A Comparison of Breath-Actuated and Conventional Metered-Dose Inhaler Inhalation Techniques in Elderly Subjects

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Background: Poor coordination of canister actuation and inspiration often prevents adequate metered-dose inhaler (MDI) usage by patients, perhaps especially so among the elderly. Breath-actuated inhalers (BAI) have been developed to prevent this problem.

Methods: We compared the adequacy of inhaler technique and patient preferences between MDI and BAI in a group of elderly subjects (mean age, 70.8 ± 5.4 years). Half of the subjects were regular MDI users; half had never before used one. Two trained observers assessed the adequacy of MDI and BAI usage subjectively while performance was monitored objectively using a light source and infrared system to detect canister actuation and a spirometer to measure the inspiratory volume. If canister actuation was not followed by at least a 50 percent vital capacity, inhaler use was deemed unsuccessful. A brief teaching session preceded inhaler usage.

Results: By subjective assessment, BAI was used successfully more often than MDI (79 vs 60 percent, p<0.05). By objective assessment, BAI was used successfully more often than MDI (64 vs 36 percent, p<0.0005), although the percentage of inhalations scored adequate was lower than when assessment was subjective. Neither device was used correctly as often by those unfamiliar with MDIs as by those who were regular users. A significantly higher percentage of patients preferred BAI to MDI (71 vs 19 percent, p<0.005), similar preferences being reported by MDI familiar and MDI unfamiliar groups.

Conclusions: We conclude that (1) elderly subjects frequently handle inhalers poorly, (2) mishandling is better detected by objective than subjective monitoring, and (3) BAI is used correctly and preferred by patients more often than conventional MDIs.

CFC = chlorofluorocarbon; MDI = metered-dose inhaler

current therapeutic approaches to obstructive airways disease emphasize the delivery of medications by the inhalation route, a route that encourages maximal therapeutic effect in the airway while reducing undesired systemic side effects.1 The most commonly used and perhaps most cost-effective inhalation technique is the conventional metered-dose inhaler (MDI). Regrettably, surveys of MDI technique in ambulatory practice show that between 14 and 89 percent of patients fail to use MDIs correctly.6 This is not altogether surprising; even physicians show poor understanding of MDI use.5,6

One of the most vexing problems of MDI use is coordinating the timing of medication canister actuation with patient inhalation. For ideal drug delivery, the MDI canister should be depressed and medications aerosolized during the inspiratory maneuver, particularly at the early or midportion. Poor MDI technique may be a more prevalent problem among the elderly, although few studies of MDI use have focused on this age group.7 If MDI technique is a problem for the elderly, many aged patients will be denied the benefits of inhaled bronchodilators or anti-inflammatory drugs at a time when the population is "graying" and diseases such as COPD are increasing in prevalence. Such problems may be obviated and inhaled therapy made more widely available by the use of adjunctive devices. One such device would be the breath-actuated MDI.

We undertook the following study to assess the adequacy of MDI technique in a population of elderly patients and to compare the adequacy of conventional MDI use with that of a newly developed, breath-actuated MDI (Autohaler, 3M Pharmaceuticals, St. Paul, Minn). Our assessment focused particularly on the problem of timing of aerosolization to inspiration. Care was taken to assess both regular MDI users and patients new to pressurized aerosols.

Methods

Subjects

Elderly subjects familiar with the use of MDIs were recruited from the population of patients referred for pulmonary function testing to the Pulmonary Function Laboratory of The Toronto Hospital, Western site. Elderly volunteers unfamiliar with the use of MDIs were recruited by word of mouth and by posted advertisement in the hospital and adjacent senior citizen facilities. Subjects were considered eligible for participation in the study if they were aged 63 years and older, indicated a willingness to participate in the study, and had a reasonable command of spoken English. Subjects were excluded if there was any evidence of serious neuromuscular disorder, if the subject had a known sensitivity to...
MDI propellants or excipients, or if there was any acute or chronic orofacial disease preventing application of the MDIs to the lips. The protocol was reviewed by the Research on Human Subjects Committee of The Toronto Hospital and written informed consent was obtained from all subjects.

Protocol

All studies in a given subject were conducted on a single study day. Patients were questioned about their familiarity with MDIs and other inhaling devices and were categorized as being MDI familiar or MDI unfamiliar on the basis of their responses. Individuals who had used an MDI at least once daily for 6 months of the preceding year were regarded as MDI familiar. Subjects were then shown a conventional placebo MDI followed by the breath-actuated placebo MDI. This fixed order of presentation was chosen so that the presentation of devices to the MDI-unfamiliar group would parallel that of the MDI-familiar group; that is, by definition, all MDI-familiar subjects were exposed to conventional MDIs before exposure to the breath-actuated device. The device was demonstrated by a trained technologist reading from a standardized, brief, English-language description of the use of the device as well as demonstrating its use by self-administration. Subjects were then allowed to handle the device and to actuate it twice for practice purposes. They were then asked to demonstrate correct technique to the technologist. After using the MDI, the breath-actuated device was demonstrated and then its self-administration was assessed in similar fashion. Subjects were instructed in the closed mouth technique from residual volume. Shaking the canister and removing the cap were performed for all subjects by the technicians. Following the use of both placebo inhalers, all patients underwent measurement of flow-volume spirometry, the best of at least three maximal expiratory efforts being chosen as the value for purposes of analysis.

Subjective Monitoring

During the use of each device, the two technologists independently monitored the patient's technique using a previously agreed-on set of criteria for correct use. In brief, both sets of criteria specified expiration to residual volume, closed mouth technique, slow inhalation to total lung capacity, breathhold at total lung capacity, and slow exhalation. In addition, the conventional MDI criteria specified canister actuation just after the onset of the inspiratory maneuver; the breath actuation criteria specified both priming of the lever that sets the valve mechanism and the need to continue inspiration after mechanically triggered canister actuation. Patients were then categorized as having used the device successfully or unsuccessfully according to this subjective evaluation; infrequent discrepancies between the two technicians were reconciled and the number of these discrepancies was noted. Following the use of each device, subjects were asked to rate the ease and comfort of use on a scale from 1 to 3, the highest score indicating greatest ease and comfort of use. After the use of both devices, patients were asked to state their preference for one or the other or to state that there was no difference.

Objective Monitoring

Placebo MDIs in conventional format and placebo breath-actuated MDIs were used for the study (placebo MDI Glaxo Canada, Inc, Mississauga, Canada, and placebo Autohaler, 3M Pharmaceuticals, St. Paul, Minn). These devices were modified to allow objective electronic monitoring of MDI usage in a modification of the technique of Shim and Williams.* In brief, in the plastic mouth portion of each device, holes were drilled on each side to allow placement of an infrared light source and infrared sensor (Fig 1). This sensor was used to detect actuation of the canister; the spray plume ejected from the canister orifice following actuation interrupted the light beam. The infrared sensor was connected to an electronic signal source recorded by a strip chart recorder (Gould Medical Electronics model TA3000, Gould Inc, Cleveland). A circular hole approximately 2.5 cm in diameter was opened in the plastic mouthpiece of each device opposite to where the lips are applied. At this posterior opening, tubing was joined to allow connection of the device to a wedge spirometer (Wedge 570, Med Science, St. Louis). Output from the wedge spirometer was connected to a strip chart recorder, thus allowing measurement of tidal volume breathing and the patient's inspiratory volume during device usage. These strip chart recordings were examined by an observer blinded to the patient's previous MDI usage. This observer compared the timing of canister actuation (as detected by infrared sensor) and inspiration (as recorded by spirometer tracing) and deemed the effort as successful or unsuccessful. The patient's effort was termed successful if the canister actuation was followed by an inspiratory volume of at least 50 percent of the vital capacity. Canister actuation preceding inspiratory flow, followed by less than a 50 percent vital capacity inspiratory effort or following the inspiratory effort were deemed unsuccessful.

\[\text{Figure 1. Schematic of the objective monitoring system. Tubing from the spirometer is connected to an opening in the inhaler sleeve opposite the mouthpiece so that inspiration is recorded spirometrically on a strip chart recorder. Holes have been drilled in opposite sides of the mouthpiece perpendicular to the path of the spray plume. At canister actuation, the spray front disrupts the light path, an event detected by a simple signal box and recorded on an adjacent channel of the strip chart recorder.}\]
Data Analysis

Continuous measures are summarized as mean ±1 SD, while categorical responses are presented as percentages. Continuous variables were compared between groups through Student's t test. Proportions of successful users of breath-actuated and conventional MDI through objective and subjective criteria were compared through the McNemar Test of correlated proportions. Differences in independent proportions were compared through χ² test of independence.

Differences were considered to be statistically discernible at the p<0.05 level.

Results

Student Characteristics

Eighty elderly subjects were recruited for participation in the study, 40 (24 men, 16 women) who were familiar with the use of MDIs and 40 (17 men, 23 women) who were unfamiliar with these devices. The mean age was 70.8 ±5.4 years (range, 63 to 85 years), the average age not being significantly different between MDI-familiar and MDI-unfamiliar groups. Spirometric endpoints differed significantly between MDI-familiar and MDI-unfamiliar groups. The FVC was 2.65 ± 0.95 L in the familiar group and 2.81 ± 0.89 L in the unfamiliar group. For FEV₁, the corresponding values were 1.62 ± 0.72 L vs 2.16 ± 0.63 L (p<0.0001).

For FEV₁/FVC ratio the corresponding values were 0.61 ± 0.14 vs 0.78 ± 0.09 (p<0.0001).

Subjective Endpoints

When scored subjectively, the breath-actuated MDI was used successfully by 78.8 percent of patients, whereas the conventional MDI was used successfully by only 60 percent of subjects (p<0.05). This apparent advantage of the breath-actuated device was similar in both patient groups. Among patients familiar with conventional MDIs, 70 percent used the conventional MDI successfully whereas 90 percent used the breath-actuated device successfully (p=0.06). Among patients unfamiliar with MDIs, 50 percent used the conventional device successfully whereas 67.5 percent used the breath-actuated device successfully (p<0.10).

Table 1 shows the percentage of patients in each group observed to use one, both, or neither device successfully. The most revealing comparison was among patients able to use only one of the devices successfully. A handful of patients were able to use only the MDI successfully; in the MDI-familiar group, 7.5 percent, and in the MDI-unfamiliar group, also 7.5 percent. By contrast, a significant percentage of patients were able to use only the breath-actuated device successfully; in the MDI-familiar group, 27.5 percent, and in the MDI-unfamiliar group, 25 percent (p<0.05).

The two technician scores were discrepant in seven patients, similarly in the evaluation of the conventional MDI and the breath-actuated MDI. The discrepancies appeared unrelated to the type of device or the subject's familiarity or unfamiliarity with the device. Instead, discrepancies between the technicians' subjective evaluations were more common at the beginning of the study than during the middle or at its conclusion.

Significantly more subjects preferred the use of the breath-actuated device as compared to the conventional MDI. Among all subjects, 71.3 percent preferred the breath-actuated device, 18.8 percent preferred the conventional MDI, and 10 percent had no preference (p<0.005). There was no significant difference between MDI-familiar and MDI-unfamiliar groups with respect to this stated preference. Among the MDI-unfamiliar group, 70 percent preferred the breath-actuated device, 22.5 percent preferred the conventional MDI, and 7.5 percent stated no preference. In the MDI-familiar group, 72.5 percent preferred the breath-actuated device, 15.0 percent preferred the conventional MDI, and 12.5 percent stated no preference.

Patient ease of use and comfort ratings were significantly higher for the breath-actuated than for the conventional MDI. Overall, the rating was 2.2 ± 0.76 for the conventional MDI vs 2.6 ± 0.63 for the breath-actuated MDI (p<0.005). This was not significantly different between groups; the MDI-familiar group rated the conventional MDI 2.3 ± 0.76 vs the breath-actuated device 2.7 ± 0.56 (p<0.05), and the MDI-unfamiliar group rated the devices 2.1 ± 0.75 vs 2.5 ± 0.68, respectively (p<0.05).

Objective Endpoints

Findings with the objective monitoring technique paralleled those observed with the subjective monitoring technique. The breath-actuated MDI was used correctly by 63.8 percent of subjects whereas only 36.3 percent of the subjects used the conventional MDI successfully (p=0.0001). As noted for the subjective monitoring technique, the advantage of the breath-actuated device was similar in both patient groups. Among patients familiar with conventional MDIs, only 45 percent used the conventional MDI successfully whereas 90 percent used the breath-actuated device successfully (p<0.005). Among MDI-unfamiliar patients, 27.5 percent used the conventional device successfully whereas 47.5 percent used...
the breath-actuated device successfully \( (p<0.05) \). Table 2 shows the percentage of patients in each group observed to use one, both, or neither device successfully according to objective monitoring. As with the subjective monitoring technique, a handful of patients were able to use only the MDI successfully; in the MDI-familiar group, 5 percent, and in the MDI-unfamiliar group, 5 percent. By contrast, a significantly higher percentage of patients was able to use only the breath-actuated device successfully; in the MDI-familiar group, 40 percent, and in the MDI-unfamiliar group, 25 percent \( (p=0.0001) \).

**Objective vs Subjective Criteria**

Significantly fewer patients used the conventional MDI correctly by objective endpoints as compared with subjective assessment of technique; for all subjects, 36.3 percent used the conventional MDI correctly as assessed by objective monitoring whereas 60 percent had used the conventional MDIs correctly as determined by subjective monitoring \( (p<0.001) \). Similarly, the breath-actuated device was used correctly significantly less often in terms of objective criteria; 63.8 percent of subjects used the breath-actuated device correctly vs 78.8 percent by subjective criteria \( (p<0.005) \). A similar pattern was seen in both MDI-familiar and MDI-unfamiliar groups. Objective monitoring disagreed with subjective perception of performance most often in terms of the adequacy of the continued inspiratory volume following canister actuation. That is, technicians were likely to overestimate the inspiratory effort following canister actuation; spirometrically monitored MDI use detected patients who failed to inspire adequately.

**DISCUSSION**

Our data show clearly that elderly subjects use conventional MDIs poorly whether familiar with or unfamiliar with these devices. However, elderly subjects, regardless of previous MDI experience, handle a breath-actuated inhaler more successfully. Although subjective monitoring of inhaler use will often detect patients who use these devices poorly, objective monitoring is more stringent and will detect more patients who have problems with inhalation technique.

Our finding of frequent improper use of MDIs is compatible with numerous previous reports. Estimates of poor MDI technique in nongeriatric adult patients range from 14 percent to 89 percent.24 This last estimate, by Epstein and colleagues,2 is particularly high, perhaps because these investigators used a restrictive set of criteria to denote adequate inhaler use. For example, 17 percent of patients were deemed to show inadequate technique for failure to exhale through the nose after inspiration, canister actuation, and breathhold. Even if this study is excluded, however, estimates of improper inhaler usage among adult patients range from 14 percent to 64 percent with an average estimate of 44 percent. If we can use this last figure as a reasonable estimate in adult nongeriatric patients, the elderly appear to have more difficulty with MDI usage. In our study, 55 percent of MDI-familiar subjects and almost 73 percent of MDI-unfamiliar subjects used the conventional MDI inadequately as determined by an objective monitoring technique. At least one study has examined the adequacy of MDI usage in the elderly with results similar to ours.7 Using observer assessment of adequate technique among elderly MDI users, Allen and Prior4 found that just 60 percent of geriatric patients used an adequate technique, a figure identical to ours using subjective scores in MDI familiar subjects. It would appear that even using somewhat generous subjective criteria for adequacy of inhaler technique, almost half of elderly subjects may use their aerosol devices poorly. This poor usage of pressurized aerosols in the elderly is of growing importance. Demographics in the developed nations are changing such that more geriatric patients are being cared for by health care systems while airway diseases such as COPD are growing in prevalence.18 With increasing emphasis on inhaled therapy, the adequacy of inhaler technique may be key to the treatment of many of these elderly patients.1,11,18 Various attempts have been made to overcome inhaler problems and in particular inhaler coordination problems. Such attempts have included the use of spacing chambers and the use of dry powder inhaling systems. The advantages of spacing chambers include improved drug delivery in patients with coordination problems, decreased deposition of drug in the oropharynx, and availability for use with a variety of medications. Against these advantages are the problems of their cumbersome shape and size that discourage some patients from using them regularly. Dry powder systems may be easier to use than conventional MDIs, but there may be problems if inspiratory flow rates are low or if cough is triggered by powder inhalation. The breath-actuated device assessed in this study circumvents a number of these difficulties. Although early versions of breath-actuated inhalers were bulky and generated a loud click when the valve mechanism was triggered, the present device displayed none of these undesirable characteristics.13

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**Table 2—Percentage of Subjects Using Inhalers Successfully by Objective Assessment**

<table>
<thead>
<tr>
<th></th>
<th>Both Devices, %</th>
<th>Neither Device, %</th>
<th>MDI Only, %</th>
<th>Breath-Actuated MDI Only, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDI-familiar</td>
<td>40</td>
<td>15</td>
<td>5</td>
<td>40</td>
</tr>
<tr>
<td>MDI-unfamiliar</td>
<td>22.5</td>
<td>47.5</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>All subjects</td>
<td>31.3</td>
<td>32.5</td>
<td>5</td>
<td>32.5</td>
</tr>
</tbody>
</table>

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**Note:** The table displays the percentage of subjects using inhalers successfully by objective assessment. The data are divided into three categories: both devices, neither device, and MDI only. A breath-actuated MDI only category is also provided. The table shows that the percentage of subjects using the breath-actuated device correctly increases significantly compared to the conventional MDI. The table highlights the differences between objective and subjective monitoring techniques.
More important, previous breath-actuated inhalers have required generous inspiratory flow rates for actuation. Currently manufactured breath-actuated devices have been reported to trigger with inspiratory flow rates of approximately 30 L/min and are reliably triggered even by those patients suffering from severe airflow obstruction. Similar to previous reports, we found that MDI-naive subjects find a breath-actuated device easier to use than conventional MDIs. Of interest, elderly patients already using conventional MDIs expressed a preference for the breath-actuated device after having used it. The rate of correct usage for conventional and breath-actuated MDIs was better in the MDI-familiar than the MDI-naive group; this difference was small. The breath-actuated device was used successfully more often than the conventional MDI by our elderly subjects but there remained a small minority who failed to use the breath-actuated device correctly. The most common error in breath-actuated inhaler usage was inadequate inspiratory volume following canister actuation. This was either because subjects halted their inspiration prematurely following canister actuation or because they had not begun inspiration at functional residual capacity or residual volume. Whether such problems can be corrected with additional teaching requires further research. Other disadvantages or possible disadvantages of the breath-actuated device should be considered and include continued use of CFC propellants, obligatory use of the closed-mouth technique, and increased complexity and possibly cost of the inhaler device.

We found that objective monitoring was a more stringent test of correct inhaler use than the subjective monitoring of two experienced respiratory technicians. This suggests that such objective monitoring may be useful in routine clinical use to detect and correct those who use prescribed aerosol inadequately. Other monitoring devices have been described previously. Coady and colleagues used pressure transducers to detect canister actuation and inspiratory efforts. However, this technique prevents aerosolization of canister contents making it an unrealistic test of patient performance. Such a technique might fail to detect patients who discontinued inspiration prematurely when canister actuation occurred, a common cause of poor performance in our study. Moreover, the device used by Coady and colleagues fails to quantify inspiratory volume. Shim and Williams described a more realistic MDI monitoring device that used a pneumotachograph to quantify inspiratory volume and detected canister actuation without occluding the canister orifice. Similar to our findings, Shim and Williams reported that 47 percent of MDI-familiar patients failed to use a conventional MDI adequately (55 percent in the present study).

Some limitations of our study should be noted. First, we studied usage of the inhaling devices after a relatively brief teaching session; no attempt was made to retrain subjects with faulty technique and to retest them. De Blanquiere and colleagues have estimated that instruction in the correct use of conventional MDIs requires an average of 15 min, slightly longer than the time allotted in the present study. The same investigators found that MDI performance deteriorates with time and suggested that the MDI teaching must be repeated. Nevertheless, we suspect that results even after a longer period of training or repeated training would parallel those we observed such that a higher percentage of patients would use the breath-actuated device adequately. This seems likely given the small differences in performance between MDI-familiar and MDI-unfamiliar groups. Most MDI-familiar subjects in our study had used their inhalers on a long-term basis and most had received instruction from their physicians or from paramedical staff; the small differences in adequacy of technique between MDI-familiar and MDI-unfamiliar groups would suggest that such recurrent training has had relatively little impact. Second, our study involved only MDI handling and did not examine the impact of technique on consequent medication delivery to the airway. It would be useful to determine in future studies if bronchodilator efficacy is affected significantly by the errors in handling technique identified by our monitoring. Certainly, the use of adjunctive devices such as spacing chambers by asthmatics with poor MDI technique has been shown to enhance bronchodilator responses. Comparable benefit may be conferred by a breath-actuated MDI; one preliminary study in a small number of subjects has shown that a breath-actuated device enhances delivery of radiolabeled drug to the airway and improves bronchodilator response in patients with poor MDI technique. Third, our study was limited to a comparison of pressurized aerosols in conventional and breath-actuated MDI formats. We did not compare the breath-actuated device with other alternative inhaling devices such as dry powder inhalers.

In summary, our data should alert clinicians to relatively frequent MDI handling problems among elderly subjects. Our findings also suggest the need for more frequent objective monitoring of MDI technique. For elderly patients using aerosols, the breath-actuated inhaler is significantly easier to use than the conventional MDI. This may offer particular advantages for those elderly patients who are new to the use of pressurized aerosols or who have difficulties using conventional aerosol devices.

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