

A comparison of global questions versus health status questionnaires as measures of the severity and impact of asthma

E.A. Barley, P.W. Jones

A comparison of global questions versus health status questionnaires as measures of the severity and impact of asthma. E.A. Barley, P.W. Jones. ©ERS Journals Ltd 1999.

ABSTRACT: This study compared estimates of the severity and impact of asthma recorded using global questions of the type used in diary cards with health status measurements obtained using comprehensive questionnaires.

Seventy-four outpatients with asthma, aged 17–76 yrs (mean 48 yrs) participated. Mean \pm SD forced expiratory volume in one second (FEV₁) was 72 \pm 26% predicted. Patients recorded morning and evening peak expiratory flow rate (PEFR) and scaled their responses to the questions: "How has your asthma been today?" (asthma severity) and "How much effect has your asthma had on your life today?" (asthma impact) for 2 weeks. They then completed Juniper's Asthma Quality of Life Questionnaire (AQLQ) and the St George's Respiratory Questionnaire (SGRQ).

Diary card scores for asthma impact were less severe than for asthma severity ($p < 0.0001$). Both correlated with AQLQ and SGRQ total scores ($r > 0.7$; $p < 0.0001$). Some patients responded 'none' for asthma severity ($n = 10$) or asthma impact ($n = 13$) on all 14 days of recording. For these patients, FEV₁ was $< 80\%$ predicted, morning PEFR was $< 90\%$ predicted and their AQLQ and SGRQ scores indicated significant health impairment.

Diary card scores for asthma severity and impact were correlated with health status, but these global questions were insensitive in mild disease. Responses to these questions were influenced by their wording, so the number of symptom-free days calculated from diary cards will depend on the questions used. Standardization is required before symptom-free days can be used as a reliable measure of treatment efficacy.

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Two different approaches are used to measure the impact of asthma: diary cards and detailed questionnaires. Diary cards usually consist of one or more global questions such as: "How bad is your asthma today?", or "How much effect has asthma had on your physical activity today?" Responses to such questions are usually scored using categories such as "none", "slight", "moderate" *etc.* A time-averaged estimate may be obtained by calculating a mean score over time, or by counting the number of symptom-free days. The latter approach is being used with increasing frequency, particularly in clinical trials [1, 2]. Its use has been encouraged recently by the American national asthma education and prevention working group on cost effectiveness of asthma care [3] and it is thought that this will be the measure of choice for studies of the health-economic impact of new treatments [4]. Diary card estimates of disease severity and impact are attractive because they are easy to use and score. There is much experience of their use in asthma, but relatively little is known about their measurement properties compared to more comprehensive measurements of health.

Detailed health status or "quality of life" questionnaires consist of a series of items relating to specific areas of impaired health due to asthma. Responses to the individual items are aggregated to provide an overall score. Examples of such instruments are the St George's Res-

piratory Questionnaire (SGRQ) [5], two asthma quality of life questionnaires [6, 7] and the Living with Asthma Questionnaire [8]. In contrast to global scales, all of these complex questionnaires have been subject to intensive scientific development, validation and testing [5, 7, 8]. Unlike diary cards, complex questionnaires provide intermittent health estimates since they are not suited to repeated daily application.

This study was designed to compare asthma diary card scores with health status measured by detailed questionnaires. Two differently worded global questions were used for the diary cards: one concerned asthma severity, the other addressed the impact of asthma on daily life. Two complex health status measures were used: the SGRQ [5] and the Asthma Quality of Life Questionnaire (AQLQ) developed by JUNIPER *et al.* [7].

Methods

Patients

Patients with a clinical diagnosis of asthma made by a consultant chest physician were recruited from two outpatient asthma clinics. None had clinically significant inter-current disease. Seventy-four subjects (female = 46) aged

Division of Physiological Medicine, St George's Hospital Medical School, Cranmer Terrace, London.

Correspondence: P.W. Jones
Division of Physiological Medicine
St George's Hospital Medical School
Cranmer Terrace
London SW17 0RE
Fax: 44 1817255955

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17–76 yrs (mean 48 yrs) agreed to participate. The mean±SD time since diagnosis was 21±17 yrs. Their mean post bronchodilator forced expiratory volume in one second (FEV₁) was 72±26% predicted. All were taking both an inhaled steroid and a β_2 -agonist, except for one who was taking a β_2 -agonist alone and one who was using an inhaled steroid only. In addition, 18 patients were currently taking oral steroids. These patients had the worst SGRQ scores. Their mean SGRQ scores were 20 units higher than those in patients not on oral steroids ($p<0.001$). Twenty-nine patients were also prescribed other asthma medication such as a xanthine, an anticholinergic or a cromone. Thirty-three patients had never smoked, 16 were current and 25 were exsmokers. Asthmatic patients with other medical conditions that may have had an impact on health related quality of life were excluded. Ethical approval for the study was provided by Wandsworth Health Authority Local Research Ethics Committee. Written consent was obtained from all patients.

Health status measures

The Asthma Quality of Life Questionnaire. This is an asthma specific measure containing 32 items referring to health in the last 2 weeks [7, 9]. The interviewer-administered version appears to have been most highly validated and was the format used in the present study. It provides a total and four domain scores: "Activities", "Symptoms", "Emotional Functioning" and "Environmental Stimuli". It is standardized except for the "Activities" domain where 5/11 items are activities chosen by the patient as areas of limitation. Each item has a 7 point response scale. Summary scores range from 1 (worst health) to 7 (perfect health). Normative data are not available.

The St George's Respiratory Questionnaire. This is an airway specific measure consisting of 76 items referring to health in the last 3 months. It is designed for supervised self-administration and is standardized [5, 10]. It provides a total and three component scores: "Symptoms" which measures the frequency and severity of respiratory symptoms; "Activity" which is concerned with activities that cause or are limited by breathlessness; and "Impacts" which measures disturbances in social and psychological functioning due to airway disease. Each item has an empirically derived weight. Scores are computed to range from 0 to 100, with 100 indicating worst health. Mean±SD normal scores, derived from 74 disease free subjects (female = 38) with a mean age 46 yrs (range 19–81), are as follows: "Symptoms" = 12±14; "Activity" = 10±11; "Impacts" = 2±4 and "Total" = 6±6.

Global estimates

For the purposes of this study, a diary card containing two global asthma specific questions was constructed. These were designed to reflect the type of questions commonly used in asthma diaries. They were: 1) "How has your asthma been today?" (asthma severity); 2) "How much effect has your asthma had on your life today?" (asthma impact). For each, responses were chosen from a 6 point scale: "none", "very mild", "mild", "moderate", "severe", "very severe".

Study design

For 14 days, patients were asked to record their responses to the two global questions each evening. During the same period they were asked to record their peak expiratory flow rate (PEFR) twice daily. To ensure standardization between patients, the morning PEFR was taken before medication and the evening measurement following medication. At the end of this period, the patients were visited at home where they completed the SGRQ and the AQLQ. The order of presentation was randomized. Their post-bronchodilator FEV₁ was recorded at the same time.

Analysis

Mean PEFR over the 14 days was calculated and expressed as a percentage of the predicted value (% pred) for each patient [11]. Mean scores for the global estimates were calculated by converting the daily diary card responses to numerical values: "none" = 0; "very mild" = 1; "mild" = 2; "moderate" = 3; "severe" = 4; "very severe" = 5. The patients' responses over the 14 days were averaged and then categorized: mean score <0.5 = "none"; 0.5–1.49 = "very mild"; 1.5–2.49 = "mild"; 2.5–3.49 = "moderate"; 3.5–4.49 = "severe"; ≥ 4.5 = "very severe". Correlations were tested using Spearman's rho (ρ) or Pearson's r , dependent upon whether the data were categorical or continuous.

Results

Patient details

FEV₁ and SGRQ measurements were available for all but 1 patient who completed the diary card, but not the interview. Three additional patients did not complete the AQLQ because they were unable to name activities in which they experience limitation. In 4 patients, diary card data was missing either completely or in part. The morning PEFR was (mean±SD) 74±25% pred; evening PEFR was 79±25% pred. Mean±SD FEV₁ was 72±26% pred. Mean "Asthma Severity" score averaged over 14 days was 1.7±1.3. Mean "Asthma Impact" score averaged over 14 days was 1.5±1.4. No patient rated themselves as "very severe" with either estimate. Mean SGRQ Total score was 40±21 and mean AQLQ Total score was 4.7±1.4.

Distribution of diary card scores

The scores from the two diary card questions correlated significantly ($\rho = 0.91$, $p<0.0001$), however, the proportion of responses indicating negligible or low levels of impact of asthma on daily life was greater than that indicating similar levels of asthma severity (fig. 1). The difference in this distribution was statistically significant (Chi-squared = 158; $p<0.0001$). Similarly, a greater percentage of symptom-free days was reported using "Asthma Impact" (39%) than using "Asthma Severity" (31%).

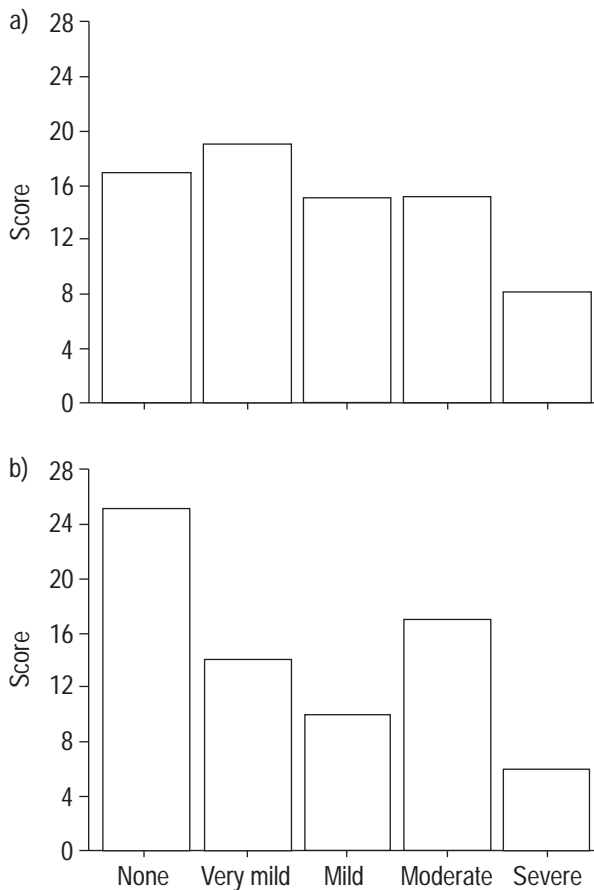


Fig. 1. – Frequency distribution of patients' mean response over 14 days to the diary card questions: "How has your asthma been today" and "How much effect has your asthma had on your life today?". a) Global estimate of asthma severity and b) global estimate of impact of asthma on life. The difference in distribution was significant (Chi-squared = 158, $p < 0.0001$).

Relationship between diary cards and detailed questionnaires

The mean scores for the two diary card questions correlated significantly with the total scores of the AQLQ and the SGRQ (fig. 2 and 3) and with all their component scores (table 1). Correlations between the global estimates and the total scores of the detailed questionnaires were marginally stronger than the corresponding correlations with the component scores. Neither age, sex nor oral steroid use had an effect on the relationship between the diary card score for "Asthma Severity" and the two health status questionnaires ($p > 0.05$). Similarly, age and oral steroid use had no effect on the relationship between "Asthma Impact" and health status, but there was a weak effect of sex on this relationship ($p < 0.05$). Women had worse AQLQ and SGRQ scores than men for each level of "Asthma Impact".

Relationship between diary card scores and lung function

The diary card scores for "Asthma Severity" and "Asthma Impact" correlated significantly with all three measures of lung function (table 2). "Asthma Severity"

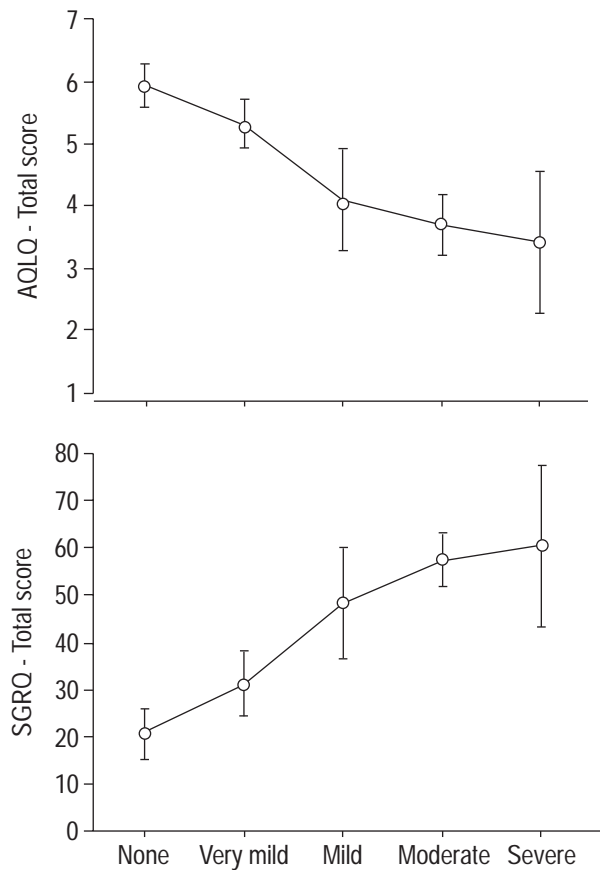


Fig. 2. – Relationships between patients' global estimate of daily "Asthma Severity" and "Total" scores from the Asthma Quality of Life Questionnaire (AQLQ) and the St George's Respiratory Questionnaire (SGRQ). Error bars indicate mean \pm 95% confidence intervals. Number of patients in each category: None, $n=17$; Very mild, $n=19$; Mild, $n=10$; Moderate, $n=15$; Severe, $n=8$.

produced the highest correlations. These relationships were not influenced by age, sex or the use of oral steroids ($p > 0.5$).

Relationship between detailed questionnaires and lung function

All of the SGRQ scores correlated significantly with PEFR (morning and evening) and FEV₁. The AQLQ "Total" score was significantly correlated with PEFR (morning and evening) but not FEV₁. Two AQLQ domains ("Activities" and "Symptoms") were significantly correlated with PEFR and FEV₁. The "Emotional Functioning" score correlated only with morning PEFR and no correlation involving the "Environmental Stimuli" component reached significance (table 2).

Patients reporting no daily asthma

The plots in figures 2 and 3 show that the patients classified using the diary card questions as having no asthma or no impact of asthma still had AQLQ and SGRQ scores that were well above the minimum score obtainable with these questionnaires. A proportion of the patients categorized in this way did indicate low levels of asthma on occasional days during the 14 day recording

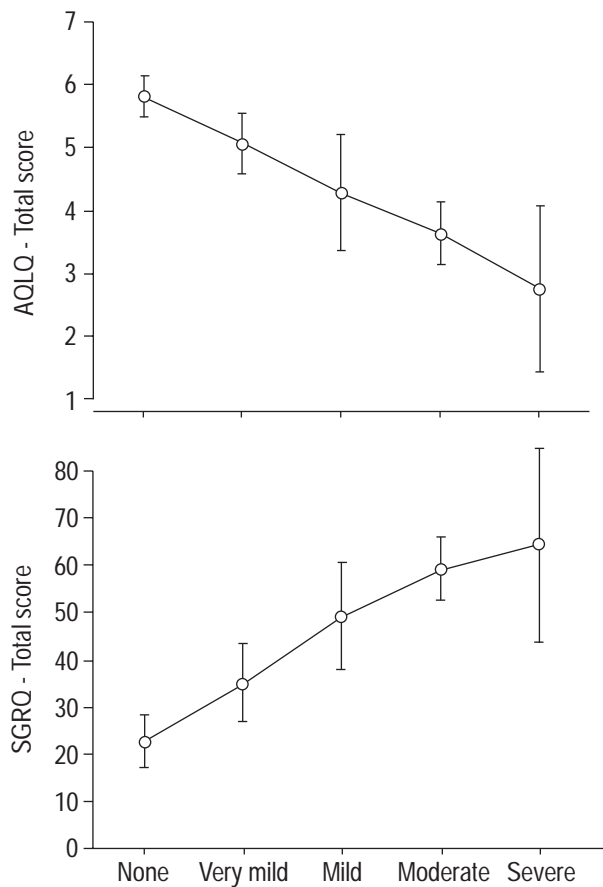


Fig. 3. – Relationship between patients' global estimate of daily impact of asthma and total scores from the Asthma Quality of Life Questionnaire (AQLQ) and the St George's Respiratory Questionnaire (SGRQ). Error bars indicate mean \pm 95% confidence intervals. Number of patients in each category: None, n=25; Very mild, n=14; Mild, n=10; Moderate, n=17; Severe, n=6.

period. To remove the effect of these individuals, a further analysis was carried out on those patients who indicated either no asthma (n=10) or no impact of asthma (n=13) on any of the 14 days of measurement. In these patients, the morning PEF_R and FEV₁ were still lower than their predicted normal and evening PEF_R lay at the lower limit of normal (table 3). The SGRQ scores for those patients indicating no asthma on any day were significantly higher than the mean scores in a healthy disease-free population (p<0.0001). This was also the case for those who recorded no impact of asthma on any day (p<0.0001). Normative data are not available for the AQLQ, but the scores in these patients do indicate the presence of an asthma-related impact on health. The highest possible score with this questionnaire is 7 (corresponding to no effect of asthma at all). A score of 6 is achieved if a patient indicates a detectable effect of asthma on each of the 32 items in the questionnaire. In fact, the score in these patients was even lower (*i.e.* worse) than this.

Patients reporting moderate to severe daily asthma

The lung function and health status scores in patients with moderate-severe asthma severity or asthma impact are shown in table 4. These patients are clearly worse than the

Table 1. – Correlations (as Spearman's rho) between global estimates of asthma severity ("Asthma Severity") and impact on daily life ("Asthma Impact") and scores obtained with the Asthma Quality of Life Questionnaire (AQLQ) and the St George's Respiratory Questionnaire (SGRQ).

	Global "Asthma Severity"	Global "Asthma Impact"
SGRQ		
Symptoms	0.71	0.70
Activity	0.68	0.67
Impacts	0.66	0.64
Total	0.73	0.73
AQLQ		
Activities	-0.65	-0.67
Symptoms	-0.75	-0.71
Emotional functioning	-0.52	-0.52
Environmental stimuli	-0.55	-0.56
Total	-0.75	-0.73

All correlations significant at p<0.0001.

corresponding patients described in table 3. The differences in AQLQ and SGRQ scores between these groups of patients were all significant at p<0.0001. The differences in morning peak flow were also significant at p<0.001. The differences in FEV₁ were of marginal statistical significance (p \geq 0.03). The mean difference in SGRQ score between patients reporting no asthma symptoms and those reporting moderate-severe asthma is 34 units. This is much greater than the 4 unit threshold for a clinically significant difference using this questionnaire [10].

Discussion

Averaged daily global estimates of the severity of the impact of asthma on patients' lives, obtained through diary cards, correlate quite well with single point estimates of

Table 2. – Correlations between health status scores and lung function (as % predicted)

	FEV ₁	Morning PEF _R	Evening PEF _R
"Asthma Severity"	-0.31 [†]	-0.53 [§]	-0.48 [§]
"Asthma Impact"	-0.30 [†]	-0.48 [§]	-0.43 [‡]
SGRQ			
Symptoms	-0.35 [†]	-0.45 [§]	-0.43 [‡]
Activity	-0.39 [‡]	-0.44 [§]	-0.46 [§]
Impacts	-0.31 [†]	-0.44 [§]	-0.35 [†]
Total	-0.38 [‡]	-0.49 [§]	-0.44 [§]
AQLQ			
Activities	0.23*	0.30 [†]	-0.30 [†]
Symptoms	0.24*	0.40 [‡]	-0.30 [†]
Emotional functioning	0.12 ^{NS}	0.26*	0.18 ^{NS}
Environmental stimuli	0.07 ^{NS}	0.15 ^{NS}	0.12 ^{NS}
Total	0.22 ^{NS}	0.35 [†]	0.28*

The forced expiratory volume in one second (FEV₁) values were single measurements, the peak expiratory flow rate (PEFR) measurements represent the mean of 14 days. Correlations involving the global questions for "Asthma Severity" and "Asthma Impact" were tested using Spearman's rho. Correlations involving the St George's Respiratory Questionnaire (SGRQ) and Asthma Quality of Life Questionnaire (AQLQ) were calculated using Pearson's r. (†: p<0.01; ‡: p<0.001; *: p<0.05; NS=p>0.05; §: p \geq 0.0001).

Table 3. – Mean±SD questionnaire score and lung function for patients reporting no daily asthma or effect of asthma on any of the 14 days of recording

	No daily asthma	No effect on life
n	10	13
FEV ₁ (% pred)	74±19	79±21
Morning PEF _R (% pred)	87±18	86±24
Evening PEF _R (% pred)	92±21	91±26
SGRQ		
Symptoms	25±14	25±16
Activity	27±20	27±19
Impacts	18±13	17±14
Total	22±11	22±12
AQLQ		
Activities	5.7±0.9	5.7±0.9
Symptoms	6.2±0.8	6.0±0.8
Emotional Functioning	5.7±1.0	5.2±1.6
Environmental Stimuli	5.8±1.2	5.7±1.1
Total	5.9±0.8	5.7±0.8

FEV₁: forced expiratory volume in one second; % pred: percentage of predicted value; PEF_R: peak expiratory flow rate; SGRQ: St George's Respiratory Questionnaire; AQLQ: Asthma Quality of Life Questionnaire.

health status obtained through disease-specific questionnaires. This relationship is sufficiently strong for some confidence to be placed in a patient's global estimate of the relative severity of their disease; *i.e.* a patient who estimates that their asthma is "moderate" will, on average, have worse health than a patient who estimates that their asthma is "mild".

Two important caveats must be made concerning the use of diary card estimates of asthma severity, however. The first concerns the wording of the global questions. A range of questions have been used in asthma diary cards, so the authors selected two different questions that captured the general themes: overall level of asthma severity and overall effect on life. The correlation between the two questions was high ($\rho=0.91$) and they showed a very similar pattern of correlations with the physiological measurements and the AQLQ and SGRQ scores. This does not mean that these questions were used in exactly the same way. Even though they were answered at the same time of day, the patients appeared to draw a subtle distinction between asthma severity and its level of impact upon them. Their scores for asthma severity were significantly worse than those for its effect on daily life, *i.e.* they experienced asthma symptoms but the impact of these was judged to be

Table 4. – Mean±SD questionnaire score and lung function for patients reporting moderate to severe "Asthma Severity" or "Asthma Impact" over the 14 days of recording

	"Asthma Severity"	"Asthma Impact"
n	23	15
FEV ₁ % pred	62±26	58±27
Morning PEF _R % pred	62±25	59±26
SGRQ-total	56±19	60±18
AQLQ-total	3.7±1.1	3.5±1.2

FEV₁: forced expiratory volume in one second; % pred: percentage of predicted value; PEF_R: peak expiratory flow rate; SGRQ: St George's Respiratory Questionnaire; AQLQ: Asthma Quality of Life Questionnaire.

significantly less than the level of the symptoms (fig. 1). Thus it is clear that the wording of this type of global diary card question has a significant effect on the response. In this study, the number of symptom-free days calculated from the "Asthma Impact" question was greater than the number calculated using the "Asthma Severity" question, with a difference of ~30% between the two. This has major implications for the use of the symptom-free or "episode-free" day as a measure of asthma control in clinical trials [1, 2]. This parameter must be standardized through the use of standard wording of the questions and standard response categories. Trials using differently worded questions may not be comparable.

The second limitation upon the use of global questions is their apparent insensitivity at the mild end of the spectrum of disease activity. Even those patients who indicated no asthma for 14 consecutive days had an FEV₁ <80% predicted and morning peak flows <90% predicted. Furthermore, the SGRQ scores in these patients were very much higher than those obtained in age-matched subjects with no history of lung disease. Similarly, the AQLQ scores in these patients correspond to a "non-zero" response to each of the 32 items in this questionnaire. It appears that comprehensive questionnaires such as the AQLQ and the SGRQ are more sensitive than global diary card estimates of asthma severity. This phenomenon does not appear to be due to a group of "poor global perceivers" since there was no discontinuity in the rank order relationship between the responses to the global questions and those to the complex questionnaires between "none" and "very mild" (fig. 2 and 3). These findings also have implications for the interpretation of symptom-free days when calculated using global questions of the type investigated in this study. Even though patients may apparently have "symptom-free" days, this does not mean that their asthma is having no effect on their lives. Data obtained using the AQLQ and SGRQ suggest that they may be experiencing very definite effects, even though this is not reflected in diary card scores.

In summary, this study has shown that global questions used in asthma diary cards do have cross-sectional validity when used to categorize patients in terms of their perceived asthma severity. In many respects, the different wording of the questions used in this study appears to have little impact upon their relationship to the other measures of asthma, except in two important aspects. Firstly, responses to the "Asthma Impact" question lay more towards the mild end of the scoring range than those for "Asthma Severity". This phenomenon was part of a general lack of sensitivity seen with both questions at the mild end of the disease spectrum. Secondly, females tended to have worse health scores than males for any given level of global "Asthma Impact". It is concluded that diary card questions may fail to reflect the impact of mild disease on daily life and that standardization of diary cards is needed before they can be used in any meaningful way to calculate symptom-free days.

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