Pharmaceutical care for patients with persistent asthma: assessment of treatment compliance and use of inhaled medications*

Atenção farmacêutica ao portador de asma persistente: avaliação da aderência ao tratamento e da técnica de utilização dos medicamentos inalatórios

Daiane de Oliveira Santos, Maria Cleusa Martins, Sonia Lucena Cipriano, Regina Maria Carvalho Pinto, Alberto Cukier, Rafael Stelmach

Abstract

Objective: To evaluate treatment compliance and use of inhaled medications of patients with asthma receiving complementary pharmaceutical care. **Methods:** A controlled prospective parallel study involving a study group and a control group. We selected 60 patients with persistent asthma and using metered-dose inhalers (MDIs), dry powder inhalers (DPIs) or both. The patients were evaluated three times over 60 days. Instructions were provided to the patients in the study group at all visits but only at the first visit to those in the control group. The patients using < 80% or > 120% of the total number of prescribed doses were classified as noncompliant. The inhalation technique was quantified by a scoring system. A satisfactory technique was defined as a score higher than 7 (maximum, 9) for MDIs and higher than 4 (maximum, 5) for DPIs. **Results:** The final study sample comprised 28 study group patients and 27 control group patients, of whom 18 (64.3%) and 20 (74.7%), respectively, were considered treatment compliant. From the first to the third visits, there were increases, in the study and control groups, in the median MDI-use score (from 3 [range, 0-5] to 8 [range, 8-9]; $p < 0.001$; and from 5 [range, 2-6] to 7 [range, 6-8]), as well as in the median DPI-use score (from 3 [range, 2-4] to 5 [range, 4-5] and from 3 [range, 2-4] to 4 [range, 3-5]). **Conclusions:** The counseling provided by the pharmacist to the patient was important to assist in the implementation of the appropriate inhalation technique, especially for MDI use.

Keywords: Asthma; Pharmaceutical services; Administration, inhalation; Metered dose inhalers; Medication adherence.

Resumo

Objetivo: Avaliar a aderência ao tratamento e a técnica de utilização de dispositivos inalatórios em pacientes com asma após atenção farmacêutica complementar. **Métodos:** Estudo prospectivo controlado com dois grupos paralelos: grupo estudo e grupo controle. Foram selecionados 60 asmáticos persistentes, utilizando regularmente inaladores dosimetrados (IDs), inaladores de pó seco (IPS) ou ambos. Os pacientes foram avaliados em três visitas durante 60 dias. As instruções foram fornecidas em todas as visitas aos pacientes do grupo estudo e apenas na primeira visita do grupo controle. Os pacientes que utilizaram < 80% ou > 120% do total de doses prescritas foram classificados como não aderentes. A manobra inalatória foi quantificada por escores, e uma técnica satisfatória foi definida por uma pontuação superior a 7 (máximo, 9) para o uso de ID e superior a 4 (máximo, 5) para o uso de IPS. **Resultados:** Concluíram o estudo 28 pacientes no grupo estudo e 27 no grupo controle, dos quais 18 (64,3%) e 20 (74,7%), respectivamente, foram classificados como aderentes. Houve um aumento nas medianas dos escores do uso de ID entre a primeira e a terceira visitas tanto no grupo estudo quanto no grupo controle (de 3 [variação, 0-5] para 8 [variação, 8-9]; $p < 0,001$; e de 5 [variação, 2-6] para 7 [variação, 6-8]), assim como nas medianas dos escores do uso de DPS (de 3 [variação, 2-4] para 5 [variação, 4-5]; e de 3 [variação, 2-4] para 5 [variação, 4-5]). **Conclusões:** A orientação fornecida pelo farmacêutico ao paciente foi importante para auxiliar na adequada realização da técnica inalatória, principalmente quanto ao uso de IDs.

Descritores: Asma; Assistência farmacêutica; Administração por inalação; Inaladores dosimetrados; Adesão ao medicamento.

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* Study carried out at the *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.
Correspondence to: Rafael Stelmach. Rua Manoel Nóbrega, 572/42, CEP 04001-002, São Paulo, SP, Brasil.
Tel 55 11 3069-5034. E-mail: pnerafael@incor.usp.br
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Introduction

Asthma is a chronic inflammatory disease with a high worldwide prevalence and increased morbidity, placing an onus on patients and their families.[1] An important aspect observed in asthma, as well as in other chronic diseases, is noncompliance with or abandonment of the prescribed treatment.[2,3] Noncompliance with physician-prescribed treatments is one of the leading causes of treatment failure.[4] It has frequently been reported that rates of compliance with the recommended treatment are low among asthma patients, only half of all asthma patients actually using the prescribed medication.[5,6] It should be emphasized that these low rates of compliance can be associated with various factors, such as difficulty in administering the medications,[7,8] unsatisfactory benefits obtained from the use of the medication, risk of adverse effects,[7] prolonged duration of treatment, use of multiple medications and periods of symptom remission.[9]

The administration of inhaled medications is a fundamental component of the clinical treatment of patients with pulmonary disease. The use of inhalers makes it possible to selectively reach the lungs, increasing the concentration of the drug and reducing systemic adverse effects.[10,11] The effectiveness of the inhaled medication depends not only on the formulation and the type of device used but also on the ability of the patient to perform the inhalation technique correctly.[12]

Pharmacists have contributed significantly to the follow-up of patients with persistent asthma.[13] The literature has demonstrated that the benefits of asthma education programs, in which pharmacists instruct asthma patients, result in better compliance with pharmacological treatment, promote the correct use of inhaled medications, detect medication-related problems and improve the quality of life of patients, as well as reducing the number of emergency room visits and hospitalizations for asthma exacerbations.[13,14]

The objective of this study was to assess compliance with pharmacological treatment and the evolution of the use of inhalation devices in asthma patients receiving pharmaceutical care, with an emphasis on proper counseling about the use of prescribed medications.

Methods

This was an open, controlled, prospective study carried out between August of 2005 and January of 2006. We selected patients with persistent asthma who were on regular maintenance treatment, had not participated in asthma education programs before and had been under follow-up at the asthma outpatient clinic of the Department of Pulmonology of the University of São Paulo School of Medicine *Hospital das Clínicas* for more than a year.

Those patients were evaluated at three time points: the first visit (V1, inclusion), at which point the patient agreed to participate in the study and gave written informed consent; and two other visits (V2 and V3, follow-up assessments), at four- and eight-week intervals, respectively.

The study participants were divided into two parallel groups: study and control. This division was performed sequentially at V2, the first patient being included in the study group, the second being included in the control group, and so on. The patients assigned to the study group were provided counseling on the correct use of the medications at all visits, whereas those assigned to the control group were provided counseling only at V1.

During the visits, the patients were submitted to the following procedures: completion of a specific anamnesis form; patient demonstration of the use of inhaled devices, which was evaluated and corrected by the pharmacist; and a second patient demonstration, after the corrections (only for the patients in the study group).

At every visit, the evaluations were performed by the same professional, who also emphasized the importance of correctly observing the frequency and time at which the medications should be taken, as well as the dose, in accordance with the medical prescription. The mean duration of each visit was approximately 60 min.

Treatment compliance was determined by counting the doses used by the patient, which made it possible to calculate the rate of compliance (number of days between the visits × number of doses prescribed per day = 100% compliance).[15] These assessments were performed at V2 and V3, considering the intervals of medication use prior to those visits.

We used a 20% margin of error, which is in accordance with the literature; the patients using less than 80% (fewer doses) or more than 120% (more doses) of the total number of prescribed doses were classified as noncompliant.[4]

The use of medications in the form of dry powder inhalers, such as Aerolizer® (budesonide, 200 µg; and formoterol/budesonide, 6/200 µg), was assessed by counting the empty capsules kept and returned by the patient and confirmed by counting the capsules remaining in the bottle. The use of medications in the form of metered dose inhalers, such as Diskus® and Turbuhaler® (salmeterol xinafoate, 50 µg; and formoterol/budesonide, 12/400 µg), was assessed by determining the doses available in the device, which were shown in the dose display itself.

The use of medications in the form of metered dose inhalers that do not allow dose count (beclomethasone dipropionate, 250 µg; and albuterol, 100 µg) was assessed by weighing the bottles after they were used by the patient. In order to determine the number of doses used in these inhalers, we instituted a weighing technique, adapted from the Brazilian Pharmacopeia, based on the technique of bottle weighing,[16] using 20 bottles of beclomethasone dipropionate (250 µg), 20 bottles of albuterol (100 µg) and an analytical scale (model AM220; Marte Balanças e Aparelhos de Precisão Ltda, São Paulo, Brazil),

Table 1 - Inhalation technique score: metered dose inhalers.

Criterion		Score
Exhales		
No		0
Yes		1
TLC is maintained		
< 10 s		0
10 s or more		1
Velocity		
Rapid or < 5 s		0
Slow or ≥ 5 s		1
Depth		
Not completely		0
Properly		1
Time point (inhalation)		
Before the spray		0
Immediately after or together with the triggering		1
Positions		
Incorrectly		0
Correctly		1
Shakes		
No		0
Yes		1
Mode of use		
Inside the mouth, without a spacer		0
Out of the mouth		1
With a spacer		2
Errors - Deduct the value(s) corresponding to the error(s) below		Score
Extremely severe	Nasal breathing	−8
Severe	Removes the spacer; starts inhalation too early; only sprays it into the mouth and does not inhale; does not shake; sprays two or more jets; inhales too late.	−4
Moderate	Uses the spacer irregularly; exhales into the spacer; inhales irregularly; mouth open to the inside.	−2
Mild	Removes the barrel; breathes shallowly with the spacer.	−1
Total: _____		

sensitive and reproducible to within 0.1 mg. The result obtained—the mean weight of each dose of beclomethasone dipropionate (250 µg) and albuterol (100 µg)—was 0.846 g.

For all patients, the assessment of the use of inhalation devices was based on the scores for the use of metered dose inhalers and the scores for the use of dry powder inhalers.[17] This scoring system is based on the most common errors made by patients. If the patient follows each step correctly, the patient receives one point for each step taken; for each error made, in addition to not receiving the point, and depending on the severity of the given error, points are deducted from those already scored. Therefore, an unsatisfactory inhalation technique was defined by a score lower than 80% of the maximum possible score.

These values were adapted and, in the present study, the maximum score was 9 points for metered dose inhalers and 5 points for dry powder inhalers (Tables 1 and 2). Therefore, a satisfactory inhalation technique was defined as scores ≥ 7 and ≥ 4, respectively, for metered dose inhalers and dry powder inhalers.

Table 2 - Inhalation technique score: dry powder inhalers.

Criterion		Score
Dose is prepared (device is triggered)		
Correctly		0
Incorrectly		1
Exhales		
No		0
Yes		1
TLC is maintained		
< 10 s		0
10 s or more		1
Velocity		
Rapid or < 5 s		0
Slow or ≥ 5 s		1
Depth		
Not completely		0
Properly		1
Errors - Deduct the value(s) corresponding to the error(s) below		Score
Severe	Nasal breathing.	−4
Moderate	Exhales into the device; inhales irregularly.	−2
Mild	Inhales shallowly.	−1
Total: _____		

The t-test was used in order to compare the study and control groups in terms of their characteristics and in terms of compliance with pharmacological treatment. In contrast, ANOVA with repeated measures was used to compare the results obtained in the assessment of the use of inhalation devices, and the median values were considered. The tests were performed using the software SigmaStat, version 2.01 (Jandel Scientific, San Rafael, CA, USA). Values of $p < 0.05$ were considered significant. The results are presented as median and interquartile range (25-75%).

Results

We included 60 patients, who were equally divided between the study and control groups. Five patients were excluded, since, for personal reasons, they failed to return for V3. The final study sample consisted of 55 patients, of whom 28 were included in the study group and 27 were included in the control group. The sociodemographic characteristics of the patients are shown in Table 3. There were no statistically significant differences between the study and control groups regarding sociodemographic aspects.

The median rate of inhaled medication use in the study group was 93.1% at V2 and 100% at V3 (range, 44.6-172.2%), compared with 92.5% at V2 and 93.0% at V3 (range, 2.5-187.5%) in the control group.

In the study group, 18 patients (64.3%) were classified as treatment compliant at V2 and V3. In the control group, 20 patients (74.7%) and 19 patients (70.4%) were also classified as treatment compliant at V2 and V3, respectively. No statistically significant differences were found between the groups during the follow-up assessment. In both groups, 13% of the patients used doses that were higher than those recommended, and 36% used doses that were lower.

In the assessment of the use of metered dose inhalers, the medians obtained in the study group at V1 were 3.0 and 8.0, respectively, before and after counseling and corrections ($p < 0.001$; Table 4). At V2, the medians were 6.0 and 8.0, respectively, before and after counseling and corrections ($p < 0.001$). At V3, the median obtained was the same (8.0) before and after counseling. A statistically significant difference ($p < 0.001$) was found between the results obtained after counseling at V1 and at V3. In

Table 3 - Sociodemographic characteristics of the population studied.

Characteristic	Study group (n = 28)	Control group (n = 27)
Gender	n (%)	n (%)
Male	8 (28.57)	4 (14.81)
Female	20 (71.43)	23 (85.19)
Age, years		
15-30	3 (10.7)	2 (7.4)
30-60	17 (60.7)	19 (70.4)
> 60	8 (28.6)	6 (22.2)
Level of education		
Illiterate	3 (10.7)	
Junior high	17 (60.7)	18 (66.7)
High school	7 (25)	6 (22.2)
College	1 (3.6)	3 (11.1)
Family income		
1 to 3 times the MW (< R$ 700.00)	20 (71.43)	22 (81.48)
3 to 7 times the MW (R$ 700.00 to R$2,000.00)	8 (28.57)	5 (18.52)

MW: (national) minimum wage.

addition, at V3, 25 patients (96.0%) achieved the maximum score of 9 points. Therefore, the analysis of the progression of the patients in the study group regarding the use of metered dose inhalers reveals the following: the quality of the inhalation technique improved and satisfactory scores were achieved after the first counseling session; there was a slight but not significant decline at V2 before the counseling session; and there was a new and significant increase after the other counseling sessions. This indicates an improvement in the results obtained over the course of the follow-up assessment.

In the control group, the medians obtained for the inhalation technique scores at V1 were 5.0 and 8.0, respectively, before and after counseling and corrections ($p < 0.001$). The medians obtained at V2 and at V3 were 6.6 and 7.0, respectively. The patients in the control group presented an increase in the quality of the inhalation technique, reaching satisfactory scores after the first counseling session at V1, followed by a slight decline, which resulted in unsatisfactory scores being obtained at V2 and at V3, at which points only 11 patients (42.0%) were able to achieve the maximum score (Table 4).

Comparing the scores in the two groups after the counseling session at V1, the medians in the study and control groups were the same (8.0), indicating that, at this point, there were no differences between the groups. In contrast, at the end of V3, the medians in the study and control groups were 8.0 and 7.0, respectively ($p < 0.001$), and this difference was statistically significant.

In the assessment of the use of dry powder inhalers in the study group, the medians obtained for the scores at V1 were 3.0 and 5.0, respectively, before and after counseling and corrections ($p < 0.01$; Table 4). At V2, the medians for this group were 3.5 and 5.0, respectively, before and after counseling and corrections ($p < 0.001$). At V3, the medians were 4.0 and 5.0, respectively. In the analysis of the scores of the patients in the study group, it was observed that improvement occurred and satisfactory scores were reached after the first counseling session, there was a slight decline at V2, with scores being unsatisfactory, and improvement occurred again, with scores being satisfactory after the second counseling session and stabilizing after V2.

Table 4 - Score obtained by the patients in the assessment of the inhalation technique.[a]

Time point	Metered dose inhalers[b]		Dry powder inhalers[c]	
	Study group	Control group	Study group	Control group
V1 pre	3 (0-5)	5 (2-6)	3 (2-4)	3 (2-4)
V1 post	8 (7-8)*	8 (7-8)*	5 (4-5)*	5 (4-5)*
V2 pre	6 (5-8)	6,5 (5-8)	3 (2-5)	3 (2-5)****
V2 post	8 (8-8)**		5 (4-5)**	
V3 pre	8 (6-8)	7 (6-8)*****	4 (3-5)	4 (3-5)
V3 post	8 (8-9)***		5 (4-5)	

V1: first visit (inclusion); V2: second visit (follow-up assessment); V3: third visit (follow-up assessment); Pre: before counseling; Post: after counseling. [a]Data expressed as median and interquartile range. [b]Maximum score for use of metered dose inhalers = 9. [c]Maximum score for use of dry powder inhalers = 5. *$p < 0.001$ (V1 pre vs. V1 post). **$p < 0.001$ (V2 pre vs. V2 post). ***$p < 0.001$ (V1 post vs. V3 post). ****$p < 0.001$ (V1 post vs. V2 pre). *****$p < 0.001$ (Study group V3 post vs. Control group V3 pre).

In the control group, the median scores for the use of dry powder inhalers at V1 were 3.0 and 5.0, respectively, before and after counseling and corrections ($p < 0.001$). The medians obtained at V2 and at V3 were 3.0 and 4.0 ($p < 0.001$), respectively. Therefore, the patients in the control group presented an increase in the inhalation technique scores at V1 and a slight but significant decline, with unsatisfactory scores, at V2.

The median inhalation technique scores were found to be the same (5.0) for both groups at V1 after the first counseling session. At V3, the last observation time point, the median scores were 5.0 and 4.0, respectively, for the study and control groups, although this difference was not statistically significant. Nineteen patients (73.0%) in the study group and 11 patients (47.0%) in the control group achieved the maximum score value.

Discussion

During the follow-up assessment of the patients included in this study, we observed positive results, with a progressive increase in the scores for the use of inhaled medications, especially among the patients using metered dose inhalers. Regarding compliance with pharmacological treatment, more than 64% of the patients included in the study were classified as compliant. However, the percentage of compliant patients did not change during the follow-up visits. Complementary pharmaceutical care increased the quality of the use of inhalation devices, even in patients who had been using such devices for a long time.

The experience of a pharmaceutical care study involving outpatients at a public tertiary hospital is important, since pharmaceutical care studies are typically conducted at community pharmacies. Hospital outpatient clinics allow interaction between pharmacists and other members of the health care staff, as well as providing access to information included in medical charts of outpatients and inpatients.

The analysis of the use of metered dose inhalers revealed an increase from the first to the last visit in terms of the results obtained in the two groups. In addition, the patients in the study group scored higher, and only 42% of the patients in the control group achieved the maximum score. These findings suggest that, over the course of the follow-up period, the patients in the study group progressively learned how to improve their use of metered dose inhalers. A single session of counseling or correction proved to be insufficient for the patients in the control group to learn to use metered dose inhalers correctly. However, the analysis of the use of dry powder inhalers revealed that there was an increase in the scores obtained in the two groups after the counseling session in the first visit, suggesting that the learning curve was similar in both groups. Nevertheless, only 47% of the patients in the control group achieved the maximum score.

Our data, compared with those reported in the literature, indicate that dry powder inhalers require a simpler technique and, therefore, shorter training times. This is due to the fact that it is easier to coordinate respiratory and mechanical movements when using a dry powder inhaler than when using a metered dose inhaler.[12,18,19]

In the present study, more than 64% of the patients were classified as compliant. This percentage is slightly higher than those usually reported in the literature, according to which only half of the patients actually use the prescribed medication.[5] The low level of education and low family income of the patients in the study group did not negatively affect treatment compliance, although, in the literature, it has been purported that compliance is affected by social, economical, educational and psychological aspects.[20] The strong institutional link between the patient and the hospital as a health care provider might explain the treatment compliance rates found in this study. In particular, the fact that our patients receive medications free of charge while they are under regular follow-up treatment might have played a role, since high compliance rates have also been observed in other studies in which medications were provided free of charge.[21]

Of the patients who were classified as noncompliant, 36% used fewer than the total recommended number of doses. According to previous studies, such patients neglect controlling their disease and become exposed to the risk of asthma-related exacerbations because they receive suboptimal doses of maintenance medication(s).[22] Conversely, 13% of the noncompliant patients used more than the number of prescribed doses, indicating overdosage, which

is not considered correct from the standpoint of compliance, even if this fact reduces the incidence of hospitalizations or emergency room visits for asthma.[22] In order to avoid underdosage/overdosage, a new strategy for asthma management has been proposed. Patients using budesonide and formoterol could be encouraged to increase the number of doses during symptomatic periods to regain control of the disease and then automatically reduce the number of doses when the disease is under control.[22]

The results of the present study could have had a greater impact if the following requirements had been met: inclusion of a greater number of patients in the study; longer follow-up assessment period; direct measurement of compliance (plasma monitoring) for comparison with results obtained by the indirect method to determine compliance, a method that is known to have limitations; measurement of compliance before the first counseling session; use of strict inclusion and exclusion criteria; and comparison of the results with those obtained for noninstitutionalized patients. In addition, there is evidence that different types of dry powder inhalers can present different degrees of efficacy, depending on the patient.[23] In this study, dry powder inhalers were considered as a whole, in terms of the principle of inhalation, so that they could be compared with metered dose inhalers. A different study design would be necessary in order to evaluate the response to different dry powder inhalers, and that was not our objective.

Another weak point in this study was that the clinical impact of asthma control was not measured. Recent studies focusing on pharmaceutical intervention have revealed a significant reduction in acute attacks and nocturnal asthma symptoms.[15] In one major study, it was observed that there was a reduction in nocturnal asthma symptoms and an improvement in asthma control, as assessed by the Asthma Control Test, together with an improvement in treatment compliance, in the quality of the inhalation technique.[15]

Prior to being included in this study, our patients had been under follow-up at a specialized clinic, being treated exclusively by physicians. They had not participated in asthma education programs, nor did had they had any contact with a pharmacist.

Data from a study conducted in Europe indicate that there is a clear need for specific training of patients in correct inhalation technique for the various devices currently available, and this should be repeated frequently to maintain the correct inhalation technique.[24]

Problems related to treatment compliance are very common in patients with chronic diseases, and, since strategies to monitor and improve compliance are included in pharmaceutical care plan, the pharmacist is in an ideal position to have access to the problems related to poor treatment compliance, which can adversely affect patient health.[18] Therefore, it is essential that pharmacists involved in the education of asthma patients master the techniques in order to provide safe training to the patient.

Despite having already been included in education programs, achieving positive results in the management of asthma, the participation of pharmacists in the treatment of patients remains minimal in many countries,[25,26] including Brazil. It is essential that this problem be addressed in graduate or postgraduate courses, which could stimulate the development of pharmaceutical care projects adapted to our health care system. Pharmaceutical care will certainly improve treatment compliance rates and will ensure the correct use of inhalation devices in order to control asthma.

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About the authors

Daiane de Oliveira Santos
Pharmacist. Department of Pharmacy, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.

Maria Cleusa Martins
Pharmacist-in-charge. Department of Pharmacy, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.

Sonia Lucena Cipriano
Director. Department of Pharmacy, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.

Regina Maria Carvalho Pinto
Attending Physician. Department of Pulmonology, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.

Alberto Cukier
Tenured Professor. Department of Pulmonology, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.

Rafael Stelmach
Adjunct Professor. Department of Pulmonology, *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo* – HC-FMUSP, University of São Paulo School of Medicine *Hospital das Clínicas* – São Paulo, Brazil.