Validation of an electronic version of the Mini Asthma Quality of Life Questionnaire

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Asthma;
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Summary
Background: The Mini Asthma Quality of Life Questionnaire (MiniAQLQ) is a validated disease-specific quality of life (QOL) paper (p) questionnaire. Electronic (e) versions enable inclusion of asthma QOL in electronic medical records and research databases.

Purpose: To validate an e-version of the MiniAQLQ, compare time required for completion of e- and p-versions, and determine which version participants prefer.

Methods: Adults with stable asthma were randomized to complete either the e- or p-MiniAQLQ, followed by a 2-h rest period before completing the other version. Agreement between versions was measured using the intraclass correlation coefficient (ICC) and Bland–Altman analysis.

Results: Two participants with incomplete p-MiniAQLQ responses were excluded. Forty participants (85% female; age 47.7 ± 14.9 years; asthma duration 22.6 ± 16.1 years; FEV\textsubscript{1} 87.1 ± 21.6% predicted) with both AQLQ scores < 6.0 completed the study. Agreement between e- and p-versions for the overall score was acceptable (ICC = 0.95) with no bias (difference (Δ) p–e = 0.1; P = 0.21). ICCs for the symptom, activity limitation, emotional function and environmental stimuli domains were 0.94, 0.89, 0.90, and 0.91 respectively. A small but significant bias (Δ = 0.3; P = 0.004) was noted in the activity limitation domain. Completion time was significantly longer for the e-version (3.8 ± 1.9 min versus 2.7 ± 1.1 min; P < 0.0001). The majority of patients (57.5%) preferred the e-MiniAQLQ; 35% had no preference.
Background

Electronic questionnaires are becoming increasingly prevalent in healthcare settings for a variety of reasons, including patient and healthcare outcomes monitoring. Electronic questionnaires have been used for pain, general, and mental health assessments. Traditional methods of data collection via paper and pencil may pose challenges during both implementation and manual input of written data into spreadsheets for analysis. Incomplete questionnaires, duplicate responses for a single question and human error in data entry can compromise data accuracy. Electronic questionnaires can also produce challenges. Computers are subject to technological errors and malfunction, create undue stress for those who are technophobic or may not meet the given participant’s personal mode of preference. Despite these challenges, electronic questionnaires can minimize and potentially eliminate challenges that can lead to compromised data. They can provide the responder with immediate prompts for incomplete answers and responses that are not acceptable, facilitate more accurate data entry that may lead to more accurate and timely analysis.

The Ontario Ministry of Health and Long-Term Care (MoHLTC) funded Kingston General Hospital’s (KGH) Asthma Program to evaluate the ability of four Primary Care Asthma Program (PCAP) sites to implement an evidence-based asthma care map. The majority of the PCAP sites use a paper copy of the program’s tools (an asthma care map and action plan), despite a number of the locations having pre-existing electronic medical records. In order to contribute to a paper-less medical record a need was identified for electronic versions of the PCAP tools and to explore the possibility of developing an electronic outcome measurement tool as a means of assessing patient-specific outcomes. One important and frequently cited patient-specific outcome is health-related quality of life (HRQOL).

The Mini Asthma Quality of Life Questionnaire (Mini-AQLQ) is a disease-specific 15-item self-administered questionnaire that was developed and validated in a paper format. The MiniAQLQ measures functional impairments in 4 domains: symptoms, activity limitation, emotional function and environmental stimuli. Patients are asked to recall their experiences during the previous 2 weeks and respond to each question on a 7-point scale (7 = no impairment, 1 = severe impairment). This questionnaire is a shortened version of the 32-item Standardised Asthma Quality of Life Questionnaire (AQLQ(S))9 and takes approximately 3–5 min to complete. It has been shown to have very good reliability, cross-sectional and longitudinal validity and responsiveness. The AQLQ(S) and MiniAQLQ have been translated into many languages and have become two of the most widely used asthma-specific quality of life instruments in research and clinical practice.10

The purpose of this study was to determine the level of agreement between scores for asthma quality of life using the traditional paper version and a newly developed electronic MiniAQLQ. In addition, we compared time required and ease of completion of the electronic and paper version of the MiniAQLQ, and determined patient preferences for the paper or electronic format. Once validated, the electronic version of the MiniAQLQ will be incorporated into one of the primary care pilot sites e-record for further evaluation of the utility of incorporating this as an outcome measure in a provincial asthma electronic record.

Methods

Development of the electronic version of the MiniAQLQ

The electronic version of Juniper’s Self-Administered MiniAQLQ was developed by Queen’s University Asthma Research Unit and Kingston General Hospital (KGH) Asthma Program team members (J. Olajos-Clow, D. Lougheed, J. Minard, P. Moyse) in collaboration with Professor Elizabeth Juniper (Department of Clinical Epidemiology and Biostatistics, McMaster University) and Cissec Corporation. The questions are identical to the paper version of the questionnaire. Each question is displayed on separate screen. There are 3 additional introductory screens for patient validation, copyright statement, and instructions on how to navigate the pages and one additional “Thank You” screen upon completion of the questionnaire. The electronic version was designed to be accessed on either a traditional desktop personal computer available in most offices or via a hand-held tablet. The questionnaire was embedded in a pre-existing charting system for asthma care called the Asthma Management Outcomes Monitoring System (AMOMS) developed by Queen’s University Asthma Research Unit researchers and KGH Asthma Program Staff.

The questionnaire includes 18 screens through which one can easily navigate using a “next”, “back”, or “quit” button (Fig. 1). The first screen identifies the individual who will complete the questionnaire, followed by an instruction and disclaimer screen. Each question has its own screen and uses a large font-size to enhance clarity and readability. It is not possible to move from one screen to the next without answering the question on the current page, and it is not possible to choose two answers for the same question. The program also allows the user to correct or change previous answers by using the “back” button. To ensure healthcare record privacy, once the patient has completed the MiniAQLQ or if they decide to stop without completing the entire questionnaire, the system is password protected. No one can access a study participant or patient’s file without the password.

Conclusion: This e-version of the MiniAQLQ is valid and was preferred by most participants despite taking slightly longer to complete. Generalizability may be limited in younger (12–17) and older (>65) adults.

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Participants

Adults (≥18 years) were invited to participate during scheduled visits at KGH’s Asthma Education Centre, Asthma Clinic or were contacted from a list of individuals from the Asthma Research Unit who had previously agreed to be contacted about research studies. Participants were included if they met Canadian Asthma Consensus Guideline diagnostic criteria,[11] were able to read English (as we were validating the English version of the self-administered questionnaire) and had an Asthma Control Questionnaire (ACQ)[12] score > 1.5 and MiniAQLQ score < 6.0 to ensure participants had current symptoms of asthma that may have an impact on their quality of life. Participants were excluded if they had a visual impairment that prevented them from reading either mode of questionnaire, chronic obstructive pulmonary disease and/or any evidence of another acute or active condition that might impact on their health-related quality of life utilizing the Charlson Comorbidity Index as a reference list.[12]

Study design

This study was a randomized crossover design to compare the electronic and paper versions of the quality of life questionnaire (Fig. 2). The study was approved by the
Results

A total of 60 subjects consented to participate and were asked to complete the electronic and paper versions of the questionnaire (Fig. 3). Four subjects in total were excluded prior to randomization due to incomplete ACQs (n = 3) and inability to perform reliable spirometry (n = 1). One subject withdrew, indicating that he didn’t want to wait the 2 h in between questionnaires. In addition, two participants were excluded from the analysis due to incomplete paper MiniAQLQ questionnaires. There were no incomplete electronic questionnaires. Forty participants with both AQLQ scores <6.0 completed the study (see Table 1). Participants were largely female (85%) and approximately 48 years of age. The mean duration of asthma was 22.6 years and mean baseline FEV1 was 87.1% predicted. Compared to those excluded, the participants had a longer duration of asthma, were on more controller medication, and took longer to complete both the electronic and paper MiniAQLQ (Table 1).

There was high agreement between electronic and paper versions for the overall score (ICC = 0.95). ICCs for the symptom, activity limitation, emotional function and environmental stimuli domains were 0.94, 0.89, 0.90, and 0.91 respectively (Table 2). The Bland–Altman plots indicated there was good agreement between overall scores for both questionnaires (difference (D) paper–electronic = 0.1; P = 0.21) (Fig. 4). In addition, there was good agreement between scores for symptom, emotional function, and environmental stimuli domains (Figs. 5, 7–8). A small but significant difference in scores (Δ = 0.3; P = 0.004) was noted in the activity limitation domain (Fig. 6).

Completion time was significantly longer for the electronic version (3.8 ± 1.9 min versus 2.7 ± 1.1 min; P < 0.0001). Despite the longer completion time for the electronic version, the majority of patients (57.5%) stated that they preferred the electronic MiniAQLQ, while 35% stated having no preference.

The majority of participants (65%) provided feedback on the study and questionnaires. Comments included that the electronic MiniAQLQ was easier to read because it included only one question per page, had larger font than the paper version, and that it was easier to correct a mistake in this format. In addition many commented that either version was fine but that they appreciated that it would be more
convenient for charting and research purposes to use the electronic version. One participant commented that they liked the paper version better as they felt they had more freedom to take their time and answer carefully. Other comments included that the study was interesting and the staff pleasant.

**Discussion**

This electronic MiniAQLQ is a valid form of the paper MiniAQLQ. The overall, symptom, emotional function and environmental stimuli MiniAQLQ scores showed a high level of agreement between the electronic and original paper version. Only the activity limitation domain showed a small but significant bias between the two versions. Although the electronic version took 1 min longer to complete, the majority of participants preferred the electronic MiniAQLQ. The electronic MiniAQLQ eliminated loss of data due to incomplete responses.

A major strength of the validation study was the use of a randomized design in keeping with the protocol provided by the author of the original MiniAQLQ. This design minimized and potentially eliminated the impact of a practice effect. Every effort was made to duplicate this protocol and provide an environment between testing that allowed some distraction (e.g. reading) without causing an impact on their quality of life (i.e. exposure to potential triggers). In similar studies,

<table>
<thead>
<tr>
<th>Variables</th>
<th>Participants included (n = 40)</th>
<th>Participants excluded (n = 15)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)a</td>
<td>47.7 ± 14.9</td>
<td>46.1 ± 14.5</td>
<td>0.73</td>
</tr>
<tr>
<td>Female (%)</td>
<td>85</td>
<td>73.3</td>
<td>0.32</td>
</tr>
<tr>
<td>Duration of asthma (years)b</td>
<td>22.6 ± 16.1</td>
<td>13.7 ± 10.4</td>
<td>0.05</td>
</tr>
<tr>
<td>Current or ex-smoker (%)</td>
<td>40</td>
<td>26.7</td>
<td>0.36</td>
</tr>
<tr>
<td>Pack yearsa</td>
<td>11.3 ± 6.5</td>
<td>7.5 ± 4.5</td>
<td>0.35</td>
</tr>
<tr>
<td>Predicted FEV1 (%)a</td>
<td>87.1 ± 21.6</td>
<td>96.7 ± 14.6</td>
<td>0.13</td>
</tr>
<tr>
<td>FEV1/FVC ratio (%)a</td>
<td>78.4 ± 12.3</td>
<td>77.4 ± 14.0</td>
<td>0.8</td>
</tr>
<tr>
<td>p-MiniAQLQ duration (min)a</td>
<td>2.7 ± 1.1</td>
<td>2.0 ± 0.8</td>
<td>0.02</td>
</tr>
<tr>
<td>e-MiniAQLQ duration (min)a</td>
<td>3.8 ± 1.9</td>
<td>2.6 ± 1.2</td>
<td>0.04</td>
</tr>
<tr>
<td>FABA (%)</td>
<td>87.5</td>
<td>80</td>
<td>0.48</td>
</tr>
<tr>
<td>FABA and ICS (%)</td>
<td>17.5</td>
<td>33.3</td>
<td>0.21</td>
</tr>
<tr>
<td>FABA + either LABA + ICS or combination or SI therapy (%)</td>
<td>75</td>
<td>46.7</td>
<td>0.05</td>
</tr>
</tbody>
</table>

FABA = Fast acting Beta-agonist; LABA = Long-acting Beta-agonist; ICS = Inhaled Corticosteroid; SI = Single Inhaler.

*a Values are mean ± standard deviation.
the time interval between questionnaires varied from 5 min to several weeks, as there is no known established standard. Validation of computerized versions of a selection of other questionnaires have utilized time intervals such as 5 min with the Short Form 36 General Health Questionnaire,3 15 min with an osteoarthritis index,14 2 h,6 3 h with a cancer quality of life questionnaire,15 and weeks (range 4–21 days) with a quality of life measure for terminally ill patients.16 Given the variable nature of asthma, the 2 h time frame utilized between testing in this study may have limited and potentially eliminated any change in participants’ clinical condition that may have affected their quality of life in the interim.

Table 2: Comparison between e-MiniAQLQ and p-MiniAQLQ.

<table>
<thead>
<tr>
<th></th>
<th>Paper (mean ± SD)</th>
<th>Electronic (mean ± SD)</th>
<th>Difference</th>
<th>Paired t-test (p-value)</th>
<th>Intraclass correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>4.5 ± 1.0</td>
<td>4.5 ± 1.0</td>
<td>0.1</td>
<td>0.21</td>
<td>0.95</td>
</tr>
<tr>
<td>Symptoms</td>
<td>4.6 ± 1.2</td>
<td>4.6 ± 1.1</td>
<td>0.0</td>
<td>0.46</td>
<td>0.94</td>
</tr>
<tr>
<td>Activity limitation</td>
<td>5.1 ± 1.2</td>
<td>4.9 ± 1.3</td>
<td>0.3</td>
<td>0.004</td>
<td>0.89</td>
</tr>
<tr>
<td>Emotional function</td>
<td>4.2 ± 1.4</td>
<td>4.2 ± 1.3</td>
<td>0.0</td>
<td>0.73</td>
<td>0.90</td>
</tr>
<tr>
<td>Environmental stimuli</td>
<td>4.0 ± 1.4</td>
<td>4.0 ± 1.4</td>
<td>0.1</td>
<td>0.59</td>
<td>0.91</td>
</tr>
</tbody>
</table>

Figure 4

Figure 5
Our study may have been limited by selection bias. Although subjects’ ages ranged from 18 to 65 years, the mean age in the mid-forties could indicate underrepresentation of the younger, computer-literate generation. If anything, however, one might expect younger individuals to be even more comfortable with use of electronics and response time for electronic version might have even been shorter. Only one participant had never used a computer prior to the study entry, potentially limiting generalizability to older, less computer-literate population. The participant in our study who did not have any computer experience indicated no preference for either format. Previous studies however,\textsuperscript{14,16,17} have found that age, education level, sex and/or computer experience did not have an effect on participant response. One can speculate that the response time for the electronic version of the MiniAQLQ may have been less if younger participants were included. Nonetheless, the results of this study may not be generalizable to individuals 12–17 years of age or over 65 years of age.

Validation of Juniper’s self-administered pediatric AQLQ and pediatric asthma caregiver’s AQLQ is currently underway. A separate validation study should be performed before this electronic version of the MiniAQLQ is used in individuals greater than 65 years.

The sample in the study was recruited from a group of subjects who had been referred to specialized asthma clinics or an asthma education centre within a tertiary care centre as well as participants in previous asthma research studies. Although this may have introduced selection bias our sample did reflect the typical gender distribution seen in the adult asthma population and baseline lung function was normal and comparable between groups. The more intense medication management regime and longer duration of asthma seen in participants versus non-participants is not surprising given that those with normal asthma quality of life were excluded from the analyses. However the two groups did have comparable lung function without obstruction and were not statically significant.
The high agreement between the electronic and paper versions of the MiniAQLQ suggests that there was minimal within-subject variance (correlation plus bias) between paper and electronic versions. The magnitude of the intraclass correlation coefficients, overall and by subcategories, was in keeping with comparisons of the MiniAQLQ and original AQLQ, and comparisons of other quality of life questionnaires and pain questionnaires.

Another strength of the study was the inclusion of the Bland-Altman analyses. This method uses the mean difference between two methods of the same test, one of which represents a ‘gold-standard’, to assess for systematic bias. In our sample, the overall MiniAQLQ scores showed no significant bias. When subcategories were analyzed separately only the activity limitation domain showed a small but significant bias between the two tools. It can be difficult to scan text on a computer screen, which may lead to more careful reading. The activity questions of the MiniAQLQ are the ones most likely to be misinterpreted if they are read in a hurry. Once could speculate that the difference observed between activity scores could be attributed to participants misinterpreting questions on the paper questionnaire and answering the question they thought they saw, whereas on the electronic format they were forced to read it more carefully.

Similar biases between paper and electronic versions of pain assessments and quality of life assessments have been documented. Cook et al. speculated that a change in pain over time might have resulted in this difference. Junker et al. speculated that a slight difference in the paper and electronic versions may have resulted in a difference in scores. In our study the questions were identical in both formats. However with the paper format participants can see all questions at once whereas in the electronic version questions are visible one at a time. Post hoc analysis found that the bias was similar regardless of which format was done first which would suggest that these reasons were not responsible for the bias. This degree of bias, despite being statistically significant, did not reach clinical significance. Nonetheless, it does mean that different questionnaire formats should not be used interchangeably. In addition, it emphasizes the need to validate electronic versions. Despite best efforts and rigorous evaluations, not all electronic versions of validated paper instruments achieve acceptable levels of agreement.

The electronic version of the MiniAQLQ took 1 min longer to complete, however the majority (57.5%) preferred the electronic version. Previous comparison studies between electronic and paper forms are inconsistent. Some comparisons have found similar results to our study with the electronic version taking longer to complete. However, in other studies, time to complete both versions was either equivalent or shorter for the electronic version. Many participants felt that the electronic version of the MiniAQLQ was easier to use than the paper version. Specifically, they stated that it was easier to read due to large font and easier to make corrections. Other studies have found that patients preferred the electronic versions of questionnaires, in part, because of the novelty of the tool. We speculated that the reason for the longer time interval for completion of the electronic format was due to participants taking the time to read each of the introductory screens versus turning the page without reading the introductory information on the paper version prior to responding to the first question. In addition, there was one extra screen that the participant was required to read in order to confirm their name and date of birth.

With an increasing number of primary care practitioners and specialists using electronic charting, the need to have validated electronic forms of questionnaires is becoming paramount. This electronic version of the MiniAQLQ provided results comparable to the paper version and was well accepted and easy to use. The slight bias in the activity domain suggests that using the paper and electronic formats interchangeably within a practice setting may not be appropriate. However the degree of bias did not reach clinical significance, which is ultimately the most relevant endpoint from both the patient’s and clinician’s perspective.

Utilization of electronic forms can aid healthcare practitioners in the collection and analysis of quality of life measures. This tool has been incorporated into Queen’s...
University's AMOMS with the intention to use it for clinical, administrative (i.e. program evaluation/ministry reporting), and research purposes in our centre’s regional asthma care program, Ontario PCAP sites and the Canadian Severe Asthma Network. Availability of validated electronic asthma quality of life instruments such as the electronic MiniAQLQ will enable inclusion of this important patient-level indicator in electronic medical records for patient outcomes monitoring, program evaluation and benchmarking.

Note: This validated electronic version of the MiniAQLQ will be used in primary and acute care settings in Ontario and in Canadian Severe Asthma Network (CSAN) centres across Canada. The use of the validated electronic questionnaire is for clinical, administrative and research purposes and at no time for purposes of financial profit.

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Conflicts of interest statement

None of the authors involved in the development of this manuscript have any conflict of interests to declare.

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