OBJECTIVE

The objective of this study was to perform an initial psychometric evaluation of the ePASD in children aged 6–11 years with mild to severe asthma to evaluate the structure, scoring, reliability, and validity of the ePASD.

RESULTS

This study commenced on 3 March 2020, but due to the spread of coronavirus disease 2019 and its health risks to pediatric patients with asthma, the study was paused on 14 March 2020, with 24 participants completing the study in person at that time. The study resumed on 7 April 2021 with virtual data-collection procedures (i.e., no in-person study visits) with an additional 27 participants and 61 unenrolled study participants were reported over the course of the study.

Item-Level Results and ePASD Structure

The ePASD items displayed satisfactory test-retest reliability and acceptable construct validity. Despite the small sample size (N = 91), the confirmatory factor analysis results indicated that 5 ePASD composite scores were reasonable candidates for further evaluation. ePASD composite scores were constructed by analyzing, using the same 0–3 response scale as most ePASD items, with higher values reflecting worse symptoms and impacts.

- **Daytime Symptom score** = average of items D1 (Daytime Cough), D2 (Daytime Wheeze), D3 (Daytime Difficulty Breathing), and D4 (Daytime Activities)
- **Nighttime Symptom score** = average of items N1 (Nighttime Cough), N2 (Nighttime Wheeze), and N3 (Nighttime Breathing)
- **Nighttime Activity score** = average of items N1, N2, N3, and N4 (Nighttime Waking)
- **Overall Symptom score** = average of items D1, N1, D2, N2, D3, N3, and D4

Composite-Level Reliability

The internal consistencies indicated the item sets are strongly related and capable of supporting a unidimensional scoring structure but not redundant. From Day 1 through Day 6, alphas ranged from 0.73 (Nighttime Symptoms scores) to 0.91 (Overall Symptoms score).

Test-retest reliabilities (all intraclass correlation coefficients ≥ 0.63) were generally satisfactory with minor exceptions (Table 2).

Table 2. Test-Retest Reliability: ePASD Composite Scores

<table>
<thead>
<tr>
<th>ePASD score</th>
<th>ICC (95% CI)</th>
<th>EAS Day 1 vs EAS Day 2</th>
<th>EAS Day 1 vs EAS Day 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Symptom score</td>
<td>0.67 (0.51, 0.78)</td>
<td>0.65 (0.64, 0.68)</td>
<td>0.78 (0.75, 0.81)</td>
</tr>
<tr>
<td>Nighttime Symptom score</td>
<td>0.60 (0.39, 0.76)</td>
<td>0.64 (0.49, 0.78)</td>
<td>0.77 (0.74, 0.81)</td>
</tr>
<tr>
<td>Nighttime Activity score</td>
<td>0.68 (0.60, 0.75)</td>
<td>0.73 (0.70, 0.76)</td>
<td>0.76 (0.74, 0.79)</td>
</tr>
<tr>
<td>Overall Symptom score</td>
<td>0.71 (0.64, 0.77)</td>
<td>0.73 (0.70, 0.76)</td>
<td>0.76 (0.74, 0.79)</td>
</tr>
</tbody>
</table>

Note: ICCs were not statistically significant for nighttime symptom scores (p > 0.05).

Composite-Level Construct Validity

Patterns of validity correlations generally supported the construct validity of ePASD composites (Table 3). As hypothesized ePASD composite scores correlated relatively strongly with the ACQ-IA-5, ACQ-IA-6, and C-ACQ ePASD symptom scores correlated moderately to strongly with PAQLQ(S) symptom scores (all correlations ≥ −0.46) and with ACQ scores (all correlations ≥ 0.42); most correlations between the ePASD composites and the PGIS are, in fact, moderate to strong (from 0.32 with the ePASD Daytime score to 0.46 with the Nighttime Symptom score).

Composite-Level Known-Groups Validity

Known-groups analyses supplied evidence of the discriminating ability of ePASD composite scores with all subgroup differences in the hypothesized direction (data not presented).

- Participants classified as “Worst” at baseline had better Day 1 ePASD scores compared with participants who were classified as “Severe” at screening (P < 0.01).
- “Stable” participants (no changes in asthma medications in the last 2 weeks) at screening had better Day 1 ePASD scores compared with “Not stable” participants (who required a medication change to improve asthma symptoms in the last 2 weeks) (P < 0.01).
- At Day 1 and EOS Day 1, participants with C-ACQ scores < 20 obtained worse ePASD composite scores compared with participants with C-ACQ scores ≥ 20; the subgroup differences were statistically significant at both timepoints for the Daytime Symptom score, Nighttime score, and Overall Symptom score.

Table 3. Composite-Level Construct Validity Correlations

<table>
<thead>
<tr>
<th>ePASD score</th>
<th>ICC (95% CI)</th>
<th>EAS Day 1 vs EAS Day 2</th>
<th>EAS Day 1 vs EAS Day 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Symptom score</td>
<td>−0.63 (−0.73, −0.52)</td>
<td>−0.62 (−0.67, −0.58)</td>
<td>−0.62 (−0.67, −0.58)</td>
</tr>
<tr>
<td>Nighttime Symptom score</td>
<td>0.49 (0.40, 0.58)</td>
<td>0.48 (0.43, 0.54)</td>
<td>0.43 (0.36, 0.50)</td>
</tr>
<tr>
<td>Nighttime Activity score</td>
<td>0.49 (0.36, 0.61)</td>
<td>0.49 (0.38, 0.61)</td>
<td>0.46 (0.38, 0.55)</td>
</tr>
<tr>
<td>Overall Symptom score</td>
<td>0.51 (0.36, 0.65)</td>
<td>0.54 (0.45, 0.63)</td>
<td>0.51 (0.42, 0.60)</td>
</tr>
</tbody>
</table>

DISCUSSION

The findings of our initial psychometric evaluation support the reliability and validity of the ePASD items and composite scores.

The distributional characteristics, factors analyses, reliability estimates, construct correlations, and known-groups tests provided important information supporting the use of the ePASD, as well as the ability of young children with asthma to self-report symptoms and impacts. An important limitation is the lack of reported symptoms and impacts and minimal change demonstrated by the ePASD items and the supportive COAs. All of the COAs included in the study—the ePASD, ACQ-IA-5, C-ACQ, PAQLQ(S), and the PGIS—were hypothesized to be relatively strong, which may explain the small and trivial longitudinal validity correlations and lack of support for responsiveness.

Further evaluation of the ePASD in the context of a clinical trial is needed so that the longitudinal psychometric properties can be evaluated and meaningful change can be estimated.

CONCLUSIONS

Our findings provide initial evidence that the ePASD is a reliable and valid measure of asthma symptoms in young children aged 6–11 years who may not be able to read independently and who have mild, moderate, or severe asthma.

REFERENCES


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