

Written Information on the Use of Aerosols in COPD patients. Can We Improve Their Use?

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Objectives. To determine whether the use of written information alone improved inhalation technique with pressurized canister inhalers in patients with chronic obstructive pulmonary disease (COPD). To compare the effectiveness of written information versus verbal explanation provided by nursing personnel on the use of inhalers.

Design. Interventional study.

Setting. Urban health center located outside the city center.

Participants. 120 patients with COPD treated with pressurized canister inhalers.

Interventions. The participants were divided randomly into three groups of 40 patients each. In one group no intervention was used, in the second group verbal explanations were provided, and in the third group written information was provided.

Main measures. We recorded percentage compliance with 5 criteria for the correct use of inhalers at the start of the study and 3 months after the intervention in all groups.

Results. Initially, performance of the inhalation technique by patients with COPD was poor (mean compliance 40%).

Performance improved significantly in both intervention groups, with no significant difference between them. Final mean compliance was 74% in the written information group and 82% in the verbal information group.

Conclusions. The use of written information about the use of inhalers for patients with COPD significantly improved utilization to a degree similar to that obtained with verbal explanations.

Key words: Aerosols. COPD. Utilization. Intervention. Inhalation technique.

INFORMACIÓN ESCRITA SOBRE EL USO DE AEROSOL EN PACIENTES CON ENFERMEDAD PULMONAR OBSTRUCTIVA CRÓNICA.

¿MEJORAMOS SU CALIDAD DE UTILIZACIÓN?

Objetivos. Identificar si el empleo de información escrita exclusivamente mejora la calidad de uso de aerosoles presurizados en pacientes con enfermedad pulmonar obstructiva crónica (EPOC). Comparar la eficacia de la información escrita exclusiva sobre el uso de aerosoles frente a la explicación oral del uso de estos dispositivos por parte del personal de enfermería.

Diseño. Estudio de intervención.

Emplazamiento. Centro de salud de la periferia de nuestra ciudad.

Participantes. Un total de 120 pacientes con EPOC en tratamiento con aerosoles presurizados.

Intervenciones. División aleatoria en tres grupos de 40 personas. En uno de ellos no se aplica ninguna intervención; en otro, intervención mediante explicación oral y en el tercero intervención mediante información escrita.

Mediciones principales. Porcentaje de cumplimiento de 5 criterios sobre el correcto uso de aerosoles inicialmente y 3 meses después de la intervención en todos los grupos.

Resultados. Inicialmente se aprecia una baja calidad en el uso de aerosoles presurizados en los pacientes con EPOC (cumplimiento medio de criterios del 40%). La calidad de uso aumenta significativamente en ambos grupos de intervención no se aprecian diferencias significativas entre ellos.

El cumplimiento medio final de criterios en el grupo de información escrita fue del 74%, frente a un 82% en el grupo de información oral.

Conclusiones. El uso de información escrita sobre el uso de aerosoles en pacientes con EPOC mejora significativamente su calidad de utilización, en grado similar a su explicación oral.

Palabras clave: Aerosoles. EPOC. Utilización. Intervención. Técnica inhalatoria.

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A commentary follow this article (pág. 10)

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Introduction

Diseases of the respiratory system continue to pose substantial public health problems, given their high morbidity and mortality. One of the most prevalent respiratory diseases is chronic obstructive pulmonary disease (COPD), and appropriate health education for these patients is necessary for self-care and control of the disease. These patient should be encouraged to quit smoking, and should be taught to use prescription medications correctly. Inhaled medications should be the treatment of choice whenever possible, as they make it possible to administer high concentrations of the active principle directly to the site of action. This diminishes systemic side effects and increases therapeutic efficacy.¹⁻⁴ However, the inhalation route also has some disadvantages, especially in that it requires some skill on the patient's part to ensure correct administration. To offset this disadvantage, several devices are available such as pressurized canister inhalers, spacers, and dry powder inhalers,⁵⁻⁸ although the most commonplace and widely used device is the pressurized canister inhaler. To ensure the correct use of these devices, health professionals usually provide brief instruction, although large patient loads often leave little time for this. The pharmacist or a relative usually provides additional information. Nevertheless, there are a number of questions remain to be answered: do our patients use pressurized canister inhalers correctly? Which kind of health education is the most effective? Is verbal information as effective as written information?^{9,10} Because of these questions, and with the aim of improving inhalation techniques in our patients, we designed the present study with two main objectives:

1. To determine whether the use of written information alone improved the performance of pressurized canister inhaler technique in patients with COPD.
2. To compare the effectiveness of written information alone on the use of inhalers with that of verbal information given by nursing staff members.

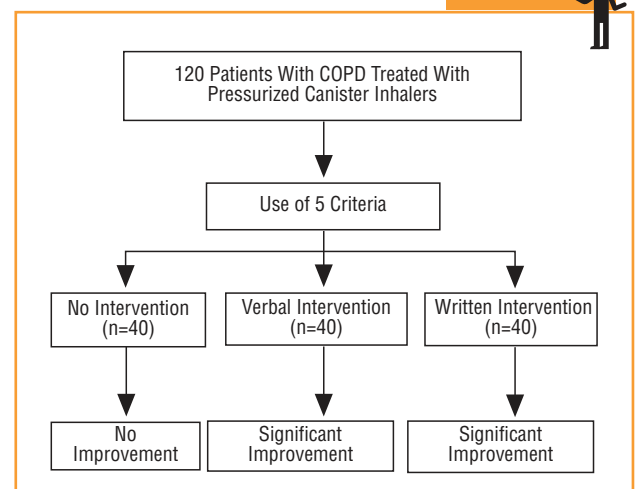
Material and Methods

This interventional study was done at an urban health center located outside the city center. The participants were 120 patients with a diagnosis of COPD who were prescribed daily treatment with pressurized canister inhalers for more than 3 months. We excluded patients who used inhalers on an as-needed basis only, or who used them only occasionally. Other criteria for exclusion were psychiatric disorder, dementia or neurological disease that might interfere with the patient's ability to coordinate the steps in the correct use of inhalers. Chronic obstructive pulmonary disease was diagnosed on the basis of spirometric criteria ($FEV_1/FVC < 70\%$).

All patients were men aged between 60 and 75 years. We excluded patients who had not received primary education or who were illiterate. Women were excluded to maximize similarity between groups, and because of the higher prevalence of COPD among men. Table 1 shows the distribution of patients according to smoking habit. All patients were recruited during the same 6-month period from among patients assigned to 5 family physicians at our health center, located in a suburban area. The 120 patients were divided randomly into 3 groups of 40 patients each, who did not differ significantly in any of the demographic characteristics. No intervention was used in the first group, verbal explanation was used as the intervention in the second group, and written information was provided as the intervention in the third group. The verbal intervention consisted of a detailed, 5-minute explanation of the inhalation technique (Table 2),¹¹ provided by a member of the nursing staff. At the end of the explanation patients were asked to demonstrate their inhalation technique with a placebo. The written intervention consisted of giving the patient a pamphlet with printed instructions (Table 2). No verbal explanation was provided, and the patient's performance of the inhalation technique was not checked. The outcome measurement consisted of calculating percentage compliance with each of the 5 criteria for the correct use of inhalers at the start of the study and 3 months after the intervention in all groups. Age, sex, and level of education (no formal education, primary school, secondary school, university) were recorded for all patients. Data on the performance of inhalation technique were recorded by a nurse specially trained in the use of inhalation systems, who observed each patient as he or she performed 2 consecutive inhalations. The following criteria were evaluated:

- Criterion 1: each patient with COPD who uses pressurized canister inhalers should exhale completely before pressing down on the canister.

Material and methods



General Scheme of the Study

Interventional study to determine the effectiveness of verbal versus written information about the use of inhalers in 120 patients with COPD.

- Criterion 2: each patient who uses inhalers to treat COPD should breath in slowly after exhaling completely. Inhalation was considered slow when it lasted more than 4 seconds.
- Criterion 3: each patient who uses inhalers to treat COPD should depress the canister only after inhalation has begun. This criterion was considered to be performed correctly only when the canister was depressed during the first second of inhalation.
- Criterion 4: each patient who uses inhalers to treat COPD should hold his or her breath for 10 seconds after inhaling the dose.
- Criterion 5: each patient who uses inhalers to treat COPD should keep his or her lips closed firmly around the mouthpiece during the procedure.

To compare the initial and follow-up findings, statistical analysis consisted of calculation, for each criterion, of absolute and relative improvement (referred to greatest possible improvement) and statistical significance (with one-tailed z tests for comparison of proportions). To create a database and analyze the data we used the SYSTAT program (version 5.0).¹² A *P* value <0.05 was considered statistically significant. On the basis of our study design, a sample size of 40 for each group was considered sufficient.

Results

We found no significant differences between groups in age, sex, or level of education. At the initial evaluation inhalers were found to be used incorrectly by our patients with COPD: mean compliance with the criteria was 40% in all 3 groups. There were no significant differences between groups at this initial evaluation, a result that confirmed homogeneity of the sample of participants. In overall terms, criterion 4 (holding breath for 10 seconds after inhaling the dose) was performed correctly by only 8% of the patients. In contrast, overall compliance with criterion 3 at the initial evaluation (i.e., before the intervention) was 72.5% (Table 3).

After verbal or written information was given, performance improved significantly for all criteria (*P*<.05) in both intervention groups, with no significant differences between them (ns). Mean final compliance for all criteria in the group that received written information was 74%, versus 82% in the group that received verbal information. Compliance with criterion 4, which was only 8% at the initial evaluation, increased to 55.5% in the group that received verbal information, and to 37.5% in the group that received written information. These figures indicate that additional improvements in compliance are desirable. Compliance with criterion 3, which was already high in the initial evaluation, increased further to 97% in the verbal intervention group, and to 95% in the written intervention group. Compliance with the other three criteria also improved significantly (Table 3).

In the group that received no intervention we found no significant improvements in compliance in the second evaluation. This group served as a control to facilitate the

TABLE 1 Percentage of Each Group Who Smoked

	Nonsmoker	Ex-Smoker	Smoker >20	Smoker < 20
No intervention	17.5	50	20	12.5
Verbal intervention oral	15	45	22,5	17.5
Written intervention	15	47.5	20	17.5

Nonsmoker: does not currently smoke and has never smoked.
Ex-smoker: does not currently smoke but used to smoke.
Smoker >20: currently smokes more than 20 cigarettes per day.
Smoker <20: currently smokes fewer than 20 cigarettes per day.

TABLE 2 Instructions for the Use of Pressurized Canister Inhalers

Stand or sit to favor maximal chest expansion
Remove the cap from the mouthpiece, hold the inhaler upright and shake gently
Exhale completely and place the inhaler 2 cm away from the mouth (ideally), or in the mouth (simpler). Keep the tongue depressed and lean the head back slightly
Inhale slowly by mouth for 4-5 seconds
Once inhalation has begun, depress the canister only once and continue to breath in deeply. It is very important not to release the dose until after inhalation has begun
Remove the inhaler from mouth and hold breath for 10 seconds
Exhale slowly
Replace the cap on the inhaler
Wait 30 seconds before inhaling a second dose
Rinse mouth to remove excess drug from mouth and throat

identification of variables that might have interfered with the results.

Discussion

The present study evaluates inhalation techniques used with the inhalation system indicated most frequently by health professionals. Initially we found that pressurized canister inhalers were being used incorrectly by patients with COPD. This indicated that despite correct prescribing practices by physicians, the results obtained are not those anticipated by the patient or the health professional. Performance improved significantly in both intervention groups, with no significant differences between the two. Hence a specific intervention for this type of treatment significantly enhances its efficacy. The results of studies such as the present one are increasingly important to maintain the viability of the current national health system in Spain.

We note that there were no significant differences in the results between the groups that were given verbal and written instructions about the correct technique for using

TABLE 3 Percentage Compliance With Each of the Criteria in the Two Evaluations (95% CI)

Criteria	No Intervention Group		Verbal Intervention Group		Written Intervention Group	
	1st Evaluation	2nd Evaluation	1st Evaluation	2nd Evaluation	1st Evaluation	2nd Evaluation
Complete exhalation	20.0%	30%	25.0%	92.5%	22.5%	87.5%
Slow inhalation	57.5%	55%	47.5%	90%	55%	85%
Timing of inhalation	70%	70%	72.5%	97%	75%	95%
Holds breath 10 seconds	10%	10%	15%	55.5%	7.5%	37.5%
Mouthpiece	45%	42.5%	42.5%	75%	45%	65%

Complete exhalation: each patient who uses inhalers should exhale completely before pressing down on the canister.

Slow inhalation: each patient who uses inhalers should breath in slowly after exhaling completely.

Correct timing of inhalation of the dose: each patient who uses aerosols should depress the canister only after inhalation has begun.

Holds breath for 10 seconds: each patient who uses inhalers should hold his or her breath for 10 seconds after inhaling the dose.

Closes lips around mouthpiece: each patient who uses inhalers should close his or her lips firmly around the mouthpiece.

pressurized canister inhalers. This may represent considerable time saved at each patient-physician contact, as simply handing the patient a pamphlet and urging the patient to read it carefully may achieve the same results as spending a few minutes to explain the technique verbally. We also found that if the patient is given no verbal or written information about how to use pressurized canister inhalers, the results will be poor, and treatment will not have the expected effect.

Madueño et al¹³ investigated whether primary care physicians in training had adequate theoretical and practical knowledge about inhalation systems. These authors found that inhalation systems were often misused, and recommended specific training for primary care professionals in the use of inhaled drug therapy. Their findings indicate that if health professionals are not familiarized with the use of these devices, we will not be able to explain to our patients how to use them appropriately. Other studies¹⁴⁻¹⁷ have also analyzed how patients use inhalers, and have found performance of inhalation techniques to be poor. These findings suggest that greater emphasis should be placed on inhalation techniques, and that physicians should ensure that the patients knows how to use the inhaler correctly. It is important to emphasize here that using an inhaler incorrectly is equivalent to not taking any medication at all.

Among the potential biases in this study is the limitation imposed by including only patients with COPD, as pressurized canister inhalers are also widely used for chronic diseases such as asthma and interstitial disorders, as well as for acute diseases such as bronchitis and pneumonia. It should be recalled that patients with an acute disease have less experience, hence the rate of incorrect inhalation technique can be assumed to be higher among them. Another potential source of bias is the fact that when we designed the study, we did not take into account measures by the pharmaceutical industry to improve patients' inhalation technique by producing improved devices that require less coordination to use correctly. It would be interesting to compare the different devices now available on the market. Future studies in this area should be designed to analyze the efficacy of information provided to the patient at the pharmacy, and to compare this information with that provided at the health center. Fomenting cooperation between pharmacies and health center professionals is a key step toward improving compliance with therapy and providing effective health education for these patients.

Discussion
Key points



What is Known About the Subject

- Chronic obstructive pulmonary disease is widely prevalent and is associated with high morbidity and mortality.
- Appropriate treatment requires the correct use of inhalation systems.
- Programs should be developed to help patients use inhalation systems appropriately.

What This Study Contributes

- Without specific intervention, patients with COPD used pressurized inhaled medications incorrectly.
- Specific intervention by health professionals led to acceptable inhalation techniques, although there was still room for improvement.
- Both verbal and written instructions were useful in improving the utilization of inhalation systems by our patients.

In conclusion, the use of written information about inhalation techniques for the use of aerosols by patients with COPD significantly improves performance, and the improvements are similar to those obtained when patients are given a verbal explanation of how to use the inhaler.

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COMMENTARY

Interventional Studies of Inhalation Technique in Patients With Chronic Obstructive Pulmonary Disease Have Methodological Drawbacks, But Are Nonetheless Necessary

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The article by Leal Hernández et al is of interest for several reasons. Firstly, few studies are available on inhalation technique in patients with chronic obstructive pulmonary disease (COPD) seen in primary care centers. Noteworthy among these studies is that by Benito et al in 1997. These authors found that at three health centers in Burgos, 52% of the patients in a group of participants who had asthma

or COPD used inhalers incorrectly.¹ Secondly, and more importantly, this was the first interventional study in the primary care setting in Spain to examine inhalation technique in patients with COPD.

The question the researchers posed to study the issue is attractive: should written or verbal information be chosen for interventions intended to teach inhalation technique?

Key Points

- Interventional studies on the use of inhalation techniques should use validated evaluation systems. Scintigraphy remains the gold standard.
- A method based on electronic monitoring has been validated in Spanish and is available to test performance of inhalation techniques.
- The study this editorial comments on does not prove that there are differences between written and verbal instructions, nor does it prove that no difference exists.
- Teaching inhalation technique is part of patient education for persons with chronic obstructive pulmonary disease.
- Correct inhalation technique does not ensure compliance with therapy. Other factors are the perceived response to bronchodilation treatment and the patient's attitudes regarding the need for bronchodilators.
- Studies designed to evaluate educational interventions for patients with COPD are needed.

However, the authors faced a number of obstacles that kept them from reaching conclusions with practical applications.

Studies of inhalation technique are not easy to carry out. Most such studies are limited to describing compliance with previously agreed criteria. In Spain, the recommendations of the Spanish Society of Respiratory Diseases (SEPAR)² are usually followed. The problem here is that these criteria have not been validated. The SEPAR guidelines claim that each step in the instructions for inhalation technique is supported by published studies, but no references are given in the guidelines themselves. In fact, it is fundamental to know whether the particles of the drug are appropriately dispersed in the gas vehicle, impact as little as possible on the pharynx, are delivered to the lungs at a suitable rate, and are diffused correctly. The fraction of the dose exhaled should be likewise contact the pharynx as little as possible. The gold standard for studies of pulmonary diffusion continues to be scintigraphy with isotope-labeled drugs.

Because such studies are impractical, systems that make it possible to monitor the steps in the inhalation process more easily have become common. Two studies are worth mentioning in this connection. De Blaquiére et al, in 1989, reported the use of a monitored system that determined inspiration, inhaler activation and duration of breath-holding.³ Cimas et al validated a checklist for inhalation technique for pressurized canister inhalers and dry

powder inhalers ("turbohalers"), using 2 electronic monitoring systems as their gold standard. This latter study is of greater interest, as it describes the only instrument validated for use in Spanish.⁴

This was not the case in the study by Leal Hernández et al, who used a nonvalidated test for which no information is given in the Material and Methods section regarding validity (sensitivity and specificity) or intraobserver reliability. (It would have been advisable to include a second observer to determine interobserver reliability.) These shortcomings raise questions about the applicability of the method these authors used.

Unfortunately, this was not the only problem with the study. Although of less concern (because it does not affect the results), it should be pointed out that the study population might not have consisted exclusively of patients with COPD. Why? Because no reversibility test was done to distinguish between patients with asthma and those with COPD among patients with spirometric findings indicative of obstruction. In the authors' defense, it should be said that it can be difficult to distinguish between these two entities. This is why many studies make no distinction between the two kinds of patient, and include both under the heading of chronic obstructive lung disease. In any case, I believe that selecting men between 60 and 75 years of age may have helped keep the number of patients with asthma low, although patients who had never been smokers but who had findings of obstruction should perhaps be analyzed separately.

Finally, the greatest drawback of the study needs to be considered. The authors state in the Discussion section that there were no differences between using written information (which is cheaper) and verbal information (which takes more time). However, it is hard to avoid the suspicion of a type II (beta) error; consequently, the only thing that can be said is that no differences between the two interventions could be established. This, however, does not rule out that such differences may in fact exist. Because the authors did not indicate the power of the study design in the Materials and Methods section, we cannot share their conclusions. What is clearly worth taking into account, however, is the authors' conclusion that verbal and written information are both superior to the control condition (no intervention). Nevertheless, it is difficult to answer the question raised in the Introduction: is information supplied verbally as effective as information supplied in writing?

To conclude, it is important to understand the role of teaching inhalation technique to patients with COPD in the context of educational measures for patients with a chronic disease. Although education for patients with asthma has been shown effective (improved quality of life and pulmonary function, and lower costs),⁵ this has not been the case for COPD. Respiratory rehabilitation seems to improve quality of life and exercise tolerance, and written

instructions about managing exacerbations may decrease the use of rescue medication (beta 2 agonists), facilitating early treatment of exacerbations with antibiotics and oral corticosteroids.⁶ In this regard, teaching inhalation technique should be seen as one more element in educational programs, along with counseling to quit smoking, incentives to exercise, and advice about nutrition and eating habits. However, teaching inhalation technique does not always improve compliance, and in patients with COPD, the lack of variation in symptoms (compared to asthma) along with the lack of perceived improvement, appear to lead to low levels of compliance. However, avoiding the overuse or underuse of inhalation treatment is useful, a factor not considered in the aims of the study by Leal Hernández et al. In contrast to asthma, the aim for patients with COPD is for the patient to enjoy an acceptable degree of health while avoiding the appearance of iatrogenic illnesses, given that the course of the disease cannot be changed (unless the patient stops smoking or uses oxygen therapy, if indicated). Naturally, the skillful performance of inhalation technique is of relevance for these patients.

Ultimately, the questions we must ask are these: what is the minimum amount of education that will be effective, and how can compliance be improved? Another important issue is of course how to obtain the greatest benefit from the time invested in teaching our patients how to use inhalers.

The efforts of Leal Hernández et al should be appreciated in an area where further research is needed along the lines

of the study these authors have published. It is hoped that their efforts will lead to further interventional studies in primary care in the field of respiratory disease.

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