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Chronic obstructive airway diseases: Is the EDL sufficient? A study done at the Heidedal CHC in Bloemfontein.

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Abstract

Background:
With the implementation of the Standard Treatment Guidelines (STG's) and Essential Drug List (EDL) in 1996 some of the traditional medication for the treatment of asthma and chronic obstructive pulmonary disease (COPD) were removed from the medication list, e.g. slow release oral theophylline. The objective of this study was to establish whether we were able to treat patients with chronic obstructive airway disease (which includes asthma and chronic obstructed pulmonary disease) effectively with the guidelines and medication on the Standard Treatment Guidelines and Essential Drug List for Primary Health Care (STG's and EDL), 1996.[1]

Method:
In this follow-up study all patients with chronic obstructive airway diseases (COAD) at Heidedal Community Health Center (CHC) over a 3-month period were evaluated and a lung function test was done on them. Their old medication was stopped and the treatment guidelines of the STG's and EDL were followed. A repeat lung function test was done on all patients after three months on the new treatment. Four indicators were used namely: FVC, FEV1, FEFmax and FEF25-75.

Results:
Fifty patients were included in the study. Improvement in all four lung functions were noted after the new guidelines were implemented.

Conclusions:
The implementation of the EDL guidelines for asthma and COPD controlled the diseases, the guidelines were easy to use and are comparable to the latest international standards. Standard guidelines also create better patient compliance and give confidence to health workers. The revised STG's and EDL for Primary Health Care (1998) are comparable with the guidelines used in this study.

Introduction

The objective of this study was to establish whether we were able to treat patients with chronic obstructive airway diseases (which includes asthma and chronic obstructed pulmonary disease) effectively with the guidelines and medication on the Standard Treatment Guidelines and Essential Drug List for Primary Health Care (STG's and EDL), 1996.[1]

The treatment of asthma and COPD changed markedly once the mechanisms of the diseases were understood more clearly. Centuries ago the Chinese started to inhale herbs with B-agonist like actions, in the 17th century Datura species (with anticholinergic actions) were discovered and at the turn of the 19th century adrenaline was first use to treat asthma. In the latter half of the 20th century inhaled steroids became part of asthma treatment.[2]

After a joint meeting in 1995 of all concerned parties involved in the treatment of asthma in Britain the Step model [3] was accepted as the gold standard for the treatment of asthma. These guidelines compare well with the guidelines in the STG and EDL.

In the treatment of COPD the use of ipratropium inhalations is associated with improvement in lung functions. It is therefore recommended that COPD must be treated with ipratropium and low dosage beta $_2$ agonists to decrease the side effects of beta $_2$ agonists. [4-9] The routine use of inhalation steroids in COPD is uncertain, but more useful in patiens with an allergic background.[10-12] This is also the same as in the STG and EDL.

The use of long acting oral theophylline is not standard according to guidelines[1,3] in the treatment of asthma, although it is much cheaper and easier for the patient to use than the metered dose inhalers. The problems with the drug are the narrow therapeutic window, unpredictable blood levels, drug interactions and toxicity even within normal values.[13, 17-18]

It is used where the cost of an effective alternative is too high .[13,19]

Lung functions and especially flow volume loops can be used with great success to identify, evaluate and monitor lung disease and the treatment thereof. A deviation of more than 20% of the predicted value can be considered abnormal. It is important to compare every patient with his/her own baseline to evaluate treatment. An increase of 15% in lung function is indicative of reversible bronchospasm.[14,15]

METHODS

All routine follow up patients with a history of asthma or COPD at the Heidedal CHC in 3 consecutive months from June 1997 to August 1997 were evaluated for inclusion in this follow-up study.

Patients who were not able to perform lung function tests either because of the seriousness of their lung condition or because they did not understand how to perform the test and patients with acute bronchospasm during the visit were excluded from the study.

All patients were clinically evaluated and thereafter a flow volume loop test was performed on them. From the patient's history and clinical notes questionnaires were filled in to get the social and demographic data as well as the current medication.

The spirometer equipment was adequately and frequently calibrated using standard methods. The procedure how to perform the test was demonstrated to the patient and with a nose clip on they then performed the test. The best of 3 acceptable curves was used. Ten minutes after 2 inhalations of a beta $_2$ agonist the test was repeated in the same way. Four different values were compared between the different flow volume loops, namely: Forced vital capacity (FVC) to measure the maximum amount of air that the patient is able to exhale after maximum inhalation, forced expiratory volume in one second (FEV_1) to measure the flow in the airways in 1 second (usually 80% of FVC if there are no obstruction), maximum forced expiratory flow (FEF_{max}) to measure the airflow in the big airways and forced expiratory flow 25-75% (FEF_{25-75}) to measure the airflow in the small airways.

According to the patient's clinical evaluation and the lung function the patient was then diagnosed either asthma or COPD. This was done according to the guidelines of the American Thoracic Society for the diagnosis of asthma and COPD.[16] The patients diagnosed with asthma then received inhalation steroids and $beta_2$ agonists to use with a spacer. The patients with COPD were treated with inhalation anticholinerg drugs regularly and $beta_2$ agonists when necessary, both with a spacer. The use of the spacer was demonstrated to all patients. Thereafter they had to demonstrate it to make sure that they could use it properly.

The use of long acting oral theophylline was discontinued in all patients because it was not available on the EDL and neither in the first line of treatment for asthma and COPD.[1]

A repeat lung function test was done on each of the patients 3 months after the slow release theophylline was stopped and the new guidelines were followed to see if there were significant changes in their lung functions. Numerous studies showed change in lung functions with the correct treatment with the maximum effect within 85 days.[4-7]

The study protocol was approved by the Ethics Committee of the Faculty of Health Sciences, University of the Free State. All patients gave written consent for inclusion in the study. Patients refusing consent would get the same drugs as the study participants, since there were no alternatives available, but there were no refusals.

RESULTS

Only 1 patient was excluded because she was unable to perform the lung function test. There were 50 patients included in the study of whom 54% were female. (Table I) The mean age of the patients were 51 years and varied between 13 and 70 years. Twenty four percent of patients were smoking for a mean of 22 years and they smoked a median of 5 cigarettes a day. (Range 2 to 22 cigarettes a day.) A further 34% never smoked and 42% quitted after smoking between 2 and 40 years. All the smokers were from the COPD group.

In 36% of cases there was a family history of asthma, mainly in the asthma group. Only one patient was exposed to an allergen at work.

All patients were on slow release theophylline at the onset of the study, after 3 months 96% were on a $beta_2$ agonist and 64% on ipratropium bromide and none on slow release theophylline.(Table II)

If the flow volume loops of the 50 patients before the onset of the trail were compared with the flow volume loops 3 months after the oral theophylline was stopped and the new guidelines were implemented the results showed an improvement in all 4 measurements (Table III). Three of the measurements were statistically significant ($p<0.05$) and the other p-value was 0.0814 which is

Table I Demographic data of patients

	Total (n=50)		Asthma (n=22)		COPD (n=28)	
	N	%	N	%	N	%
Gender: Male	23	46	8	36	17	61
Female	27	54	14	64	11	39
Smoking: Yes	12	24	0	0	12	43
No	17	34	14	64	3	11
Quitted	21	42	8	36	13	46
Allergies: Yes	22	44	14	68	7	25
No	16	32	3	14	12	46
Unknown	12	24	4	18	8	29

Table II Medication of patients (n=50)

Drug	% at onset of study	% after 3 months
Slow release theophylline	100	0
Ipratropium bromide	4	64
Inhalation steroid	6	40
Beta 2 agonist	24	94
Other non COPD drugs (for example hypertension and pain drugs)	32	40

Table III Comparison of the mean lung function at onset and after 3 months EDL treatment. (n=50)

	Mean onset	Mean after 3/12	Mean change	95% CI for mean change	p-value
FVC (liter)	2.60	2.68	+0.08	-0.01; 0.18	0.0814
FEV_1 (liter)	1.70	1.81	+0.11	0.04; 0.19	0.0039
FEF_{max} (l/sec)	4.45	5.00	+0.55	0.30; 0.80	0.0001
FEF_{25-75} (l/sec)	1.35	1.55	+0.20	0.05; 0.34	0.0079

Table IV Comparison of mean lung function between previous lung function and at onset of study. (n=23)

	Mean previous	Mean onset	Mean change	95% CI for mean change	p-value
FVC (liter)	2.57	2.46	-0.11	-0.20; -0.02	0.0193
FEV_1 (liter)	1.65	1.60	-0.05	-0.08; -0.02	0.0035
FEF_{max} (liter/sec)	4.33	4.13	-0.20	-0.48; 0.09	0.1692
FEF_{25-75} (liter/sec)	1.39	1.30	-0.09	-0.14; -0.04	0.0015

close to statistical significance. There were no significant differences between the patients with asthma and COPD.

Out of the 50 patients included in the study there were previous flow volume loops available for 23 of them since they had previous records in the clinic. These flow volume loops were performed between 5 and 24 months before the onset of the study. From the comparison of the old flow volume loops and the flow volume loops at the beginning of the study it is demonstrated that the lung functions decreased in all 4 measurements with time despite treatment (Table IV). This is a normal physiological process. Furthermore, the 23 for whom flow volume loops were available, may be a biased subgroup of patients. Their characteristics were compared to those of the patients with no records, and the only variables on which there were close to significant differences were diagnosis (70 % of those with records had COPD compared to 44% of those without records) and consequently also type of medication.

DISCUSSION

The demographic data of the patients showed a very high prevalence of smoking in the COPD group. A large 89% of them still smoke or smoked previously in their lives. Smoking is the main cause of COPD. Intervention to stop smoking in this group is very important. In the asthma group 68% reported to be allergic to substances. It is unfortunately not so easy to prevent allergens and most of the time the allergen is not known. Before the implementation of the EDL guidelines our treatment compared well to that of other developing countries[19], with almost all the patients on oral theophylline and very few patients on inhaled steroids. With the implementation of the guidelines no patients were on oral theophylline and all asthmatic patients on inhalation steroids and all patients with COPD on anticholinergic drugs. They used their $beta_2$ agonists as necessary.

Unfortunately records on previous flow volume loops were only available for 23 (46%) of the participants. Their results may not be generalisable to the whole group.

The improvement in all four measured lung functions after implementation of the guidelines, showed that the guidelines in the EDL for the treatment of asthma and COPD are effective and can help to improve the lung functions in these patients. It is easy to use and give new and cost effective ways for the management of these patients. As it is a policy all health care workers must now follow the same guidelines that will help with patient compliance. It also gives confidence to health workers as they have tested guidelines to use. These guidelines compare well with the latest worldwide guidelines for the treatment of asthma and COPD.[3,16]

Although slow release theophylline was added in the revised STG's and EDL for Primary Health Care 1998 edition it is still a last step in the treatment of asthma and COPD.

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