Validity of symptom and clinical measures of asthma severity for primary outpatient assessment of adult asthma

TZE PIN NG

SUMMARY

Background. *Symptom and pulmonary function measures of asthma severity are used for severity classification in practice guidelines. However, there is limited methodological evidence in support of their validity and utility.*

Aim. *To validate initial symptom and forced expiratory volume (FEV_1) measures of asthma severity with the subsequent risks of exacerbations resulting in emergency room (ER) visits, hospitalisation, and sickness absence from work. In addition, symptom-based measures of change in asthma severity were also evaluated against the concurrent risks of asthma exacerbations.*

Method. *A cohort of 361 adult asthmatic patients in general outpatient clinics was studied. At initial interview, frequencies of asthmatic symptoms and nocturnal exacerbations, FEV_1, and a severity score combining these measures, were recorded. At re-interview in the third year, the frequencies of asthma exacerbations resulting in ER visits, hospitalisation, and sickness absence, and a self-assessed global measure of change in severity and serially-assessed change in symptom frequencies, were measured.*

Results. *All individual symptom and FEV_1 measures were strongly related to the subsequent risks of ER visits, hospitalisation, and sick absence. A severity score of more than 3 (moderate to severe asthma) and self-assessed change in asthma severity were most strongly and significantly associated with greatly increased risks of all outcomes. Individual symptoms and FEV_1 measures alone did not show high sensitivities, but the severity score combining these measures gave much more satisfactory validity. Perhaps not surprisingly, self-assessed change in asthma appeared to give the most satisfactory validity.*

Conclusion. *These results support the validity and clinical utility of a simple clinical score based on symptom and FEV_1 measures, and self-assessed measure of change in severity, for risk classification in contemporary clinical practice guidelines.*

Keywords: *asthma; symptom measures; pulmonary function measures; FEV_1.*

Introduction

SYMPTOM and clinical measures of asthma severity are widely used in clinical research and are recommended for classification of asthma severity in some, but not all, clinical practice guidelines. *Ad hoc* categorisations of asthma severity are recommended in some guidelines but they have not been validated.[1] Asthma is a chronic disease characterised by intermittent exacerbations. Asthma severity may therefore be measured in terms of (i) the underlying disease severity (airway obstruction) and (ii) airway lability (or the potential for frequency of exacerbations).[2] The baseline forced expiratory volume in one second (FEV_1) is widely accepted as a good surrogate of underlying disease severity over the long term, as there is a body of data to support the reliability and validity. Airway lability in clinical practice is best measured objectively by serial measurements of peak expiratory flow (PEF) variation. Although the validity of PEF is well supported, recent studies strongly suggest that, owing to patient compliance factors in practice, the favourable outcomes from PEF-based self-management plans compared with symptom-based plans are not evident.[3-5] As an alternative to measuring airway lability, the perception of symptoms is a simple and explicit measure of asthma severity.

To measure asthma severity, symptoms may be described in terms of their intensity, duration and (nocturnal) characteristic of a given acute episode, and the frequency of acute episodes. Symptom measures have been developed for clinical research,[6-10] but, except for nocturnal dyspnoea,[5] there are limited methodological data in support of their validity.[11] It is convenient in many studies to employ concurrent criterion measures of validity.[6-10] However, symptom measures are subject to personal, short-term, temporal, and associative recall biases, especially if they are recorded concurrently with self-reported outcome measures. There are no prospective studies that have evaluated the predictive validity of symptom and clinical measures using follow-up outcome data.

The utility of symptom and FEV_1 measures of asthma severity is also dependent upon the clinical context in which they are employed. Unlike hospital-based care, outpatient care of asthma covers a wider spectrum of disease severity, and the continual assessment of asthma severity is less intensive and more long term, with the therapeutic goal of 'keeping the patient out of hospital as much as possible'. An important relevant aspect of care is the assessment of severity and risk classification in terms of the future likelihood of recurrent exacerbations resulting in the need for emergency room (ER) visits or hospitalisations, or for taking excessive sick leave. This clinical assessment needs to employ only simple and inexpensive but validated health status measures.

In this paper, these issues are addressed in a prospective study of adult asthmatic patients in the outpatient care setting. The primary objective was to validate initial symptom and FEV_1 measures of asthma severity with the subsequent risks of exacerbations resulting in ER visits, hospitalisation, and sick absence from work. In addition, symptom-based measures of change in asthma severity were also evaluated against the concurrent risks of asthma exacerbations.

Method

Study design

A prospective study was conducted in which symptom and FEV_1 measures of asthma severity were recorded for 361 adult asthmatic patients at initial interview. At re-interview in the third year, data were collected on surrogate outcome measures of asth-

T P Ng, MD, MFPHM, associate professor, Department of Community, Occupational and Family Medicine, National University of Singapore, Singapore.
Submitted: 17 July 1998; final acceptance: 5 May 1999.

ma exacerbations, self-reported change in asthma severity, and repeat measures of symptom frequencies (Figure 1).

Study setting

The subjects in this study were asthmatic patients receiving ambulatory care in Ministry of Health primary care clinics. Primary care clinics in Singapore are the public sector equivalents of private general practices and provide first-line primary level of care, both episodic and continuing. Cases of acute severe asthma exacerbation are given as-needed daytime-only ER (but not inpatient) treatment, or are referred to hospitals. Patients are educated on self-management of asthma attacks and environmental allergen control.

Study subjects

In 1993, we studied a cohort of 787 asthma patients in the register of five large primary care clinics in Singapore.[12] They were adult patients aged between 21 and 54 years who were treated for asthma symptoms in the past year. The diagnosis of asthma was confirmed by case records reviewed by trained and experienced physicians, one at each study centre, using consensus standard clinical criteria. No bronchial provocation tests were done and peak flow monitoring was not in routine use in the clinics. We excluded from the cohort four subjects of 'other' ethnicity who were transient foreign workers. The resulting cohort of 783 subjects comprised 22% patients who were aged 21 to 29 years, 34% aged 30 to 39 years, and 44% aged 40 to 54 years: 58% were females, 49% were Chinese, 32% were Malays, and 19% were Indian.

Measures at initial interview

Symptom measures, based on the frequency of asthma symptoms and nocturnal symptoms in the past one year, were obtained with an interviewer-administered structured questionnaire (Table 1). The ordered responses to these questions allowed for reclassification into severity levels that correspond, within limits, with those recommended in contemporary practice guidelines. As an example, the response categories in the Singapore Asthma Questionnaire are shown against the recent United States National Heart Lung and Blood Institute (NIH-NHLBI) classification of asthma severity.[13]

The patient's FEV_1 was measured with a hand-held microspirometer (Microspirometer™, Micro Medical, Rochester, England), following American Thoracic Society (ATS) recommended procedures for standardisation of pulmonary function measurements. The repeatability and validity of the instrument has been studied in the local population, and regression formulae for normative values for the instrument have been derived for each sex and ethnic group (Chinese, Malay, and Indian).[14] The FEV_1 was expressed as a percentage of the value predicted by the patient's age and height.

Follow-up interview

A trained nurse successfully conducted telephone re-interviews for a total of 361 patients. Except for having slightly more female patients and those with family histories of asthma, re-interviewed patients were very similar to those not re-interviewed, especially with respect to measures of initial asthma severity (Table 2).

Measures at follow-up interview

At re-interview, the patients were asked the number of times, in the past one year, that he or she had exacerbations of asthma that required ER visits or hospitalisation, as well as the number of days that he or she was sick-absent or incapacitated from work because of asthma. In addition, the patient was asked whether, since the last interview, his/her asthma had become 'better', 'the same', or had become 'worse'.

Statistical analyses

In the primary analysis, the predictive validity of symptom and FEV_1 measures was evaluated by the subsequent risks of asthma exacerbations resulting in ER visits, hospitalisation, and sick-absences. The relationship between predictor and outcome variables was evaluated using the Mantel-Haenszel method to calculate chi-squares for tests of linear trend and point estimates and 95% confidence intervals (95% CI) of relative risk.

In other analyses, three measures of symptom *change* between the initial and follow-up interviews were evaluated for their concurrent criterion validity against the outcome measures. The three measures included a global self-assessed change in severity ('better', 'the same', and 'worse') determined at the second interview, and a serially assessed change in frequencies of day symptoms and nocturnal symptoms between the initial and follow-up interviews. They were graded 'better', 'the same', or 'worse' according to the differences in the two scores for the same symptom.

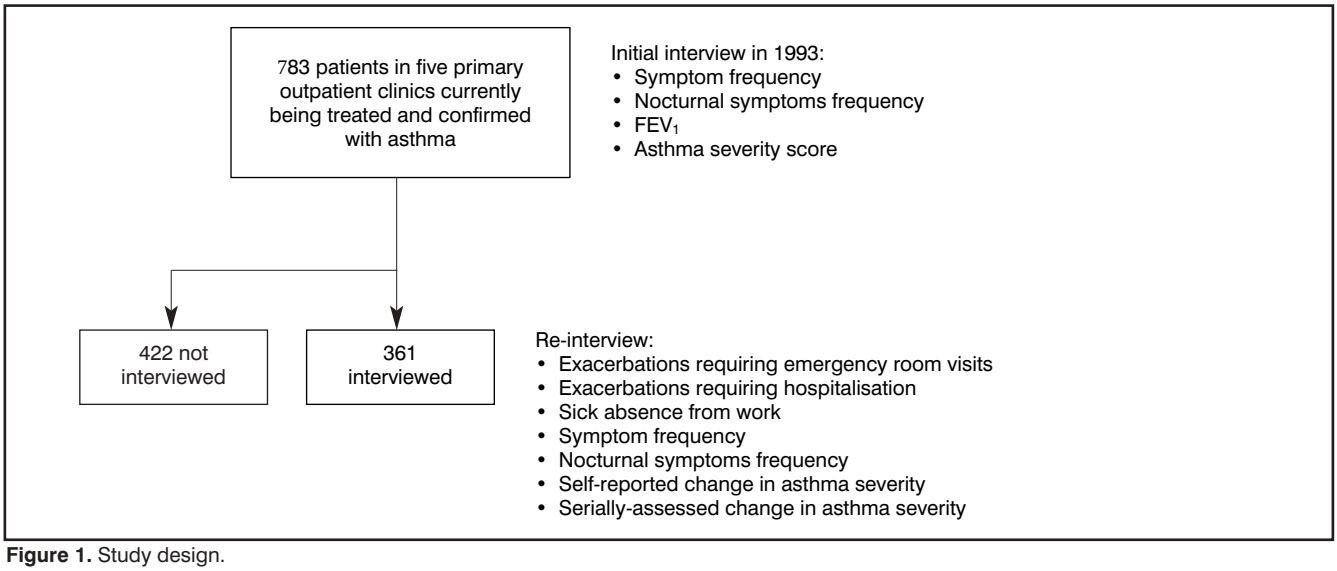

Figure 1. Study design.

Table 1. Asthma symptom questions.

Singapore Asthma Questionnaire items	Singapore Asthma Questionnaire	NIH (NHLBI) Guidelines
In the past year, how often did you have asthma symptoms?[a]	1-3 times a month or less 1-3 times a week, 4-6 times a week Almost every day	£2 times a week >2 times a week but <1 time a day Daily symptoms
In the past year, how often were you woken up at night or in the early morning with an attack of asthma?	7-11 times a year or less 1-3 times a month 1-3 times a week, 4-6 times week Almost every night	£2 times a month >2 times a month > 1 time a week Frequent

[a]'Asthma symptoms' were explained as the onset of cough, wheezing, shortness of breath, or chest tightness.

Table 2. Demographic, clinical, and asthma severity characteristics of patients at initial interview.

	Not re-interviewed n = 422	Re-interviewed n = 361	Significance
Sex			
Male	46%	36%	
Female	54%	64%	P = 0.004
Ethnicity			
Chinese	50%	49%	
Malay	20%	19%	
Indian	30%	33%	P = 0.73
Age groups			
< 30 years	21%	23%	
30-39 years	33%	36%	
>= 40 years	46%	41%	P = 0.30
Educational level			
Primary or less	20%	21%	
Secondary	37%	32%	
Post-secondary	43%	47%	P = 0.33
Atopy	54%	60%	P = 0.06
Family history of asthma	47%	59%	P = 0.001
Symptoms			
£2 times per week	80%	77%	
>2 times per week but <1 time a day	10%	12%	
Daily	10%	11%	P = 0.50
Nocturnal symptoms			
£2 times per month	54%	52%	
>2 times per month	16%	15%	
>1 time per week	9%	11%	
Daily	22%	22%	P = 0.79
FEV1 % predicted			
[3] 80%	57%	55%	
60% to <80 %	20%	25%	
£60 %	23%	21%	P = 0.23
Severity scores			
3	31%	28%	
4-6	50%	48%	
>7	20%	24%	P = 0.43

[s]The severity score was derived as a summed score by assigning, for each level of the measures, an ordinal rank score (1 to 4 for nocturnal symptoms, and 1 to 3 for symptoms in the day and FEV_1 percent of predicted), with minimum and maximum values ranging from 3 to 10. In line with contemporary guidelines on classification of asthma severity, the presence of one of the features of severity was sufficient to place a patient in that category, and an individual was assigned to the most severe grade in which any feature occurs.

In the final analyses, the clinical utility of each severity measure was evaluated by calculating the sensitivities (true-positive rates), one minus specificities (false-positive rates), and likelihood ratios (true-positive rates/false-positive rates).[15-18] These measures were calculated for each of a number of appropriate cut-offs using receiver-operating characteristics (ROC) techniques.[17,18] A series of results of sensitivities, one minus specificities, and likelihood ratios were obtained for various appropriate dichotomous 'cut-offs' in individual predictor variables. From the values of the likelihood ratio, one can determine the optimum cut-off that gives the maximum number of true-positives for the least number of false-positives, and these are reported for each of the asthma severity measures.

Results

Predictive validity of symptom and FEV_1 severity measures

The frequencies of asthma symptoms and nocturnal symptoms were strongly related to the subsequent risks of ER visits, hospitalisation, and sick absence, with statistically significant linear trends (Table 3). *Daily* frequencies of asthma symptoms were

Table 3. Risks of emergency room visitation, hospitalisation, and sick absence associated with symptom and FEV_1 severity level.

	Emergency room visits >4		Hospitalisation >1		Sick absence >4 days	
	No. (%) RR	(95% CI)	No. (%) RR	(95% CI)	No. (%) RR	(95% CI)
Symptoms:						
<2 times per week	26 (9.4%)	1.00	23 (8.3%)	1.00	33 (11.9%)	1.00
>2 times per week but <1 time per day	4 (9.3%)	0.99 (0.36-2.70)	5 (11.6%)	1.40 (0.56-3.52)	6 (13.9%)	1.17 (0.52-2.65)
Daily symptoms	11 (26.8%)	2.86 (1.52-5.39)	11 (26.8%)	3.23 (1.70-6.14)	12 (29.3%)	2.46 (1.36-4.45)
Chi-square for trend	P = 0.004		P = 0.001		P = 0.006	
Nocturnal symptoms:						
<2 times per month	9 (4.8%)	1.00	17 (9.0%)	1.00	12 (6.3%)	1.00
>2 times per month	9 (16.7%)	3.50 (1.52-8.07)	3 (5.6%)	0.62 (0.19-1.98)	9 (16.7%)	2.62 (1.18-5.82)
>1 time but <4 times per week	6 (15.4%)	3.23 (1.25-8.32)	5 (12.8%)	1.42 (0.55-3.67)	10 (25.6%)	4.04 (1.93-8.45)
³4 times per week or every night	17 (21.5%)	4.52 (2.24-9.11)	14 (17.7%)	1.97 (1.02-3.79)	20 (25.3%)	3.99 (2.14-7.43)
Chi-square for trend	P = 0.001		P = 0.037		P = 0.001	
FEV_1 % of predicted:						
³80	19 (9.6%)	1.00	15 (7.6%)	1.00	26 (13.2%)	1.00
>60 to £80	9 (10.1%)	1.05 (0.49-2.23)	8 (9.0%)	1.18 (0.52-2.69)	10 (11.2%)	0.85 (0.43-1.68)
<60	13 (17.3%)	1.80 (0.93-3.46)	16 (21.3%)	2.80 (1.48-5.29)	15 (20.0%)	1.51 (0.85-2.71)
Chi-square for trend	P = 0.104		P = 0.003		P = 0.239	
Asthma severity score						
£3	2 (2.0%)	1.00	4 (4.0%)	1.00	5 (4.9%)	1.00
4-6	23 (13.2%)	6.64 (2.01-21.90)	21 (12.0%)	3.03 (1.15-8.00)	27 (15.4%)	3.12 (1.33-7.31)
³7	16 (18.8%)	9.51 (3.03-29.82)	14 (16.5%)	4.16 (1.57-11.02)	19 (22.3%)	4.51 (1.95-10.46)
Chi-square for trend	P = 0.001		P = 0.006		P = 0.001	

The outcome variables were dichotomised as follows: the number of emergency room visits (four or more/less than four times a year), the number of hospitalisations (one or more/none), and sick absence due to asthma (seven or more days/less than seven days).

associated with statistically significant increases in the risks of all outcome measures. For nocturnal symptoms, frequencies greater than two times a month were associated with statistically significant increases in ER visits and sick absence, and frequencies greater than four times a week or daily were associated with increased risks of hospitalisation. FEV_1 level was only weakly associated with an increased risk of ER visits or sick absence, but a level below 60% or below the level predicted was significantly associated with an increased risk of hospitalisation. A severity score of more than 3 (moderate to severe asthma) was strongly and significantly associated with greatly increased risks of all outcome measures.

Concurrent validity of symptom severity change measures

The three measures of change in asthma severity were significantly related to the outcome measures (Table 4). Patients who were serially assessed to have 'worse' change in day symptoms had significantly increased risks of ER visits and sick absence but not hospitalisation. On the other hand, a serially-assessed change in nocturnal symptoms for the 'worse' category showed a stronger relationship with all outcome measures. However, a self-assessed change in asthma severity was even more strongly associated with outcomes. Compared with patients who reported a 'better' change in severity, patients who reported the 'same' or a 'worse' change in severity both showed increased risks of exacerbations.

Clinical utility of asthma severity measures

With few exceptions, the observed maximum likelihood ratios shown in Table 5 are above the value of 2, indicating twice the *post-hoc* probability of true-positives than false-positives. Given these likelihood ratios, the sensitivities are, however, not high for symptoms frequencies and FEV_1 alone, although they are somewhat better for nocturnal symptoms. However, the combined severity score (using a cut-off of ≥6) gave much higher values than any of these measures alone. Also, the global self-assessed change in asthma severity appeared to give the best values.

Discussion

The results of this study support the validity and usefulness of a simple severity scoring system based on symptoms and FEV_1 measures in the outpatient assessment of adult asthma. While symptom and FEV_1 measures individually did not show high sensitivities, a severity score combining these measures showed reasonably high sensitivity, especially for the future risks of hospitalisation. Nocturnal symptoms were shown to be a better predictor of asthma exacerbations at lower threshold frequencies than day symptoms. This supports the usefulness of nocturnal symptoms as an important symptom characteristic for patient assessment. Previous studies have likewise shown it to be correlated with non-specific airway responsiveness[6] and with the patient's perception of asthma severity and the frequency of medications.[6,19,20]

The poor sensitivities shown for individual symptom and FEV_1 measures could be explained by the fact that they ignore the intensity of symptom exacerbations, which may be mild, moderate, or severe at a given level of frequency or FEV_1. Although they do not address all components of symptom parameters, the results do validate the severity classification recommended by most clinical guidelines including the NIH-NHLBI guideline.[13] This study suggests that a simple severity scoring system based on combining the information on symptom and FEV_1 measures is a useful measure for clinical assessment.

Many scoring systems based on symptom questionnaires have been developed for clinical research, mostly clinical trials.[6-10] As they are focused on measuring short-term changes in response to

Table 4. Self-reported versus serially-assessed change in asthma severity in association with emergency room visits, hospitalisation, and sick absence.

	Emergency room visits >4		Hospitalisation >1		Sick absence >4 days	
	No. (%) RR	(95% CI)	No. (%) RR	(95% CI)	No. (%) RR	(95% CI)
Self-reported severity change						
Better	11 (4.5%)	1.00	10 (4.1%)	1.00	12 (5.0%)	1.00
Same	17 (18.1%)	3.98 (2.03-7.80)	20 (21.3%)	5.15 (2.69-9.87)	23 (24.5%)	4.93 (2.72-8.96)
Worse	13 (52.0%)	11.44 (6.24-20.97)	9 (36.0%)	8.71 (4.24-17.91)	16 (64.0%)	12.91 (7.46-22.31)
Chi-square for linear trend	P = 0.000		P = 0.000		P = 0.000	
Serially-assessed severity change						
Symptoms						
Better	18 (10.4%)	1.00	21 (12.1%)	1.00	22 (12.7%)	1.00
Same	9 (7.3%)	0.70 (0.33-1.50)	7 (5.7%)	0.47 (0.21-1.04)	10 (8.1%)	0.64 (0.32-1.29)
Worse	14 (21.5%)	2.07 (1.09-3.91)	11 (16.9%)	1.39 (0.71-2.74)	19 (29.2%)	2.30 (1.33-3.94)
Chi-square for linear trend	P = 0.07		P = 0.71		P = 0.014	
Nocturnal symptoms						
Better	19 (9.4%)	1.00	16 (7.9%)	1.00	24 (11.8%)	1.00
Same	8 (9.4%)	1.00 (0.46-2.21)	6 (7.1%)	0.90 (0.36-2.21)	10 (11.8%)	0.99 (0.50-1.99)
Worse	14 (19.2%)	2.05 (1.09-3.87)	17 (23.3%)	2.96 (1.60-5.44)	17 (23.3%)	1.97 (1.12-3.46)
Chi-square for linear trend	P = 0.04		P = 0.001		P = 0.031	

Table 5. Clinical utility of symptom measures of asthma severity in predicting recurrent asthma exacerbations in long-term primary outpatient care of adult asthma.

	Emergency room visits			Hospitalisation			Sick absence		
	Sensitivity %	1-specificity (false-positive rate)	Maximum likelihood ratio	Sensitivity %	1-specificity (false-positive rate)	Maximum likelihood ratio	Sensitivity %	1-specificity (false-positive rate)	Maximum likelihood ratio
Symptoms: daily symptoms	26.8	9.4	2.85	29.0	9.4	3.08	23.5	11.0	2.14
Nocturnal symptoms: ³4 times a week	41.5	19.5	2.13	30.8	16.2	1.90	76.5	42.9	1.78
FEV_1 % of predicted: ³60% predicted	31.7	19.4	1.63	41.0	18.3	2.24	29.4	19.4	1.51
Asthma severity score (cut-off ³6)	58.3	30.0	1.94	79.5	47.2	1.68	51.0	30.3	1.68
Self-reported severity change (worse)	73.2	27.8	2.63	74.4	28.0	2.66	76.5	25.8	2.97

The sensitivity and 1-specificity values are optimal values associated with the maximum likelihood ratio (sensitivity/1-specificity) from receiver operating characteristic (ROC) analyses.

asthma therapies, they are therefore too elaborate to be useful in routine clinical practice. Few studies have addressed the predictive validity of simple measures for severity assessment in clinical practice. The symptom measures evaluated in this study were those that are recommended in most practice guidelines, and the outcome measures that were used address specifically an explicit goal of asthma therapy, namely 'to prevent recurrent exacerbations of asthma and minimise the need for emergency department visits or hospitalisations'.[13]

Self-assessed change is a global measure of asthma severity. Singly, it appeared to show much better validity and utility than other measures. This is perhaps not surprising, as personal assessment is also involved in the decision-making process of using ER and hospital services and taking sick leave from work. The patients' recall of events related to exacerbations of asthma and sick days off may be considered to be very subjective and therefore weak measures of outcomes. However, insofar as the patient is much more sensitive to global changes in his/her personal condition, it may be argued that self-assessments are probably sometimes to be preferred over vicarious estimates *('experto credo'*). In the same context, one should also consider recent evidence indicating that most patients prefer and are better at making self-management decisions based on symptoms rather than on their PEF.[3-5,20]

The present research documents the validity and utility of a simple clinical scoring measure to classify patients according to their future risks of asthma exacerbations. This risk assessment is an important part of clinical management for long-term and continuing care of asthma patients in general practice. Patients identified to be at increased risk could then receive closer monitoring and more intensive asthma self-management education.

Conclusion

Simple measures of asthma symptom frequencies and pulmonary function are predictive of the risks of recurrent exacerbations resulting in ER visits, hospitalisation, and sick absence. This study supports the validity and utility of a simple clinical severity score based on symptom and pulmonary function measures and a self-assessed change in asthma severity for asthma risk classification in contemporary clinical practice guidelines.

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Address for correspondence

Dr Tze Pin Ng, Department of Community, Occupational and Family Medicine, Faculty of Medicine, National University of Singapore, Lower Kent Ridge Road, Singapore 119260.