conclude that the GASE Scale is a potentially useful tool for assessing the severity of epilepsy in both clinical and research settings.**

KEY WORDS: **Epilepsy severity, Global ratings, Validity, Reliability, Responsiveness.**

The severity of epilepsy has been assessed predominantly with measures of the severity of seizures. These measures fail to address other dimensions of epilepsy such as disability caused by disease and side effects of antiepileptic drugs (AEDs). Most existing scales are limited by the difficulty of use and inadequate evidence supporting validity, reliability, and responsiveness to change.[1] The International League Against Epilepsy (ILAE) has emphasized the importance of broader assessment tools to better capture the severity of epilepsy.[2]

The Global Assessment of Severity of Epilepsy (GASE) Scale is a single-item, 7-point global rating

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Key Points

- GASE Scale captured important clinical aspects in assessing overall severity of epilepsy in >300 children with newly diagnosed epilepsy
- GASE Scale's validity is supported by moderate/strong correlations with clinical aspects, with seizure frequency/intensity and interference being strongest
- Both distribution-based and anchor-based methods provided evidence that GASE Scale detected within-patient changes in severity of epilepsy
- GASE Scale showed potential to discriminate "stable" and "changed" patients according to select clinical criteria and to a composite score
- Further research is needed to define meaningful stability and change for clinical criteria and the GASE Scale

scale. It was developed as a clinician-report measure to assess the overall severity of epilepsy in children and to provide a simple and efficient tool to capture the multidimensional nature of epilepsy. Previous research provided preliminary evidence to support the GASE Scale's content and convergent validity, inter-rater and test–retest reliability, and discriminative properties for three types of epilepsy syndromes using a clinical case scenario method.[3] The purpose of this study was to further assess the measurement properties of the GASE Scale when applied by neurologists to assess patients in their care using data from a large prospective cohort study. Specifically, we assessed the GASE Scale's construct validity, reliability, and responsiveness to change in the severity of epilepsy.

We hypothesized that the GASE Scale would have at least a moderate degree of construct validity and test–retest reliability, and be sensitive to changes in the severity of epilepsy.

Methods

Data source and study sample

The Health-Related Quality of Life in Children with Epilepsy Study (HERQULES) provided the data for this study. HERQULES is a 2-year prospective cohort study assessing the course and determinants of health-related quality of life (HRQL) in children with new onset epilepsy across Canada.[4] Using a two-stage clustered sampling strategy between April 2004 and April 2007, 53 (74%) of practicing pediatric neurologists in Canada recruited parents of children with epilepsy (median: nine families per physician). The sample included children ages 4–12 years with ≥2 unprovoked seizures. The children were seeing a pediatric neurologist for the first time and had not received confirmation of the diagnosis of epilepsy previously. Details of HERQULES have been described previously.[4]

Measures

At baseline, and at 6, 12, and 24 months following the diagnosis of epilepsy, a questionnaire collected parent-report of their children's HRQL and a series of child and family characteristics, while a physician-report form collected information on clinical characteristics of the child's epilepsy. HRQL was measured using the Quality of Life in Childhood Epilepsy Questionnaire (QOLCE)[5] and the Child Health Questionnaire (CHQ).[6]

Parent report

Parents' responses to two questions contained in the QOLCE were used to represent parents' perceptions of their child's health. The first question asked: "Compared to other children his/her age, how do you think your child's health has been in the past 4 weeks? Please consider your child's epilepsy as part of his/her health when you answer this question." Response options were: 1 = "Poor"; 2 = "Fair"; 3 = "Good"; 4 = "Very good"; and 5 = "Excellent." The second question asked: "Compared to 1 year ago, how would you rate your child's health now?" Response options were: 1 = "Much better now than 1 year ago"; 2 = "Somewhat better now than 1 year ago"; 3 = "About the same now as 1 year ago"; 4 = "Somewhat worse now than 1 year ago"; and 5 = "Much worse now than 1 year ago."

Physician report

The GASE Scale asked physicians to rate the overall severity of each child's epilepsy at the time of clinical assessment.[3] It is a single-item, 7-point Likert scale that asks: "Taking into account all aspects of this patient's epilepsy, how would you rate its severity at his/her last visit? Please check *one* answer." Response options are 1 = "Not at all severe"; 2 = "A little severe"; 3 = "Somewhat severe"; 4 = "Moderately severe"; 5 = "Quite severe"; 6 = "Very severe"; 7 = "Extremely severe."

Physicians also documented the following seven core clinical aspects (selected by an expert clinical panel)[3] of each patient's epilepsy: frequency of seizures, intensity of seizures, falls or injuries during seizures, severity of the postictal period, amount of AEDs (denoting the combination of number and dosage), side effects of AEDs, and interference of epilepsy or drugs with daily activities. These aspects were rated on a 7-point Likert scale with 1 = "none or never" and 7 = "extremely frequent, severe, or high." As additional indicators of severity, physicians also recorded the occurrence of convulsive status epilepticus, whether seizures were exclusively nocturnal, and the number of AEDs currently.

Analysis

Construct validity was assessed by measuring the correlation of GASE Scale scores with neurologists' ratings of

clinical characteristics of epilepsy and with parents' perceptions of their child's health at baseline, and at 6, 12, and 24 months postdiagnosis. We used Spearman rank-correlation coefficient; values of 0.10–0.30 were regarded as weak; 0.30–0.50 as moderate; and >0.50 as strong correlations.[7] Multiple linear regression was used to assess the specific relationship between GASE Scale scores and the seven core clinical aspects of epilepsy, while adjusting for the effects of the other aspects. R^2 from multiple regression analyses (with 95% confidence interval [CI]) assessed the proportion of total variation in GASE Scale scores explained by the seven core clinical aspects of epilepsy.

Test–retest reliability was assessed on the basis of seven clinical criteria informed by clinical experts: frequency of seizures, intensity of seizures, falls or injuries during seizures, severity of the postictal period, convulsive status epilepticus, exclusively nocturnal seizures, and number of AEDs currently; as well as a composite score of these items and the parents' perceptions of their child's health. We chose the 6–12 month postdiagnosis interval to assess test–retest reliability because this 6-month interval is when patients were most likely to be clinically stable.[8] Patients were classified as "stable" on the clinical criteria if there was zero change from 6 to 12 months and "changed" if scores were different during this time period.

Test–retest reliability was quantified using intraclass correlation coefficient (ICC) with 95% CI, and paired *t*-test calculated for GASE Scale scores from 6 to 12 months postdiagnosis for each "stable" subsample. An estimated ICC value for reliability of measurements over time[9] above 0.7 was regarded as adequate reliability.[8,10] The paired *t*-test was additionally used to test the difference in mean GASE Scale scores at 6 and 12 months postdiagnosis for the stable subgroup.

Responsiveness was assessed using both distribution-based and anchor-based methods. The standardized response mean was used to assess internal responsiveness.[11] Specifically, at each time point compared to baseline, the mean change in GASE Scale score was divided by the standard deviation of the respective change in scores.[12] To interpret the standardized response mean, the probability of change statistic was also calculated based on the cumulative normal distribution. Probability of change ranges between 0.5 (no ability to detect change) and 1.0 (perfect ability). A probability of change >0.5 suggests that the scale is able to detect changes.[11]

For the anchor-based analysis, we used as external criteria the change scores between baseline and 12 months postdiagnosis in the seven clinical aspects of epilepsy used to assess reliability, their composite score, the parents' perceptions of their child's health, and the GASE Scale. This period of time was expected to show the largest change in the study patients. Only 12 months postdiagnosis was used for the second question assessing parents' perceptions of change in their child's health, which uses a global rating of change over the previous year. Patients were classified as "stable" or "changed" as described earlier. For each "changed" subgroup, Guyatt's responsiveness statistic was calculated for GASE Scale scores and interpreted using Cohen's conventions for effect size as small (0.2); moderate (0.5); and large (0.8).[7] The area under the receiver operating characteristic (ROC) curve and 95% CI were used to assess the ability of GASE Scale change scores to discriminate between "stable" and "changed" patients with an area under the ROC curve of 0.50–0.70 classified as low; 0.70–0.90 as moderate; and >0.90 as high.[8] All statistical analyses were conducted using SAS Version 9.3 (SAS Institute Inc., Cary, NC, U). Statistical tests were two-sided and performed at the 0.05 level of significance.

Results

Patient characteristics

Of 456 parents, 374 (82%) completed the baseline questionnaire and 283 (62%) completed all four. Compared with those who completed the study (n = 283), children who were lost to follow-up (n = 91) were not significantly different ($p > 0.05$) in mean age, sex, severity of epilepsy, behavior problems, or levels of HRQL. However, parents returning all questionnaires were more likely to be older, married, and have higher education and income. Complete patient characteristics have been described previously.[4]

At baseline, the mean age of children was 7.5 (SD 2.3) years, and 52% were male. The majority of children were initially diagnosed with less severe types of epilepsy syndromes, specifically 38.5% with generalized epilepsies, 39.6% with localization-related (partial/focal epilepsies), 20.0% with partial/focal onset and secondary generalization, and 1.9% not determined as focal or generalized. The mean GASE Scale score was 2.57 (SD 1.19) (between "a little severe" and "somewhat severe" epilepsy). By 24 months, the mean GASE Scale score had decreased to 1.7 (SD 1.06).

Construct validity

Table 1 summarizes the association between GASE Scale scores and seven clinical aspects of epilepsy. All correlations were statistically significant at $p = 0.05$, except for amount of AEDs at baseline ($p = 0.20$). In most cases, the seven clinical aspects were moderately correlated with the GASE Scale. The strength of the correlations increased over time for all clinical variables. At every time point, three clinical aspects consistently showed the highest correlations with the GASE Scale: frequency of seizures, intensity of seizures, and interference of epilepsy or drugs with daily activities. The clinical variables showing the highest correlation with GASE Scale scores varied over time, that is, intensity of seizures at baseline, frequency of seizures at 6 months, and both frequency of seizures and interference with daily life at 12 and 24 months postdiagnosis. In the multiple lin-

Table 1. Spearman rank correlations of GASE Scale scores with seven clinical aspects of epilepsy assessed by neurologists at baseline, and 6, 12, and 24 months postdiagnosis

		Clinical aspects of epilepsy						
		Frequency of seizures	Intensity of seizures	Side effects of AEDs	Interference of epilepsy or drugs with daily activities	Falls or injuries during seizures	Severity of the postictal period	Amount of AEDs
Baseline	Spearman Rho	0.30	0.33	0.13	0.34	0.30	0.14	0.07
	95% CI	0.21, 0.39	0.23, 0.42	0.03, 0.23	0.25, 0.43	0.20, 0.39	0.04, 0.24	−0.04 to 0.17
	p-Value	<0.0001	<0.0001	0.0128	<0.0001	<0.0001	0.007	0.20
6 Months	Spearman Rho	0.51	0.45	0.30	0.47	0.28	0.24	0.28
	95% CI	0.42, 0.58	0.36, 0.53	0.20, 0.40	0.39, 0.55	0.18, 0.38	0.14, 0.34	0.17 to 0.37
	p-Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
12 Months	Spearman Rho	0.49	0.48	0.38	0.49	0.31	0.24	0.23
	95% CI	0.40, 0.57	0.36, 0.53	0.29, 0.47	0.41, 0.57	0.21, 0.40	0.14, 0.34	0.13 to 0.33
	p-Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
24 Months	Spearman Rho	0.60	0.58	0.46	0.60	0.42	0.37	0.38
	95% CI	0.53, 0.67	0.50, 0.64	0.37, 0.54	0.52, 0.66	0.32, 0.50	0.27, 0.46	0.28 to 0.47
	p-Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

ear regression analysis, the adjusted R^2 for the seven clinical aspects increased over time (from 28% at baseline to 70% at 24 months) (Table 2). Intensity of seizures explained the most variation in GASE Scale scores at baseline but at 6, 12, and 24 months, the frequency of seizures and interference of epilepsy or drugs with daily activities accounted for the most variance when all clinical aspects were included in the model.

GASE Scale scores were weakly associated with the parents' perception of poorer child health at baseline ($r = -0.17$; 95% CI −0.27 to −0.07; $p = 0.0013$) and 6 months ($r = -0.23$; 95% CI −0.33 to −0.12; $p < 0.001$). However, correlations increased to moderate at 12 months ($r = -0.31$; 95% CI −0.41 to −0.20; $p < 0.001$) and 24 months ($r = -0.34$; 95% CI −0.45 to −0.23; $p < 0.001$).

Test–retest reliability

As predicted, the majority of GASE Scale scores (48.8–73.3%) did not change in patients for whom neurologists reported stability in the key clinical aspects of epilepsy and the composite score (Table 3). Although GASE Scale change scores varied as much as ±4 points from 6 to 12 months, the changes were close to zero, and few patients had larger changes.

For all external criteria, the ICC ranged between 0.52 and 0.64 (Table 3). Relative to other clinical aspects, frequency of seizures was most strongly related to physicians' overall

Table 2. Multiple-linear regression analysis showing the coefficient of determination for each model (R^2) of the cross-sectional association between GASE Scale scores and seven clinical aspects of epilepsy at baseline, and 6, 12, and 24 months postdiagnosis

	Regression coefficients			
	Baseline	6 Months	12 Months	24 Months
Intercept	0.90*	0.42*	0.41*	0.01
Frequency of seizures	0.10*	0.28*	0.35*	0.47*
Intensity of seizures	0.24*	0.17*	0.03	0.12
Falls or injuries during seizures	0.15*	0.07	0.24*	0.14
Severity of the postictal period	−0.07	−0.10	−0.17	−0.22*
Amount of AEDs	−0.09	0.13*	−0.01	0.07
Side effects of AEDs	0.17*	0.10	0.25*	0.11*
Interference of epilepsy or drugs with daily activities	0.23*	0.24*	0.26*	0.42*
R^2	0.28*	0.43*	0.44*	0.70*
Adjusted R^2	0.27*	0.42*	0.43*	0.69*
95% CI for R^2	0.19, 0.35	0.34, 0.50	0.34, 0.51	0.63, 0.75
n	345	338	332	321
Missing	42	49	55	66

*Statistically significant at $p < 0.05$.

Table 3. Test–retest reliability (ICC and *t*-test) for GASE Scale scores from 6 to 12 months postdiagnosis among "stable" patients (see text for description)

External clinical indicator	ICC (95% CI)	*t*-test	n	No change in GASE Scale scores n (%)
Frequency of seizures	0.64 (0.54 to 0.72)	2.43 (p = 0.02)	176	118 (67.0)
Intensity of seizures	0.60 (0.50 to 0.69)	0.62 (p = 0.54)	170	110 (64.7)
Falls or injuries during seizures	0.53 (0.44 to 0.61)	1.64 (p = 0.10)	252	140 (55.6)
Severity of postictal period	0.54 (0.43 to 0.63)	2.03 (p = 0.04)	203	120 (59.1)
Convulsive status epilepticus (no at both times)	0.52 (0.43 to 0.59)	2.27 (p = 0.02)	295	144 (48.8)
Exclusively nocturnal seizures	0.55 (0.46 to 0.62)	2.40 (p = 0.02)	292	148 (50.7)
Number of AEDs currently	0.53 (0.42 to 0.60)	2.40 (p = 0.02)	268	139 (52.0)
Composite score				
[a]Frequency + Intensity + Falls + Postictal + CSE + ENS + AEDs	0.61 (0.47 to 0.72)	1.42 (p = 0.16)	101	82 (72.6)

[a]Frequency, frequency of seizures; Intensity, intensity of seizures; Falls, falls or injuries during seizures; Postictal, severity of the postictal period; CSE, convulsive status epilepticus; ENS, exclusive nocturnal seizures; AEDs, number of AEDs currently used.

assessment of stability in the GASE Scale scores, whereas convulsive status epilepticus was the least related. Results of the paired *t*-test showed evidence of stable GASE Scale scores (no significant difference $p > 0.05$) only for the subgroups classified as stable based on intensity of seizures, falls or injuries during seizures, and the composite score.

For children who were "stable" according to the parents' perception, the ICC for GASE Scale scores was 0.53 (95% CI 0.38–0.65) with $t = 1.7$ ($p > 0.05$).

Responsiveness to change

Distribution-based methods

For comparisons of all three subsequent time points with baseline, the standardized response means showed a moderate magnitude of change and the corresponding probability of change was >0.5, and it increased with comparisons at longer intervals (0.69 for 6 months to baseline, 0.72 for 12 months to baseline, and 0.75 for 24 months to baseline) (Table 4).

Anchor-based methods

There was a moderate correlation between change in mean GASE Scale scores from baseline to 12 months and change in the composite score, intensity and frequency of seizures, and severity of the postictal period over the same time period, ranging from 0.33 to 0.47. Change in GASE Scale scores from baseline to 12 months were only weakly associated with increases in falls or injuries during seizures and with the parents' perception of a decline in their child's health.

For all "changed" patients (based on clinical aspects and the composite score), GASE Scale scores from baseline to 12 months demonstrated a moderate to large magnitude of change (Guyatt's responsiveness statistic range: 0.56–0.84) (Table S1). The Guyatt's responsiveness statistic was highest for patients who "changed" in frequency and intensity of seizures (Guyatt's responsiveness statistic = 0.84). GASE Scale scores also demonstrated a moderate to large magnitude of change when parents reported a change in their child's health (Guyatt's responsiveness statistic range: 0.61–0.70).

The area under the ROC curve ranged from 0.50 to 0.67 for clinical aspects and parents' perception of change. It was highest for frequency of seizures, followed by the intensity of seizures and severity of the postictal period.

Table 4. Responsiveness indices, standardized response mean, and probability of change statistic for the GASE Scale scores at baseline compared with 6, 12, and 24 months postdiagnosis

GASE Scale change score	Standardized response mean (95% CI)	Probability of change (95% CI)
6 Months – baseline	−0.49 (−0.61 to −0.37)	0.69 (0.65 to 0.73)
12 Months – baseline	−0.58 (−0.71 to −0.45)	0.72 (0.68 to 0.76)
24 Months – baseline	−0.68 (−0.81 to −0.55)	0.75 (0.71 to 0.79)

Discussion

We found that the GASE Scale captured several important clinical aspects of overall severity of epilepsy in a sample of >300 children across Canada with newly diagnosed epilepsy, and provide further evidence for its measurement properties.

Construct validity of the GASE Scale is supported by at least moderate correlations with the majority of key clinical aspects. Frequency and intensity of seizures and interference of epilepsy or AEDs with daily activities contributed most strongly to the physician's assessment of epilepsy severity using the GASE Scale. This is consistent with preliminary findings of the relationship between GASE Scale scores and physician-rated clinical aspects,[3] and with

preliminary reports of moderate correlations between GASE Scale scores and frequency of seizures in adult patients with epilepsy.[13] The increasing strength in correlations between the GASE Scale and clinical parameters over time deserves further study. Plausible explanations include uncertainty at the time of diagnosis, and the effect of increasing familiarity with the patient's condition and response to medications. In addition, physician-rated assessments of clinical aspects and GASE Scale at baseline are primarily based on free historical recall from parents rather than on direct clinical observation. By 6 months, there may have been greater clarity to aid diagnosis and a more coherent assessment of severity. Some components of epilepsy severity become important only after the initial visit. For example, side effects of AEDs will have relatively less impact on severity at the time of diagnosis if physicians have not yet prescribed medication. It is also possible that as the epilepsy syndrome and type of seizures became clearer over time, the clinical features pertaining to each syndrome had a more stable and stronger influence on the overall assessment of severity in the clinician's mind.

Parents' perceptions of their child's health did not correlate strongly at every time point with the physician's assessment of severity of epilepsy. This may be because parents and physicians perceive the child's epilepsy differently[14] or because they were asked to rate different constructs. Although parents were asked a question with specific instruction to rate their child's health compared to other children his or her age and in doing so to consider their child's epilepsy as part of his/her health, physicians were asked to rate severity of epilepsy specifically, without any instruction to compare with a reference population. The increase in correlation over time may be attributed to physicians and parents sharing their unique expertise and experience with each other, thereby influencing their own understanding of the child's epilepsy.[14]

Although the results showed that GASE Scale scores did not completely remain stable when key clinical aspects of epilepsy indicated stability over a 6-month period, most patients changed by only one point on the GASE Scale from 6 to 12 months postdiagnosis. For stability according to the parents' perceptions, GASE Scale scores at the two time points also did not differ significantly, providing some evidence of the stability of GASE Scale scores over the 6-month period. This suggests that using "zero change" to define stability may have been over-restrictive and underrepresentative of clinical situations assessed with a single-item scale. A broader definition of stability may be more meaningful and may provide a more realistic interpretation of the reliability of the GASE Scale.

Several factors may have contributed to decreased test–retest reliability. The long interval for the current assessment of stability was limited by the data collection schedule of HERQULES, where the shortest interval was 6 months and longer than the typical interval recommended for assessing test–retest reliability. During this time, patients with newly diagnosed epilepsy may have experienced changes in therapy and health. Another reason could be the method used for classifying patients as stable according to individual clinical variables. Although reliability was higher when patients were classified by the composite score, the GASE Scale was designed to encompass all aspects of epilepsy including those that were not explicitly explored.

Both distribution-based and anchor-based methods provided evidence to support the ability of the GASE Scale to detect within-patient change over time in the severity of epilepsy in children. Results indicated a >50% probability of detecting change and suggests that the GASE Scale is sensitive in detecting change in the severity of epilepsy in children. The relatively low area under the ROC curve might be attributed to the restrictive definition of "stability" or nonspecific definition of "changed" patients. The results indicate potential for the GASE Scale to discriminate "stable" and "changed" patients according to select clinical criteria and to the composite score. However, a more thorough analysis is required to assess other aspects contributing to severity of epilepsy and to establish precise definitions of stability and change in the clinical criteria as well as in the GASE Scale.

This study has several strengths. The data derive from a 2-year, multicenter, prospective cohort study with a large sample size, a strong response rate, and high retention rates. Participating children were incident cases of epilepsy and represented diverse types of epilepsy syndromes. Although the majority of children had less severe epilepsy, the eligibility criteria did not specifically preselect patients of a particular level of severity, and the sample derived from clinics across the country. The validity of the GASE Scale was explored with several common statistics used for this purpose and the analyses included an assessment of responsiveness to change using anchor-based and distribution-based methods. Here the anchor-based method refers to linking the change in GASE Scale to a meaningful external anchor, whereas the distribution-based method refers to assessing responsiveness on the basis of statistically significant changes of the GASE Scale in relation to the probability that the change has occurred by chance.[15] This will allow for comparison with other studies and with other scales tested under similar circumstances.

Our study also has some limitations. Items included in the HERQULES questionnaires did not allow for comparisons of the GASE Scale with other common measures of severity of seizures or syndromes and limited further assessment of construct validity. In addition, all results pertain to proxy assessments; only the physicians' and parents' perceptions were evaluated, not the children's. Validity also varies according to the population and context. As a result, the measurement properties of the GASE Scale in this study may not be applicable to all other situations.[16] The minimal change in the GASE Scale scores that constitutes clinically

meaningful changes for patients and physicians was not formally explored. However, other researchers have proposed that a change of 0.5 in a 7-point Likert scale in various conditions constitutes a minimum clinically important change.[8,17,18] Another proposed metric of clinically important change, with applicability across a broad range of instruments and conditions, corresponds to "half a standard deviation" of the instrument's score.[19] For the GASE Scale (SD = 1.19), this corresponds to 0.6, which is remarkably similar to the 0.5 proposed by others.

The use of a single-item scale deserves comment. There are advantages and disadvantages to using single-item global ratings, as opposed to multi-item questionnaires, to assess such domains as severity of illness, patient attitudes, or overall satisfaction.[3] The literature surrounding the measurement of severity of epilepsy advocates for a simple, broad, and flexible instrument that incorporates all of the complex factors affecting severity.[1] We espouse the view that a single-item scale with demonstrated measurement properties can yield meaningful information and can be used readily in busy clinical or research settings adding minimal respondent burden. It is notable that the GASE Scale also provides information on a domain that is not readily explored by existing instruments, that is, severity of epilepsy.

Our analyses provide additional evidence to support the validity of the GASE Scale. Further research will continue the process of validation, with an emphasis on filling in the gaps in defining the severity of epilepsy, verifying reliability, comparing the GASE Scale with other epilepsy-related severity assessment instruments, and identifying minimal clinically important change. When used together with other measures of epilepsy and severity, the GASE Scale can provide a more comprehensive evaluation of the multidimensional nature of epilepsy.[20,21]

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Disclosure

None of the authors has any conflict of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Responsiveness (Guyatt's responsiveness statistic) for GASE Scale scores from baseline to 12 months postdiagnosis among patients classified as "changed" by external criteria.