

Implementation of asthma guidelines in health centres of several developing countries

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SUMMARY

SETTING: Nine selected out-patient clinics caring for asthma patients in Algeria, Guinea, Ivory Coast, Kenya, Mali, Morocco, Syria, Turkey and Vietnam.

DESIGN: Prospective enrolment of consecutive patients considered by the practitioner to have asthma with evaluation of adherence of the practitioner with recommended standard case management, including proportion of patients confirmed to have asthma, proportion in whom severity was correctly graded and proportion in whom treatment with inhaled corticosteroids corresponded to severity grade.

RESULTS: Of 499 consecutive patients, 456 (91%) were enrolled and evaluated. The diagnosis was confirmed in 263 (58%). Agreement between the practitioner and the guidelines in assigning grade of severity was moderate

overall ($\kappa = 0.42$). It was higher for assignment of grade using symptoms ($\kappa = 0.51$), but poor for assignment of grade using peak expiratory flow (PEF) rate ($\kappa = 0.29$), with practitioners tending to underestimate the severity. Agreement between the practitioners' assessment of severity and treatment with inhaled corticosteroids was poor ($\kappa = 0.18$), with underutilisation of inhaled corticosteroids.

CONCLUSIONS: Practitioners caring for asthma patients in this study tended to underutilise the PEF rate in assessing their patients and underutilised treatment of patients with inhaled corticosteroids.

KEY WORDS: asthma; guidelines implementation; peak flow meter; variability

CONSIDERABLE EFFORTS have been made to rationalise and standardise the management of asthma patients: since 1990 several national consensus reports^{1–7} and an International Consensus Report⁸ have been published. In 1995, the National Heart, Lung, and Blood Institute (NHLBI) and the World Health Organization (WHO) collaborated in the preparation of a document entitled 'Global Initiative for Asthma' (GINA),⁹ which proposed guidelines that are based on the latest scientific developments. In 1996, the International Union Against Tuberculosis and Lung Disease (The Union) adapted these guidelines in a publication as a basis for recommendations to its members for organising asthma management in developing countries.¹⁰

This publication proposed the use of the implementation framework for delivery of a 'technical package' of asthma management fully integrated into the existing national health services structure. Diagnosis and follow-up of patients are based on the evaluation of the frequency of symptoms and on the level and variability of peak expiratory flow (PEF) measured on different occasions. A long-term stepwise method of treatment is proposed, using inhaled salbutamol, inhaled beclomethasone and oral prednisolone. The information system proposed includes a treatment card for each asthma patient and an asthma register to record all new patients suffering from persistent asthma.

To evaluate the application of the proposed guidelines, a prospective study was conducted in several

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developing countries. The first part of this study has been published in a previous article,¹¹ and showed that the cost and availability of inhaled corticosteroids represent important barriers to application of these guidelines in low- and middle-income countries. The principal aim of the second part of this study is the evaluation of the use of guidelines in routine practice for the management of asthma patients, particularly for the confirmation of diagnosis, the classification of disease severity and the prescription of inhaled steroids according to the asthma severity grade.

MATERIALS AND METHODS

A prospective study was conducted in 1998–2000 in selected health structures in nine countries: Algeria (two centres, Algiers and Tizi-ouzou), Guinea (Conakry), Ivory Coast (Abidjan), Kenya (Nairobi), Mali (Bamako), Morocco (Tangiers), Syria (Lattakia), Turkey (Istanbul), and Vietnam (Ho Chi Minh). The centres chosen represented a convenience sample of centres where various Union members worked and who expressed interest in participating in the study.

All the physicians are specialists working at the first referral level of health structures, as recommended in Union guidelines for the long-term organisation of asthma management.

Consecutive patients consulting in each centre for the first time and considered by the physician to have asthma were eligible for inclusion in the study. Each centre was requested to apply a common protocol and follow published guidelines¹⁰ to: 1) set up a standardised information system (patient treatment card and asthma register), 2) establish the diagnosis of asthma, 3) evaluate the severity of the disease, and 4) prescribe a stepwise standardised treatment according to asthma severity.

The case definitions used in the study were the following:

- 1 Confirmed asthma: a patient with symptoms that are typical of asthma and PEF variability $\geq 20\%$ (variability of PEF % = maximum PEF in l/min – minimum PEF in l/min / PEF minimum in l/min $\times 100$)
- 2 Non confirmed or probable asthma: a patient with symptoms that are typical of asthma, with a history of disease that is characteristic of asthma, after exclusion of other diagnoses, a PEF variability $< 20\%$ and a decision of the physician to treat as a case of asthma.

To evaluate the severity of asthma, clinical and functional evaluations were carried out. The clinical severity of asthma was evaluated according to symptom frequency during the previous 6 months. The symptoms were graded as:

- 1 intermittent when they occurred less than once a week and disappeared for certain period of time;

- 2 persistent when they never went away for more than 1 week, with three grades of severity:
 - i mild persistent symptoms (less than once per day)
 - ii moderate persistent symptoms (every day, or affect activities and sleep at least once a week)
 - iii severe persistent (symptoms continuous with frequent attacks, activities limited by symptoms and frequent night time symptoms).

Functional severity was evaluated according to the PEF result, expressed as per cent of predicted value, after stabilisation following initial treatment: 1) without impairment (PEF $\geq 80\%$), 2) moderate (PEF 60–79%) and 3) severe (PEF $< 60\%$).

The worse of the two evaluations (clinical and functional) was taken as the disease severity grade.

The asthma severity of each patient based on symptoms severity and PEF level was evaluated by local physicians and independently by the study coordinator.

Standardised treatment given stepwise, according to the disease severity grade, was recommended with salbutamol as needed and defined daily dosages of beclomethasone for each severity grade, with dosages of beclomethasone recommended as follows:

- 1 first step—mild persistent asthma: 500 μg for adults, 250 μg for children;
- 2 second step—moderate persistent asthma: 1000 μg for adults, 500 μg for children;
- 3 third step—severe persistent asthma: 2000 μg for adults and 750–1000 μg for children.

All participating centres were provided with copies of the guide. No specific training was given for health care workers involved in the study. However, the first five treatment cards of each centre were sent to the Union coordinator for verification, and advice on the correct completion of the forms was given where errors were noted.

All the information required for the analysis of the study was recorded on the patient treatment card, and the data were entered into the computer using Epi Info (Centers for Disease Control and Prevention, Atlanta, GA, USA). Data were then sent in Epi Info and hard copy to the coordinating centre in Paris. Analysis was performed using SPSS (SPSS Inc, Chicago, IL). Data were evaluated and corrected for errors. They were then cross-tabulated and analysed. Categorical data were analysed using χ^2 . Where multiple variables were considered simultaneously, logistic regression analysis was employed. For determination of agreement of evaluation between the practitioner and the guidelines and for comparison of severity grade and prescription of medications, the kappa statistic was calculated.¹² The agreement was considered fair for values between 0.21 and 0.40, moderate between 0.41 and 0.60, substantial between 0.61 and 0.80 and almost perfect between 0.81 and 1.00.¹³

RESULTS

A total of 499 patients were eligible for the study, and complete data were available for 456 patients (91%). Fifteen patients were not enrolled and information was not complete for 28. There were no differences between the patients analysed and those for whom data was not complete in relation to sex, smoking habit, symptom severity grade or PEF. However, the difference in distribution by age group was statistically significant ($P < 0.001$), with more children in the group of patients with missing data.

Table 1 outlines the characteristics of the 456 patients with complete data. Of these, 263 (58%) fulfilled the criteria for confirmation of the diagnosis of asthma. There was a statistically significant difference in age distribution between those with a confirmed diagnosis as compared with those without confirmation ($P < 0.001$, χ^2). A higher proportion of children were confirmed. Among adults, the proportion confirmed increased steadily with advancing age. The rate of asthma confirmation increased with increasing PEF impairment, from 16% for PEF $\geq 80\%$ to 92% for PEF $< 60\%$. PEF impairment increased with age: the proportion of patients with PEF $< 60\%$ varied from 22% for patients 15–24 years of age to 72% for patients aged ≥ 55 , and the proportion of patients with PEF $\geq 80\%$ decreased from 36% for patients aged 15–24 years to 1.9% for patients aged ≥ 55 .

In the univariate analysis, there was no difference between confirmed and unconfirmed cases with respect to sex or smoking habit. In a multivariate model constructed to evaluate differences within centres, only the proportion of confirmed asthma and physician's asthma severity evaluation were significantly different; no significant difference was found in age group, sex, smoking habit, severity of symptoms, PEF impairment and prescription of inhaled steroids.

Table 1 Personal characteristics and habits associated with confirmation of asthma diagnosis, according to recommended PEF rate variation of 20%

	Confirmed n (%)	Non-confirmed n (%)	Total n (%)	P value
Total	263 (58)	193 (42)	456 (100)	
Age group, years				
0–14	48 (68)	23 (32)	71 (100)	
15–24	34 (37)	58 (63)	92 (100)	
25–34	61 (54)	53 (46)	114 (100)	
35–44	49 (60)	33 (40)	82 (100)	
45–54	27 (63)	16 (37)	43 (100)	
≥ 55	44 (81)	10 (19)	54 (100)	< 0.001
Sex				
Female	144 (59)	101 (41)	245 (100)	0.608
Smoking*				
Never smoked	150 (53)	131 (47)	281 (100)	
Ex-smoker	39 (62)	24 (38)	63 (100)	
Smoker	26 (63)	15 (37)	41 (100)	0.275

* Those < 15 years of age excluded.
PEF = peak expiratory flow.

Table 2 Characteristics of asthma associated with confirmation of asthma diagnosis, according to recommended PEF rate variation of 20%

	Confirmed n (%)	Non-confirmed n (%)	Total n (%)	P value
All cases	263 (58)	193 (42)	456 (100)	
Symptoms				
Intermittent	73 (57)	55 (43)	128 (100)	
Mild persistent	73 (47)	83 (53)	156 (100)	
Moderate persistent	98 (67)	49 (33)	147 (100)	
Severe persistent	19 (76)	6 (24)	25 (100)	0.001
PEF grade				
$\geq 80\%$	20 (16)	105 (84)	125 (100)	
60–79%	95 (56)	75 (44)	170 (100)	
$< 60\%$	148 (92)	13 (8)	161 (100)	< 0.001
Overall asthma severity				
Intermittent	11 (23)	37 (77)	48 (100)	
Mild persistent	7 (13)	47 (87)	54 (100)	
Moderate persistent	96 (51)	92 (49)	188 (100)	
Severe persistent	149 (90)	17 (10)	166 (100)	< 0.001

PEF = peak expiratory flow.

Table 2 displays the clinical characteristics of the group of patients according to confirmation of the diagnosis. Of the 456 patients, 128 (28%) had intermittent symptoms, 156 (35%) mild persistent, 147 (32%) moderate persistent and 25 (5%) severe persistent. The difference in distribution of symptom severity was statistically significant ($P = 0.001$, χ^2) between the confirmed group compared with those who were not confirmed, with a much higher proportion of confirmed patients having higher grades of severity of symptoms. A similar distribution was observed with respect to severity graded according to PEF rate. The concordance between severity of symptoms and severity of PEF impairment was poor ($\kappa = 0.10$). These two measures combined resulted in a marked difference in distribution of severity grade among the confirmed as compared with the non-confirmed. When a multivariate model was constructed to determine the statistically significant predictors of confirmation, among age, sex, smoking habit, severity of symptoms and category of PEF rate, only age and PEF rate were significantly associated with confirmation of diagnosis.

Table 3 displays a comparison between the severity grades according to the guidelines as compared with that assigned by the physician. Of the 456 patients analysed, 65 (14.3%) were assigned a grade that was at least two levels lower by the physician as compared with the severity grade recommended in the guidelines. On the other hand, only one patient (0.2%) was assigned a severity grade that was at least two steps higher by the physician as compared with the severity grade recommended in the guidelines. The physician diagnosis was more accurate for the milder grades of asthma (approximately 75% for intermittent and mild persistent asthma), but poorer for the severe grades (53% and 47%, respectively, for moderate persistent and severe asthma).

Table 3 Comparison of physicians' assessments of severity with those recommended in the guidelines

Physician assessment	Assessment according to guidelines				Total <i>n</i>
	Intermittent <i>n</i>	Mild persistent <i>n</i>	Moderate persistent <i>n</i>	Severe persistent <i>n</i>	
Total	48	54	188	166	456
Intermittent	36	1	30	24	91
Mild persistent	11	44	41	11	107
Moderate persistent	1	9	100	53	163
Severe persistent	0	0	17	78	95

The kappa statistic for agreement between the physician and the guidelines was 0.42. This difference in assessment was more marked in relation to PEF rate than to symptom severity (14.0% lower and 0.4% higher for PEF as compared with 0.2% lower and 8.1% higher for symptom severity grade). The kappa statistic for agreement between the physician and the guidelines was 0.51 for symptom-based grade of severity and 0.29 for functional grade of severity.

Table 4 outlines the treatment prescribed by the physician according to the severity of disease as judged by the physician. Only 18% of patients requiring inhaled corticosteroids did not receive them. However, among those who did receive them, the dose was frequently incorrect. Among the 456 patients evaluated, 50 (10.9%) were prescribed a dose of inhaled steroids at least two steps lower than recommended by the guidelines for the severity level of the diagnostic grade, while 26 (5.7%) were prescribed a dose at least two steps higher than recommended. The underdosage of prescribed medications was related more to severity grades assessed by PEF rate (12.3% lower dosage and 2.6% higher dosage) than for severity grade assessed by symptom category (6.6% lower and 11.8% higher dosage). The kappa statistic for correspondence between the physician's assessment of severity and prescription of treatment according to the guidelines was 0.18.

DISCUSSION

The establishment of a consensus on the management of asthma, based on scientific evidence, has been an

Table 4 Comparison of physicians' prescription of inhaled corticosteroid medications with the prescription of medications recommended by the guidelines according to the degree of severity of disease

Physicians' prescription	Guideline recommendations				Total <i>n</i>
	None <i>n</i>	Step 1 <i>n</i>	Step 2 <i>n</i>	Step 3 <i>n</i>	
Total	144	44	221	47	456
None	62	11	18	0	91
Step 1	36	13	50	8	107
Step 2	38	16	86	23	163
Step 3	8	4	67	16	95

important step in improving the quality of care of the millions of people who suffer from the disease. However, the mere establishment of such guidelines is insufficient; they must also be utilised. The present study was designed to determine to what extent the presence of such guidelines, in the absence of any other interventions, might be associated with good clinical practice.

Several studies have been reported on the compliance of practitioners with guidelines, and have shown that, even if guidelines can aid their practice, many physicians do not adhere to such guidelines.¹⁴⁻¹⁷ Means to improve the implementation of guidelines have been investigated in industrialised countries.¹⁵⁻²² Those shown to be associated with improved outcomes include: employment of a practice nurse, use of computers and carrying out audits. To what extent these approaches might be adapted to services in developing countries is unclear.

In this report, we have shown that, among all patients treated for asthma in the collaborating centres, just over one half had their diagnosis confirmed. Physicians collaborating in the study clearly made more use of symptoms in evaluating the severity grade of their patients, while their use of PEF measurements was much less systematic. Moreover, although they were participating in a study specifically looking at the quality of care, their prescription of treatment did not correlate well with their diagnosis. This may be explained, in part, by the patients' ability to pay for inhaled steroids and in part by the limited availability of such medications in some locations.¹¹ However, these observations of underestimation of asthma severity and underuse of inhaled steroids have also been reported in other large studies conducted worldwide. In a large study published in 2004, it was observed that the use of anti-inflammatory preventive medications, even in patients with severe persistent asthma, was low, ranging from 26% in Western Europe to 9% in Japan, as was the use of objective lung function testing.²³

In seven European countries, current asthma patients were identified in 3488 households, and 2803 patients (80.4%) completed the survey. In the previous 4 weeks, more patients had used prescriptions of quick-relief medication (such as short acting beta

agonists, theophylline or ipratropium bromide) (63%) than inhaled corticosteroids (23%).²⁴ In a large cross-sectional survey conducted in urban centres in eight areas of China, Hong Kong, Korea, Malaysia, the Philippines, Singapore, Taiwan and Vietnam, with a population sample of 3207 respondents with physician-diagnosed asthma, current use of an inhaled corticosteroid was reported by only 13.6% of respondents.²⁵

The present study has several limitations. As participating specialist physicians volunteered for the study, it is impossible to generalise these results to the practice of all physicians involved in asthma management. The duration of the study was limited and clearly does not reflect the results of long-term routine practice.

Despite these limitations, this study demonstrates that it is technically possible to implement standardised asthma management and to set up an information system for its routine evaluation in developing countries. However, the routine use of PEF measurement is inadequate and needs to be improved. Moreover, better results could probably be obtained if a permanent, affordable supply of drugs could be assured and if specific training and supervision of health personnel could be provided. Training should have a particular focus on the adequate use of peak flow meter measurements to establish asthma diagnosis and to classify disease severity, and should also focus on correctly filling in the treatment card and register, which are vital tools for routine evaluation.

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R É S U M É

LIEUX : Neuf services de consultation externe prenant en charge des asthmatiques en Algérie, Guinée, Côte d'Ivoire, Kenya, Mali, Maroc, Syrie, Turquie et Vietnam.

TYPE D'ÉTUDE : Étude prospective incluant des consultants consécutifs considérés par le médecin comme ayant de l'asthme et évaluant l'adhérence du médecin aux recommandations de prise en charge standardisée des patients. L'évaluation a porté en particulier sur la proportion de confirmation du diagnostic, celle du classement adéquat de la sévérité de la maladie et sur celle de malades ayant reçu le traitement aux corticoïdes inhalés correspondant à la sévérité de leur asthme.

RÉSULTATS : Sur 499 patients consécutifs, 456 (91%) ont été inclus dans l'évaluation. Le diagnostic a été confirmé chez 263 patients (58%). L'accord entre les mé-

decins et les directives pour la classification de l'asthme des malades selon le degré de sévérité était modéré ($\kappa = 0,42$). Cet accord était plus élevé en utilisant les symptômes ($\kappa = 0,51$), mais faible lorsqu'on utilisait le niveau du débit expiratoire de pointe (DEP) ($\kappa = 0,29$), avec pour conséquence une tendance des médecins à sous-estimer la sévérité de l'asthme des patients. L'accord entre la classification de la sévérité de l'asthme faite par les médecins et le traitement aux corticoïdes inhalés était faible ($\kappa = 0,18$), avec une sous-utilisation des corticoïdes inhalés.

CONCLUSIONS : Dans cette étude, les médecins prenant en charge les asthmatiques avaient tendance à sous-utiliser le niveau du DEP pour la classification de la sévérité de l'asthme des malades et à les sous traiter en corticoïdes inhalés.

R E S U M E N

MARCO DE REFERENCIA : Nueve consultorios de atención a los pacientes ambulatorios con asma en Argelia, Guinea, Costa de Marfil, Kenia, Malí, Marruecos, Siria, Turquía y Vietnam.

MÉTODO : Un estudio prospectivo de pacientes seleccionados consecutivamente entre aquellos con diagnóstico de asma establecido en la consulta. Se evaluó la observación de las recomendaciones para el tratamiento normalizado de casos por parte del médico, en particular la proporción de pacientes con confirmación del diagnóstico de asma, la proporción de pacientes con una clasificación correcta de la gravedad y la proporción de casos en los cuales la dosificación de los corticoesteroides inhalados correspondió al nivel de gravedad.

RESULTADOS : De 499 pacientes consecutivos se incluyeron y evaluaron 456 (91%). El diagnóstico se confirmó en 263 pacientes (58%). La concordancia entre el juicio

del médico y las normas de clasificación de la gravedad del asma fue globalmente moderada (índice $\kappa = 0,42$); fue mayor cuando se evaluó la gravedad de acuerdo con los síntomas (índice $\kappa = 0,51$), pero baja cuando se basó en las cifras de flujometría (flujo espiratorio máximo [FEM]) (índice $\kappa = 0,29$), y se observó en los médicos una tendencia a subestimar la gravedad del asma. La correspondencia entre la clasificación de gravedad establecida por el médico y la dosificación de los corticoesteroides inhalados fue baja (índice $\kappa = 0,18$), debido a una subutilización de los corticoesteroides.

CONCLUSIONES : En el presente estudio, los médicos que atendían pacientes con asma utilizaron poco las cifras del FEM para clasificar la gravedad de la enfermedad y mostraron una tendencia a tratar sus pacientes con dosis insuficientes de corticoesteroides inhalados.