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A Comparison of Albuterol Administered by Metered-Dose Inhaler and Spacer With Albuterol by Nebulizer in Adults Presenting to an Urban Emergency Department With Acute Asthma

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A M E R I C A N C O L L E G E O F



P H Y S I C I A N S[®]

A Comparison of Albuterol Administered by Metered-Dose Inhaler and Spacer With Albuterol by Nebulizer in Adults Presenting to an Urban Emergency Department With Acute Asthma*

Kenneth B. Newman, MD, FCCP; Scott Milne, MD; Cathy Hamilton, MPH; and Kent Hall, MD

Study objectives: To determine the efficacy of albuterol by metered-dose inhaler (MDI) and spacer compared to a nebulizer.

Design: A prospective, open-label study.

Setting: Large urban emergency department (ED).

Patients: All consecutive adult asthma patients over a 2.5-year period.

Interventions: ED personnel used a standardized treatment algorithm, which included albuterol administered by nebulization, for patients presenting to the ED during the first 12 months of the study. The treatment algorithm then was switched to one that utilized albuterol administered by MDI/spacer as the primary mode of delivery for the following 18 months. As part of the conversion to MDI/spacer, ED staff counseled patients on self-management and supplied patients with a peak flowmeter, an MDI/spacer, and an inhaled steroid for home use.

Measurements: Pulmonary function, clinical outcome, laboratory data, and financial data were assembled and analyzed from 2,342 ED visits and 1,420 patients.

Results: While there was no significant difference in hospital admission rates between patients in the MDI/spacer group and the nebulizer group (13.2% and 14.6%, respectively), there was a statistically greater improvement in peak flow rates in the MDI/spacer group (126.8 vs 111.9 L/min, respectively; $p = 0.002$). The MDI/spacer group also spent significantly less time in the ED (163.6 and 175 min, respectively; $p = 0.007$), had a lower total albuterol dose (1,125 μg and 6,700 μg , respectively; $p < 0.001$), and showed a greater improvement in arterial oxygen saturation ($p = 0.043$). Relapse rates at 14 and 21 days were significantly lower ($p < 0.01$ and $p < 0.05$, respectively) among patients treated with the MDI/spacer and were associated with asthma education and the provision of a peak flowmeter, a spacer, and an inhaled corticosteroid for patients' home use.

Conclusions: Albuterol administered by MDI/spacer is an efficacious and cost-effective alternative to nebulization in adults with acute asthma who present at a large urban ED.

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Key words: acute asthma; bronchodilators; corticosteroids; education; emergency department; therapeutics

Abbreviations: ED = emergency department; HR = heart rate; MDI = metered-dose inhaler; PEFR = peak expiratory flow rate; SaO_2 = arterial oxygen saturation

Current guidelines¹ for the treatment of patients with acute asthma have recommend the use of inhaled, short-acting β_2 -agonists to reverse airflow

obstruction. In the emergency department (ED), β_2 -agonists are administered by intermittent or continuous nebulization^{2,3} or by metered-dose inhaler (MDI), usually with an attached spacer. Historically, nebulization has been the preferred method for

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administering β_2 -agonists to young patients or to those patients who were unable to coordinate their inhalation with the actuation of an MDI due to agitation or severe obstruction.¹ However, in routine clinical situations, and under the supervision of trained personnel, bronchodilation equivalent to that of nebulization can be achieved with high doses of a β_2 -agonist delivered by an MDI fitted with a spacer.⁴⁻⁶

While the effectiveness of nebulization is widely recognized, the method nevertheless has several disadvantages. Studies indicate that nebulization can be an inefficient method of delivering aerosol medication. Compared to an MDI/spacer combination, a nebulizer dispenses more medication but without added therapeutic benefit.^{7,8} The potential for excess drug exposure is of concern since the inhalation of β_2 -agonists in high doses can cause nonpulmonary adverse effects such as tremor and anxiety.⁷ The costs associated with nebulization, which include purchasing and maintaining equipment and supervising its use, make this method of administering bronchodilators more expensive than the MDI/spacer.⁹ Power requirements, higher drug dosing, and the costs of maintaining nebulizers and their peripheral equipment are particularly burdensome for patients in developing regions of the world.¹⁰

Many previous studies comparing nebulized bronchodilators to MDI-dispensed medication have been conducted using relatively small numbers of patients in strictly controlled settings. We conducted a large, prospective, open-label study of consecutive adult asthma patients over a 2.5-year period to determine whether albuterol administered by MDI/spacer could replace albuterol administration by nebulization in a busy urban ED. We utilized an innovative study design in which ED personnel administered albuterol by nebulization for 12 months and then switched to an MDI/spacer as the primary mode of drug delivery for the following 18 months. As part of the conversion to the MDI/spacer, the ED staff counseled patients on self-management and supplied patients with a peak flowmeter, a spacer, and an inhaled corticosteroid for home use.

MATERIALS AND METHODS

Patients

Patients who were admitted to the study were consecutive adult patients who were > 18 years of age and had presented to the ED of the University of Cincinnati Medical Center from October 1994 to April 1997 with an acute exacerbation of asthma. All patients with acute asthma who were seen by physicians in the ED during this period were included in the study. A total of 2,342 ED visits for acute asthma were recorded and statistically evaluated. Smoking was not an exclusion criterion in this study.

Study Design

The study was designed as an unblinded, nonrandomized trial comprising two consecutive phases. For the first 3 months of the study, ED physicians were allowed to treat patients in their customary fashion. After the first 3 months, a uniform departmental asthma treatment protocol was implemented, which included nebulized albuterol as the initial therapy for acute asthma. This protocol was modeled after National Institutes of Health guidelines. At an interim evaluation, it was observed that the strategy used by ED physicians to treat patients during the first 3 months of the study was essentially the same as that recommended by the National Institutes of Health guidelines. Therefore, all patients who were seen during the first year of the study were pooled and analyzed as a single population. This phase of the study (phase 1), during which all patients received nebulized albuterol exclusively, comprised 913 individual ED visits.

During the following 18 months of the study (phase 2), all ED physicians were instructed to treat acute asthma patients with albuterol from an MDI delivered via a spacer (AeroChamber; Monaghan Medical Corp; Plattsburgh, NY). Patients were treated initially with 5 puffs of albuterol. They then received an additional 3 to 5 puffs every 20 min, as needed. To facilitate the implementation of this protocol and to encourage patient education, all subjects were given an "asthma bag," which contained the following materials: an MDI/spacer, an MDI-albuterol canister, a peak flowmeter, an instructional pamphlet that included a personal asthma diary, and a canister of an inhaled corticosteroid (Aerobid; Forest Laboratories; New York, NY). At their discretion, physicians were permitted to break protocol if in their judgment the patient's physical or mental status would benefit from a different mode of therapy. A total of 22.6% of phase 2 patients received nebulized albuterol rather than albuterol by MDI/spacer. The change was usually based on the clinical judgment of a physician or was due to the unavailability of MDI/spacer supplies (approximately 2% of patients). A significant proportion of phase 2 patients (38.4%) who received nebulized albuterol were switched to albuterol administered by MDI after receiving an initial dose by nebulizer.

Statistical Analysis

During phase 2 of the study, patients were analyzed on an intention-to-treat basis, not by the therapy they had received. In excess of 100 individual data fields were identified prospectively, with data elements for each patient recorded on a physician questionnaire, which then were entered into a microcomputerized database program. This method allowed the data to be easily collected, manipulated, and imported into the statistical evaluation program (SPSS, version 8.0; SPSS Inc; Chicago, IL). The questionnaire used as an instrument for the collection of standard patient information that included the hospital patient number and pertinent biographic data such as gender, age, race, phone, primary physician, or clinic location. Medically significant issues pertaining to each ED visit also were abstracted. Such issues included the following: presumptive presenting diagnosis; current medications; and the method and dosage of first and subsequent medications given in the ED. Issues pertaining to patient administration and finance also were collected. These included the total amount of time spent in the ED, the length of time before the patient was seen by a physician, and the charges for the visit. The latter represented the total dollar charges that were billed and did not include indirect costs and other ancillary expenses.

The initial and final values of specific physical findings, vital signs, and laboratory findings were collected and entered into the

database. Important standard indexes of respiratory status included the following: first and last peak expiratory flow rate (PEFR); first and last respiratory rate; first and last heart rate (HR); first and last arterial oxygen saturation (SaO₂) level. Relapse rates were calculated based on the number of patients in each phase of the study who, after presenting to the University of Cincinnati Medical Center ED with acute asthma, appeared at the same site within 14 days or 21 days with a second episode. Hospital charges were recorded, including ED charges and any charges resulting from hospitalization, but not including indirect costs and other ancillary expenses. All continuous variables were compared across groups using the *t* test, and proportions were compared using the χ^2 test of homogeneity or Fisher's Exact Test.

RESULTS

The majority of patients participating in the study were African-American (75.4%). Most were women (58.6%), and the mean (\pm SD) age of participants was 35.5 \pm 13.5 years. Data entries were gathered and compiled from a total of 2,342 ED visits. The total number of unique patients seen at these visits was 1,429. There were no significant differences in demographic characteristics between patients in phase 1 (nebulizer) and those in phase 2 (MDI/spacer) [Table 1].

Medication use at the time of presentation to the ED is listed in Table 2. There is no significant difference between the two periods. Overall, approximately one third of patients had been receiving an inhaled corticosteroid prior to the ED visit. During the ED visit, 61.7% of patients in phase 1 and 60.6% of patients in phase 2 received treatment with systemic steroids. At the time of hospital discharge, oral steroids were prescribed for 60.9% of patients in phase 1 and 57.2% of patients in phase 2.

In Table 3, key clinical and hospitalization parameters for patients treated during phases 1 and 2 of the study are summarized. Measures of patient pulmonary status at presentation (*eg*, premedication

Table 1—Demographics and Patient Characteristics

Characteristics	Phase 1 (n = 617)	Phase 2 (n = 864)	Combined (n = 1,481)
Age, yr			
Mean \pm SD	36.26 \pm 13.77	35.07 \pm 13.22	35.54 \pm 13.45
Range	7–87	8–88	7–88
Sex, %			
Male	41.0	41.3	41.2
Female	59.0	58.7	58.8
Race, %			
Asian	0.1	0.3	0.2
African American	76.6	75.4	75.8
White	23.2	23.9	23.6
Hispanic	0.1	0.5	0.3
Total ED visits	913	1,429	2,342

Table 2—Prior Medications*

Medications	Phase 1	Phase 2
β_2 -agonists	76.1	75.9
Inhaled corticosteroid	30.1	34.5
Theophylline	26.8	20.6
Prednisone	16.0	11.5
Ipratropium	4.9	3.5
Cromolyn	2.6	2.9

*Values given as %.

PEFR and SaO₂) revealed no significant differences between the two treatment groups, indicating that the acute episodes of asthma were, in general, of equal severity in both groups of patients.

Significant differences favoring albuterol administration by MDI/spacer were noted in several measures of pulmonary function. These included post-medication PEFR, which was 11.0% higher in phase 2 patients than in phase 1 patients, and change in PEFR, which was 13.3% higher in the phase 2 group. Improved pulmonary gas exchange also was observed among patients receiving MDI/spacer-delivered albuterol, with the change in SaO₂ being significantly higher (*p* = 0.043) in the latter group.

We observed significantly lower relapse rates, both at 14 and 21 days, among patients in phase 2 of the study. The 14-day relapse rates were 6.6% in the MDI/spacer group vs 9.6% in the nebulizer group. The 21-day relapse rates for these two groups were 10.7% and 13.5%, respectively.

We found a significant difference in the amount of time spent by patients in the ED. Patients receiving therapy by MDI/spacer spent, on average, 6.5% less time in the ED than those undergoing nebulizer therapy. A highly significant and very large difference was found between groups in the amount of albuterol used during treatment. On average, more than six times as much albuterol was dispensed from nebulizers as from MDI/spacers. While the average ED charges in the nebulizer group were higher than for the MDI/spacer group, the difference did not rise to the level of statistical significance (*p* = 0.15).

DISCUSSION

This large study of 2,342 consecutive ED visits for acute asthma demonstrated that the delivery of albuterol by MDI/spacer was as effective as delivering albuterol by nebulizer. There was statistically greater improvement (13.3%) in PEFR values in the MDI/spacer group than in the nebulizer group. However, this did not result in a statistically significantly lower hospital admission rate, with 13.2% of patients in the MDI group and 14.6% of patients in

Table 3—Clinical and Nonclinical Parameters for Phase 1 vs Phase 2*

Parameter	Phase 1	Patients, No.	Phase 2	Patients, No.	p Value†
Premedication PEFR, L/min	211.4 ± 105.7	768	220.4 ± 100.3	1,277	0.056
Postmedication PEFR, L/min	308.1 ± 114.2	617	342.0 ± 130.3	1,119	0.001‡
Change in PEFR	111.9 ± 86.8	614	126.8 ± 102.12	1,119	0.002‡
Hospital admission rate, %	14.6		13.2		NS
Change in heart rate, beats/min	-4.8	493	-4.9	818	NS
Premedication SaO ₂	96.2 ± 3.6	804	96.2 ± 4.1	1,284	NS
Postmedication SaO ₂	96.1 ± 3.3	268	96.4 (± 2.8)	425	NS
Change in SaO ₂	1.4 ± 4.1	266	2.0 ± 4.1	425	0.043‡
Time in ED, min	175.0 ± 96.7	903	163.6 ± 100.5	1,418	0.007‡
ED charge, \$	1,163.50 ± 5,261.49	909	917.46 ± 2,083.45	1,135	NS
Total albuterol dose per patient, µg	6,700 ± 3,775		1,125 ± 612		0.001‡
Relapse rate, %		913		1,429	
14-d	9.6		6.6		< 0.01‡
21-d	13.5		10.7		< 0.05‡

*Values given as mean ± SD, unless otherwise indicated. NS = not significant.

†Phase 1 vs phase 2.

‡Significant difference ($p < 0.05$). NS difference is $p > 0.1$.

the nebulizer group being admitted to the hospital, which is, roughly, a 10% decrease in hospitalizations. Patients in the MDI/spacer group, compared to those in the nebulizer group, spent less time in the ED (by 11.4 min) and had a slightly better increase in SaO₂ (0.6%).

The clinical significance of these differences favoring the MDI/spacer group is unclear. We chose a study design that interfered with conditions and procedures in the ED as little as possible, and we studied consecutive patients, imposing minimal enrollment conditions beyond those of age and a diagnosis of acute asthma. However, the use of a nonrandomized, nonconcurrent protocol is a limiting factor in the interpretation of the data. It potentially allows for the introduction of bias because this design does not allow for complete control of all the possible confounding variables. However, there were no differences in patient demographics in the two periods, which suggests the absence of a confounding variable. There also could be temporal changes, for example in the prescribing habits of physicians. This possibility is minimized in this study by using specific treatment algorithms for both time periods. Finally, there is the possibility of a selection bias in that the pool of patients could be different in the two periods. However, the use of this study design allowed for the enrollment of a large number of consecutive patients in order to have a comprehensive database of asthma management variables.

Our results are similar to those from a number of previous studies, which found approximately equivalent performance for MDIs and nebulizers in adults,⁹ children,¹⁰⁻¹² and infants¹³ who had acute obstructive respiratory disease requiring aerosol β_2 -

agonist therapy. The earlier studies were, for the most part, conducted in small populations of patients under highly controlled conditions. However, a current systematic review¹⁴ of 16 controlled trials noted that the length of stay of children in the ED was significantly shorter when the spacer/holding chamber was used.

We compared nebulized albuterol to albuterol administered by MDI with an attached small volume spacer. Spacers are known to improve compliance, to enhance the efficiency of drug delivery, and to reduce oral deposition compared to MDIs without spacers or holding chambers. Their use is particularly valuable in patients who have poor timing and do not adequately coordinate inhalation from an MDI with the actuation of the device.¹⁵

Potential dose-related adverse effects of β_2 -agonists have been reported in studies comparing the use of nebulizers to MDIs in asthma patients. Extrapulmonary sympathetic effects such as tremor, anxiety, and arrhythmias were found in one study to be more prevalent in patients receiving nebulized medication compared to MDI/spacer-delivered medication.⁷ Of parameters that might indicate adverse effects due to β_2 -agonist overexposure, we measured HR change. We found no significant difference in this parameter between the two groups, with HR actually decreasing in each of the two treatment groups. The likely reason for the decrease was the alleviation of respiratory difficulty by the medication.

Although ED and hospital charges were examined in this study, we detected a strong trend for difference, which did not reach statistical significance ($p = 0.15$), between the two treatment groups. However, charges, in contrast to costs, tend not to reflect

overhead and other indirect costs. A number of studies that have compared MDI/spacer to nebulizer therapy have assigned a cost advantage to MDIs. Conversions to MDI resulted in cost savings derived from a reduced need for medication, as well as reductions in labor costs and supplies.^{16–18} In a study of young children with asthma, Leversha et al¹⁹ found that bronchodilation therapy by nebulizer was 55% more costly than by MDI/spacer (AeroChamber). The methods were equally efficacious. They observed a lower hospital admission rate in the group using MDIs.

We are unable to differentiate the effects of specific materials given to patients during phase 2 of the study and how they might have influenced efficacy variables. It seems reasonable to conclude that the asthma bag given to patients might have contributed to the reduced relapse rate that we observed in the MDI/spacer group. The bag contained a spacer, an MDI-albuterol canister, a peak flowmeter, an instructional pamphlet with a personal asthma diary, and a canister of an inhaled corticosteroid. Counseling and instruction in asthma self-management are generally regarded as being cost-effective adjuncts to asthma therapy, with multiple studies showing asthma education leading to decreased ED visits, hospital admissions, and costs.^{20–22} We believe that a follow-up study will be necessary to ascertain what, if any, clinical or quality-of-life benefits the counseling and demonstrations aspects of the phase 2 protocol might have had. Of particular interest would be the measurement of the respective contributions of the asthma bag and the counseling program on the reduction in asthma relapse rates that we observed. There were two unique aspects of the educational program that was administered in the present study. The program was brief, and it was delivered in the ED by staff nurses. The inhaled corticosteroid also probably contributed to the decreased asthma relapse rate. Studies of budesonide have shown a decreased asthma relapse rate when the inhaled steroid was given to patients for home use after ED discharge.²³

In conclusion, we found that in adult asthma patients presenting to a busy urban ED, albuterol delivered by MDI/spacer was at least as efficacious as nebulized albuterol. Patients in the former group had greater improvement in PEFV values but no significant decrease in hospital admission rates. A significantly lower asthma relapse rate was found when the MDI/spacer approach was used in the ED in association with asthma teaching and the provision of a peak flowmeter, a spacer, and an inhaled corticosteroid for home use. We found that patients in the MDI/spacer group received a much smaller

dose of albuterol than did patients in the nebulizer group. Therefore, the use of an MDI with spacer provides an important alternative to the use of nebulizers in treating patients with acute asthma in the ED.

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Arthur E. Pitchenik, MD, FCCP



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Arthur E. Pitchenik, MD, FCCP, Professor of Medicine, University of Miami Medical School, and Chief of Pulmonology Section, VA Medical Center, Miami Beach, FL, is one of the 23 award recipients honored by The CHEST Foundation with a 2001 Governors Community Service Award.

The program, “They’re Rich, You’re Dead,” which Dr. Pitchenik started as a volunteer program in 1995, serves a dual purpose of influencing a large number of youth to take a stand against tobacco use and allowing physicians-in-training to learn and practice how to influence healthy behavior. In addition to locally produced, youth-oriented teaching materials (*ie*, videos and interactive CD-ROMs), this program is unique in that it enlists the assistance of patients with smoking-related diseases to help present the program at the schools and to teach children not to make the same mistakes they did. The videos have been translated into Spanish and Mandarin Chinese and are available on request by contacting Dr. Pitchenik at <arthurpit@aol.com>.

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