

## Evaluating the Outcome of Two Teaching Methods of Breath Actuated Inhaler in an Inner City Asthma Clinic

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**Objectives:** Our objective was to compare two different teaching methods used to educate patients in the use of a breath actuated inhaler (BAI) and to assess the impact of its continued use on their metered-dose inhaler (MDI) technique. **Design:** Prospective, randomized, controlled trial. **Setting:** Adult Pulmonary/Asthma clinic of Cook County Hospital, Chicago, IL. **Patients:** Diagnosed, stable asthmatics. **Intervention:** The patients were randomized into two groups. The experimental group received verbal instructions and demonstration on breath actuated inhaler technique while the control group received written instructions only on BAI use. The metered dose inhaler technique of both groups of patients was also evaluated. **Measures:** A checklist evaluating the key aspects of proper BAI and MDI inhalation techniques was used to assess the use of both types of inhalers at entry into the study and upon postintervention follow-up at 8 to 20 weeks. **Results:** At baseline, 97% of patients in the experimental group and 83% of patients in the control group were initially able to demonstrate BAI inhalation technique correctly. Upon follow-up, 82% of the control group and 68% of the experimental group were able to use the BAI correctly, which was a statistically significant deterioration in the experimental group. In both of these groups, there was a statistically significant improvement in MDI technique. **Conclusions:** Written instructions alone may be an adequate teaching tool for proper inhalation technique of BAI. Continued BAI use appears not to impact adversely on proper MDI technique.

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**KEY WORDS:** asthma clinical trials; metered-dose inhaler; breath actuated inhaler; inhaler technique; patient education.

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## INTRODUCTION

Aerosol drugs, both bronchodilators and steroids are the mainstay of treatment of bronchial asthma.<sup>(1)</sup> Metered-dose inhalers (MDI) are a convenient and portable source of aerosol medication. The major drawback to the use of MDIs is that a significant proportion of patients do not know how to use them correctly.<sup>(2)</sup> The inability to coordinate the timing of canister activation with inhalation and the inability to control inhalation are frequent problems encountered in MDI use. Some patients cannot learn the technique despite repeated instructions.<sup>(3)</sup> Spacer devices have been developed to improve patient adherence to proper technique.<sup>(4)</sup> Problems with the spacer devices include bulkiness and difficulty in carrying them so that patients may not use them.<sup>(3)</sup> The breath actuated inhaler (BAI) has been developed as an adjunctive therapy to help promote proper technique and enhance adherence.<sup>(5-8)</sup>

The purpose of this study was to compare two different educational methods in teaching proper inhalation technique using the BAI: verbal and written instructions with demonstration vs written instructions only. Specifically, we were interested in seeing if written instructions alone were sufficient in enabling patients to use the BAI correctly. Our study evaluated patients' techniques over a follow-up period of 8–20 weeks unlike most earlier studies in which observations were limited to a single point in time.<sup>(4,5,6,9,10)</sup> We also assessed whether the use of the BAI led to the deterioration of proper MDI inhalation technique because inhaled corticosteroids, important in asthma therapy, are presently available only in the MDI design technique.

## METHODS

### Study Design

We enrolled patients from the Pulmonary/Asthma Clinic (an inner-city asthma clinic) of Cook County Hospital. Informed consent was obtained from each patient prior to enrollment in the study. Patients were randomized either to an experimental group or control group in order to evaluate two different teaching methods. Checklists evaluating proper inhalation techniques were used for both the BAI and MDI, respectively (see Table I). All patients had their MDI and BAI inhalation technique evaluated at enrollment (baseline) and during a follow-up period of 8–20 weeks. The study was approved by the Cook County Hospital Institutional Review Board.

### Subjects

Asthmatics who had been in the Pulmonary/Asthma clinic for 6 months were eligible. Patients were excluded if they (a) missed more than 25% of appointments in the previous 6 months, (b) had an Emergency Department visit in the month prior to entry or two or more visits in the prior 6 months, (c) were taking more than 10 mg of oral prednisone daily or 30 mg every other day, or (d) were unable

**Table I.** Checklists for Proper Inhalation Techniques

Checklist for proper inhalation technique of MDI	
___ (a)	Takes off cap
___ (b)	Shakes
___ (c)	Holds inhaler upright
___ (d)	Activates inhaler during inspiration
___ (e)	Inhales slowly and deeply
___ (f)	Holds breath for 5–10 seconds
___ (g)	One puff at a time
___ (h)	15–60 seconds between puffs
Checklist for proper inhalation technique of BAI	
___ (a)	Takes off cap
___ (b)	Shakes
___ (c)	Holds inhaler upright
___ (d)	Lifts lever each time
___ (e)	Closes mouth around inhaler
___ (f)	Inhales slowly and deeply after the medication is triggered
___ (g)	Holds breath for 5–10 sec
___ (h)	One puff at a time
___ (i)	15–60 sec between puffs

to read or understand English. English reading proficiency levels were not addressed, but were assumed balanced because of the experimental design.

### Intervention

At study baseline, a trained instructor gave patients in the *experimental group* verbal instructions along with a demonstration of the proper BAI inhalation technique (Table II). Patients were asked to demonstrate their inhalation technique to the instructor (baseline competence in experimental group for BAI). The instructor counseled the patients until their technique was deemed proper. They were also given written instructions (Maxair™ autohaler™ package insert instructions). Patients in the *control group* received written instructions only (Maxair™ autohaler™ package insert instructions). After receiving these written instructions, control patients also demonstrated their technique to the instructor and their baseline compe-

**Table II.** Demographics of Patient Population

	Experimental <i>n</i> = 36	Control <i>n</i> = 32	<i>p</i> -Value
Age			
Mean (SD)	49.48 (16.49)	43.58 (13.48)	0.11
Sex			
Male	21.21%	27.78%	0.72
Female	78.79%	72.22%	0.52
Patients instructed on how to use MDI prior to study	96.97%	94.44%	0.60
FEV1 (liters) prestudy			
Mean (SD)	2.18 (0.95)	2.05 (0.75)	0.53
FEV1 (liters) poststudy			
Mean (SD)	2.42 (1.12)	2.17 (0.96)	0.36

tence was measured and recorded. The instructor gave no feedback on the correctness of the control group patients' technique. All patients were instructed to revert back to their MDI from their BAI if they did not feel comfortable with the use of the BAI because all of our patients had albuterol in an MDI available to them. We used Albuterol as the drug in the MDI and Pirbuterol as the drug in the BAI.

Both experimental and control group patients demonstrated their MDI technique to the instructor upon enrollment (baseline MDI). The instructor then gave them a demonstration of MDI technique and counseled them on the correct use of the MDI.

### Follow-up and Outcome Measurements

At baseline, a competency score was assigned to all patients for both BAI and MDI technique. Scoring was based on competency features repeated in scientific literature (Table I).<sup>(2, 10, 12)</sup> Subjects had to complete all steps successfully for each of the respective inhalers to be given a score of 1. If any one of the steps was missed, the subjects were given an overall score of zero for that inhaler technique.

Patients were followed up for 8–20 weeks. At follow-up (i.e., study endpoint), patients demonstrated their BAI and MDI techniques to an independent physician who was blinded as to their group assignment. Patients again received detailed instructions on how to use both their BAI and MDI properly.

### Statistical Methods

First, all study variables were subjected to univariate descriptive analysis. Second, we addressed possible threats to the integrity of the experimental design. *t* tests and Cochran-Mantel-Haenssel chi-square procedures were used to gauge the success of study randomization procedures by examining the equivalency of Experimental vs Control (E vs C) groups on a host of background measurements taken cross-sectionally at baseline. Third, we examined E vs C cross-sectional differences at study end-point with respect to all of our independent samples hypotheses, i.e., that there would be no differences in patient practices between E vs C groups. Finally, we examined within-subject longitudinal changes in patient practice/administration patterns from baseline to study endpoint. For this within subject analysis, we performed pair matched *t* tests.

### Sample Size and Power

Study power was calculated prospectively in the planning phase for the independent samples hypothesis. We also evaluated our resultant sample retrospectively in the analytic phase. Based on the total sample size of  $n = 68$  (i.e.,  $n = 34$  for each E vs C), we were able to detect a 30–35% event frequency differences in all categorical outcome measure distributions, assuming Alpha = 0.05 and Beta = 1–4 (alpha) or 0.80. We use the term “trend” to infer E vs C differences which approach statistical significance, but fall within  $0.05 > p < 0.10$ .

**Table III.** Between-Group Effects of Intervention on BAI and MDI Use

	Experimental Group <i>n</i> = 32 Mean (SD)	Control Group <i>n</i> = 28 Mean (SD)	<i>p</i> -Value
Independent samples test for BAI			
BAI competence score			
Baseline	0.96 (0.17)	0.83 (0.37)	0.06
BAI competence score			
Study end point	0.68 (0.47)	0.82 (0.39)	0.23
Independent samples test for MDI			
MDI competence score			
Baseline	0.40 (0.49)	0.36 (0.48)	0.56
MDI competence score			
Follow-up	0.76 (0.43)	0.68 (0.47)	0.99

## RESULTS

There was no significant difference between groups in demographic or clinical features upon entry (Table I). This indicated that randomization was successful. A total of 68 patients were entered into the study. Ninety five percent of patients reported having learned how to use the MDI in the past.

Our results for Experimental vs Control ‘between’ group differences are reported in Table III, and ‘within’ group differences in Table IV. Our results show that at initial baseline evaluation, 83% of the patients who were given only written instructions (control group) were able to use the BAI correctly. Of patients given oral instructions and demonstration (experiments group), 96% were able to use the BAI correctly. This experimental group ‘difference’ was not statistically significant but it did approach significance ( $p = 0.06$ ). At follow-up, 82% of the control patients were still able to use the BAI correctly. This 1% difference was not statistically significantly different than their baseline evaluation. However, only 68% of the experimental group were able to use the BAI correctly upon follow-up, which was a statistically significant ‘within’ group deterioration ( $p = 0.005$ ) from their initial evaluation. When the follow-up evaluation of the BAI for the control (1%) group was compared with the experimental group (28%), there was a 27% difference. While this change was dramatic, it did not reach statistical significance based on our sample size ( $p = 0.23$ ).

**Table IV.** Mean Change (Gain or Loss) in Scores for Intervention Within Groups from Baseline to Study End-Point

	BAI Competence Mean (SD)	<i>p</i> -Value	MDI Competence Mean (SD)	<i>p</i> -Value
Experimental group <i>n</i> = 32	-0.28 (0.45)	0.005	+0.40 (0.70)	0.009
Control group <i>n</i> = 28	+0.03 (0.57)	0.74	+0.41 (0.68)	0.002

\**p*-Value is for the pair-matched *t* test.

At baseline evaluation, even though 96% of our patients said that they had been previously taught how to use an MDI, only 36% of the control group and 40% of the experimental group were able to correctly use their MDI. At follow-up, there was a statistically significant 'within' group improvement in MDI use in both the groups (Table IV). However, while 68% of the controls and 76% of the experimental subjects demonstrated correct MDI use, this 8% difference among independent samples was not statistically significant ( $p = 0.99$ ).

## DISCUSSION

This is the first study to our knowledge which longitudinally (i.e., over 8 to 12 weeks) evaluated BAI use. In the initial evaluation of the BAI inhaler technique, experimental group patients did better than the control group patients. However, this was a trend which only approached statistical significance ( $p = 0.06$ ). This finding was supported by several previous studies.<sup>(11, 12)</sup> However, upon follow-up evaluation, there was a significant deterioration in the BAI technique of the patients in the experimental group whereas no change was seen in the patients in the control group. This finding is contrary to the observation made in previous studies.<sup>(11, 12)</sup> Reesor-Nimmo *et al.*, concluded that written instructions alone are insufficient in teaching correct technique; however, their observations were in reference to the diskhaler and the turbuhaler.<sup>(11)</sup> BAI was not tested in their study and their observation may not be applicable to the BAI. Kelloway *et al.* have shown that those patients who were given modified written instructions fared significantly better in the use of the BAI and that instructions have a significant influence on the subjects' ability to correctly use BAI.<sup>(12)</sup> In their study, there was no group which received a demonstration of technique. In our study, the patients in the control group did not show deterioration in the BAI technique. One explanation would be that they read and retained the written instruction more thoroughly as compared to the patients in the experimental group, and due to the fact that they (control group) did not receive practical demonstration of the proper technique. The patients in the experimental group, on the other hand, may have not read the instructions well after the initial demonstration, thus leading to a problem with recall and a significant deterioration in their technique. This finding is consistent with adult learning theory which postulates that patients who master techniques "on their own" will retain knowledge longer and more completely.<sup>(13)</sup>

Patients received the inhalational medications as per the formulary at Cook County Hospital. All patients had access to albuterol in an MDI and pirbuterol in BAI. Pirbuterol and albuterol were shown to be equally efficacious in experiments, so both medications could have produced similar results.<sup>(14, 15)</sup>

Both the control and the experimental groups showed significant improvement in MDI technique as we re-educated every patient about MDI technique. This re-emphasizes that repeated instructions are necessary for proper technique even in well-trained patient groups. The introduction of BAI did not lead to the deterioration of MDI technique, which we feared. This is significant since inhaled steroids

are only available in MDI design at present. We can therefore safely give patients two different inhaler designs to treat their asthma.

We scored competency for the BAI and MDI on an all or none basis. If the subject completed all the steps (Table I) correctly, he/she received a full score of one. If the subject missed even one step, he/she received a score of 0. We believed that all the steps were important. We re-analyzed the data by eliminating some of the more trivial steps including (1) takes off cap, (2) shakes, and (3) 15–60 sec between the puffs (Table I). However, the results were the same.

### CONCLUSION

Patients may initially learn appropriate BAI use with verbal instructions and demonstrations, but there is a high likelihood they will not maintain proficiency over time. This finding questions whether the added time and cost invested in doing so is worthwhile. Our study showed that if patients are not routinely reinforced with verbal counseling and demonstrations, but are required to carefully read written instructions, they retain knowledge of proper BAI use better over time. In the absence of continuous reinforcement by counselors, written instructions are 80% effective over time. This finding is consistent with adult learning theory, and is of value to patient education and managed care programs. At present, for populations such as those participating in this study, there is no inhaler device that does not require repetitive demonstration over time to maintain proper patient technique above the 80% level.

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