

# Metered-Dose Inhaler Technique in Asthmatic Patients- A Revisit of the Malaysian Scene

L C Loh, MRCP\*, C L Teng, MFamMed\*, P N Teh\*, C N Koh, MPH\*\*, P Vijayasingham, FRCP\*\*\*, T Thayaparan, FRCP\*\*\*

\*IMU Lung Research, International Medical University, Clinical School, \*\*Klinik Kesihatan Seremban \*\*\*Department of Medicine, Hospital Seremban, Seremban

## Summary

Inefficient metered-dose inhaler (MDI) technique results in poor drug delivery, suboptimal disease control and possibility of inhaled medication overuse. The MDI technique of 134 government hospital and clinic followed-up adult asthmatic patients followed-up in a government hospital and a health clinic was pragmatically assessed based on the 3 obligatory steps of adequate lip seal, appropriate hand-breath coordination and sufficient breath holding after inhalation. The relationship between technique efficiency and frequency of daily short-acting  $\beta_2$ -agonist (SABA) use via the MDI and asthma exacerbations over a 12-month period was also assessed. Fifty-six patients (42%) had inefficient MDI technique. All demographic and asthma-related variables between the 'efficient' and 'inefficient' technique groups of patients were comparable except for significantly longer mean years of MDI use in the 'efficient' technique group [mean (SD): 10 (7) vs. 7 (5);  $p=0.003$ ]. There were no significant differences between the two groups in relation to frequency of daily SABA use or asthma exacerbations over the past 12 months. Despite having been available in Malaysia for a considerable period of time, the MDI device is still poorly handled by a large proportion of adult asthmatic patients. Changing to other more user-friendly devices or use of spacer devices to facilitate delivery should be considered for these patients.

**Key Words:** Metered-dose inhaler, Technique, Asthma, Malaysia

## Introduction

The metered-dose inhaler (MDI) is currently the most widely used device in the treatment of adult asthma. Up to 70% of all UK adult asthma prescriptions are for an MDI<sup>1</sup> and up to 3 million asthmatic patients worldwide use this device<sup>2</sup>. However, the effective delivery of medication using the MDI is hugely dependent on the correct use of the device, and many studies have shown that without sufficient attention being paid to education and training, the correct use of this device can be a serious problem among patients<sup>3,4,5,6</sup> and healthcare professionals<sup>7,8,9</sup>. Moreover, reinforcement is strongly advocated as regression of the correctly taught

technique can occur as early as 6 weeks<sup>10</sup>, even in medically trained personnel<sup>11,12</sup>. Incorrect use of the MDI poses the danger of asthma being under-treated leading to higher morbidity and mortality caused by persistence or escalation of asthma symptoms, frequent hospitalisation for severe exacerbations and even fatal attacks.

The MDI has been available in Malaysia for over 20 years. The Second National Health and Morbidity Survey conducted by the Public Health Institute, Ministry of Health Malaysia in 1996<sup>13</sup> indicated that up to 38% of asthmatic patients in Malaysia were on

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Corresponding Author: Li-Cher Loh, Department of Medicine, Clinical School, International Medical University, Jalan Rasah, Seremban 70300, Negeri Sembilan, Malaysia

inhaler therapy. This figure is probably higher now because of the increasing trend in the use of inhaler therapy. Zainudin and Sufarlan<sup>14</sup> conducted the first study on Malaysian asthmatic patients regarding MDI technique in 1989. They showed that 62% of patients followed up in their respiratory outpatient clinic did not use MDI correctly. Liam<sup>15</sup> showed that in a teaching hospital in Malaysia, only 21% of the 37 doctors in the Department of Medicine involved in instructing asthma patients on the MDI technique handled MDI device completely correctly.

We studied the MDI technique in adult asthmatic patients followed-up in a government hospital and a health clinic and the association with patient demographic factors and asthma-related variables such as duration of disease, length of MDI use and lung function.

Poor MDI technique may lead to overuse as the patient attempts to gain control of symptoms. Patients with poor technique may also suffer an increase in asthma exacerbations compared to those who use the MDI efficiently. In this study, we specifically examined whether inefficient MDI handling is associated with greater use of rescue medications for symptom relief and more frequent asthma exacerbations. Finally, to validate the concept that correct MDI technique has an impact on optimal drug delivery resulting in improved clinical effectiveness, we studied a subgroup of patients with inefficient technique, taught them the correct technique and then reassessed their forced expiratory volume in one second (FEV<sub>1</sub>) after 4 weeks.

## Materials and Methods

### Patients and Data Collection

Over a period of 13 months (August 2001 through September 2002), asthmatic patients aged between 12 and 70 years who were being followed-up in the medical outpatients clinic of a 800-bed state government hospital, and in a large health clinic located next to the hospital, were recruited. Data on demographic factors and asthma-related variables were collected using a standard questionnaire [Table I]. We excluded from the study patients who were not on a MDI or had been using MDI for less than a year and those who used other types of inhaler devices. Current cigarette smokers and ex-smokers who had smoked more than 10 pack years were also excluded to avoid including patients with chronic obstructive pulmonary disease. Patients who gave the history of

having asthma 'since birth' were standardised as having onset of asthma at the age of 3 years. The Forced Expiratory Volume in One Second (FEV<sub>1</sub>) data collected was post-bronchodilator and corrected to Asian values [Vitalograph (UK) 2120 Spirotrac IV]. The frequency of MDI used to deliver short acting  $\beta_2$ -agonist in a 24-hour day for relief of asthma symptoms was defined as the number of puffs used. This figure was obtained by asking the patient specifically about the average number of puffs required in a day over the past one week. No diary cards were used for this purpose and therefore the data could not be validated. The patients were categorised as 'low rate' users if they required an average of  $\leq 2$  puffs a day or 'high rate' users if they required an average of  $> 2$  puffs a day. The cut-off point of two puffs a day was arbitrarily chosen, based on the observation that many of our asthmatic patients with mild symptoms had the habit of routinely taking 1 or 2 puffs of SABA, especially in the mornings. It was deemed that by choosing patients who took more than 2 puffs a day as 'high rate' users, we were more likely to discriminate those who had a genuine need for rescue SABA. Asthma exacerbations were defined as emergency visits to doctors or healthcare personnel where, at least, a nebulised bronchodilator was given as part of the treatment. The accuracy of data on exacerbations was largely validated from hospital and emergency department medical records (the practice being that medical records are kept by patients and brought in by them each time they visit the emergency department). The patients were categorised as having few exacerbations if they had  $\leq 2$  exacerbations in the past 12 months or frequent exacerbations if they had  $> 2$  in the past 12 months. The choice of this cut-off point was based on a study on patients with severe persistent asthma which suggested that patients who had two or more exacerbations in a year might have a different airway pathology compared to those with fewer exacerbations<sup>16</sup>.

### Assessment of MDI technique

The proper MDI technique comprises of seven steps i.e. removing the cover, shaking the device, expiring fully, adequate lip closure; inhaling slowly with timed pressing (hand-breath coordination); breath-holding for at least 5 seconds; and finally, administering one dose for each inhalation. We adopted a pragmatic approach in that only three obligatory steps (adequate lip closure; inhaling slowly with timed pressing and breath-holding) were necessary for the MDI technique to be considered as 'efficient'. Failing to perform any one of these three steps constituted 'inefficient' technique.

The rationale was that these steps are the basic steps for efficient MDI use; the other steps are seldom done wrongly and even if so, easily corrected.

### Follow-up Study

A subgroup of patients whose MDI technique was inefficient, were taught the correct technique and reviewed 4 weeks later. They were selected on the basis that their asthma control did not require any changes in their existing drug treatment regime apart from correcting the MDI technique. This subgroup was comparable to the parent group with respect to age, sex, asthma duration and daily dose of inhaled corticosteroids (ICS), and at 4 weeks, their technique was examined again to ensure that it was correct. During this period, their anti-asthma medications remained the same. In this 'real life' clinic setting, change in median FEV1 was used to determine whether correction of MDI technique was clinically significant.

### Statistical Analysis

Descriptive statistics were used to summarise patient demographic factors and asthma-related variables. The differences between groups with 'efficient' and 'inefficient' technique were examined using student t tests (unpaired) and Chi-squared tests as appropriate. Due to the small sample size, non-parametric tests, Wilcoxon-signed rank tests, were used to study differences of median FEV1 before and after correction of inhaler technique in the follow-up study. A p value of less than 0.05 was considered as statistically significant. All analyses were conducted using statistical package SPSS version 11 for Windows (SPSS, Chicago, Illinois, USA).

### Results

One hundred and thirty four adult asthmatic patients [mean age, years (SD): 45 (15); % male: 31] were recruited during the study. Seventy-eight (58%) had 'efficient' while 56 (42%) had 'inefficient' MDI technique. There were no significant differences between the two groups with respect to mean age, gender, ethnic origin, education level, mean duration of asthma or age of onset, mean duration and mean daily dose of ICS or mean FEV1 (absolute value or % predicted normal). However, mean years of MDI use in the 'efficient' group was significantly longer than in the 'inefficient' group [mean (SD): 10 (7) vs. 7 (5),  $p=0.003$ ]. All, except twenty-one patients [9 in 'efficient' group; 12 in 'inefficient' group] were not on regular ICS as controller treatment for asthma.

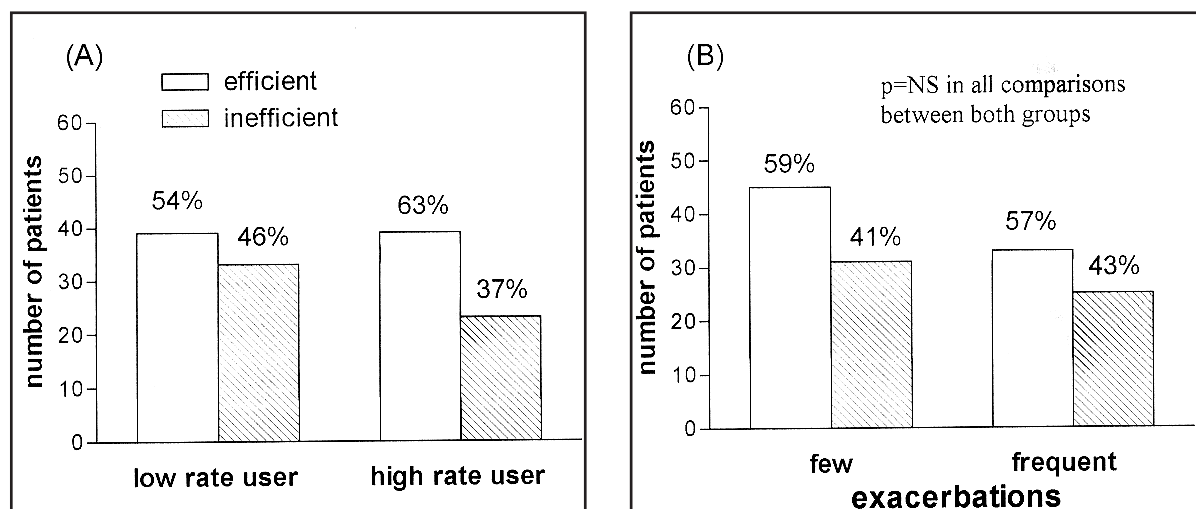
There was no significant difference between the 'efficient' and 'inefficient' groups with respect to rate of MDI use of SABA [Figure 1A]. Similarly, there was no significant difference between the 'efficient' and 'inefficient' groups with respect to frequency of asthma exacerbations in the past 12 months [Figure 1B].

In the follow-up study, only nine patients from the 'inefficient' group were eligible because many patients had their medication regime changed in addition to correcting MDI technique. In these nine patients, the median FEV1 increased by 16% (from 1.42 to 1.65 litres), 4 weeks after correction of the MDI technique. This difference approaches statistical significance (one-tail  $p=0.06$ ; Wilcoxon-signed rank test) [Figure 2]. All nine subjects maintained the correct technique at follow-up after 4 weeks.

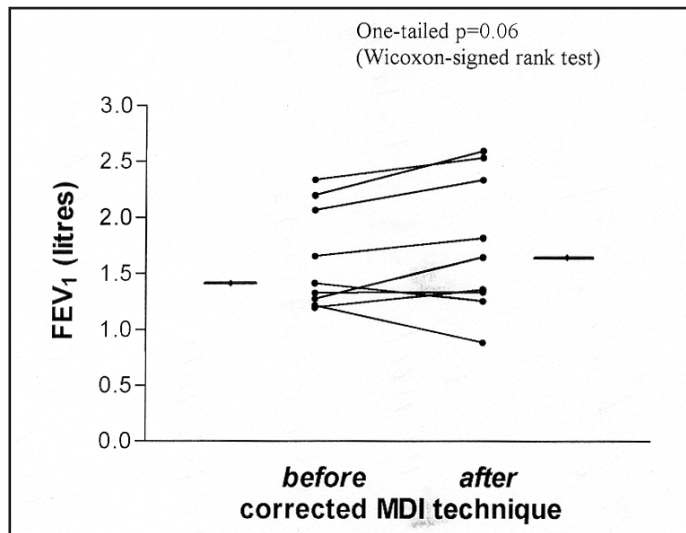
**Table I: Demographic and asthma-related variables in patients with efficient and inefficient MDI technique**

	MDI TECHNIQUE	
	Efficient	Inefficient
Patients, n (% total)	78 (58)	56 (42)
Mean age±SD, years	44±15	41±16
Male, n (%)	25 (27)	17 (41)
Malay/ Chinese/ Indian, n	36/14/ 28	19 /11/26
Education % :		
primary/ secondary/tertiary	47/59/69	52/41/30
Mean duration of asthma±SD, years	18±12	17±12
Mean age±SD at diagnosis of asthma, years	26±16	24±14
Mean duration of ICS* use±SD, years	7±5	5±4
Mean ICS* dose±SD, µg day <sup>-1</sup>	533±287	489±300
Mean FEV1 (L)	1.65±0.60	1.60±0.69
Mean FEV1 (% predicted)	62±18	60±18
Mean duration of MDI use±SD, years	10±7	7±5

MDI: metered dose inhaler; SD: standard deviation; ICS: inhaled corticosteroids; \*: all except for 9 in 'efficient' group and 12 in 'inefficient' group took regular ICS; FEV1: Forced Expiratory Volume in one second. Differences between groups not significant for all variables except mean duration of MDI use ( $p=0.003$ ).



**Fig 1: Effect of MDI technique on (A) rate of MDI use of short-acting b2-agonist (SABA) in 24 hrs and (B) frequency of asthma exacerbations in the past 12 months. NS= not significant**



**Fig 2: Change of median FEV<sub>1</sub> following correction of MDI technique at four weeks (n=9). Horizontal bar= median**

**Discussion**

We have shown that among asthmatic patients followed up in a government hospital and a health clinic, a large proportion have inefficient MDI technique. There were no discernable differences in demographic factors or asthma-related variables between the groups with 'efficient' and 'inefficient' technique except for the longer mean years of MDI use in the 'efficient' group. To confirm that correction of MDI technique has clinical relevance, we demonstrated a trend towards improvement in airflow limitation in the subgroup of patients who were taught the correct MDI technique.

MDI devices have been available in Malaysia for more than 20 years. In our study, 42% of patients did not use their MDI correctly compared to 62% in the first study on MDI technique in Malaysian asthmatics done over 10 years ago<sup>14</sup>. It is evident that there has been some improvement on revisiting this issue, but still nearly half of the patients studied could not use the MDI correctly. The figure for inefficient MDI use in this study may be conservative because of our pragmatic approach to the assessment of technique based on three key steps alone. Limiting assessment to three steps can reduce the margin of observational error among investigators but can nonetheless positively identify those with inefficient technique. In studies showing poor handling of MDI among asthmatic patients<sup>3,4,5,6</sup>, figures

vary from 71% in western countries<sup>4</sup> to 93% in primary healthcare clinics in Singapore<sup>5</sup>. Compared to our study, these high failure rates are most likely a reflection of the more stringent criteria used where more than the three crucial steps (in some up to 7 steps) in MDI technique was assessed and rated. While illiteracy may have a role<sup>17</sup>, education and regular reinforcement can ensure that most users can be successfully taught<sup>1,2</sup>. Although in our study, there was no difference in education levels between the two groups, there was a trend towards a greater proportion of patients with higher education level in the 'efficient' group. The failure to reach statistical significance might be due to our sample size not being sufficient large.

Our finding that many patients in the 'inefficient' group had been using MDIs for a considerable period of time (average 7 years) is of concern. This suggests that our healthcare professionals are not checking or reinforcing the correct technique, or perhaps themselves incorrectly teaching the patients<sup>15</sup>. A study in a major teaching hospital in UK<sup>8</sup> showed that only 40% of emergency department medical officers and nurses routinely checked the inhaler technique of asthmatic patients. Although simple reinforcement is usually sufficiently effective<sup>12</sup>, without it, regression of MDI technique has been shown to occur as early as 6 to 8 weeks<sup>10,11</sup>. A study in an urban emergency department in the United States<sup>6</sup> has shown that all their

asthmatics with poor MDI technique could be successfully taught in an average time of 8 minutes.

In our study, we could not show that inefficient MDI technique was associated with an increase in asthma exacerbations or increased use of rescue medication. These possibilities are highly conceivable and have been postulated by some<sup>18</sup>. There are however, no major studies that specifically address these issues, perhaps due to the inherent difficulties of conducting studies of this nature. Other factors may have a larger contribution to increase in daily use of SABA or frequency of asthma exacerbations. These include patient compliance to treatment, adequacy of treatment with maintenance ICS, differences in asthma phenotype<sup>19</sup> and differences in perception of dyspnoea among asthmatic patients<sup>18</sup>.

To support the assumption that teaching the correct technique would make a difference, we carried out a follow-up study to demonstrate that in our population of asthmatics, right technique does translate into clinical improvement.

To date, the MDI is the most economical inhalation device and this explains its popularity among healthcare providers<sup>1,20</sup>. However the problem of correctly handling the device faced by many doctors and patients has apparently changed little over the years and remains a serious issue in adult asthmatic

patients, at least in the Malaysian government clinic setting. One alternative is to use spacer devices to facilitate drug delivery, but patients are required to purchase it themselves. This may pose a problem to poorer patients. Another alternative is to prescribe dry power, breath-actuated devices such as the turbohaler or easyhaler. These devices require far lesser hand-breath coordination, produce higher degree of lung deposition with less intra-subject or inter-subject variability<sup>21,22</sup> and have been shown to be popular among patients<sup>23</sup>. These devices have recently been made available for government patients and their use may overcome the problem of inefficient MDI technique and the struggle in assessment, teaching and reinforcement in a busy government ward or clinic. The cost of such devices may appear prohibitive but in the long term, these may be cost saving from reduced hospital admissions and emergency visits resulting from better disease control. As such, advocating the wider use of such devices should be considered.

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