

## Emphasizing of Shaking the Inhaler as Part of Inhalation Instruction is Important in Young Asthmatic Children

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### Abstract

**Background:** Current guidelines recommend to monitor inhalation technique in asthmatic children every 3-6 months. The aim of this study was to investigate inhalation technique 6 weeks after instruction in young asthmatic children, using a pressurized metered dose inhaler with spacer.

**Methods:** 91 asthmatic children, 4-8 years, from our outpatient clinic, demonstrated their inhalation technique with a pressurized metered dose inhaler with spacer. Errors in inhalation technique were scored on an inhaler specific standardized checklist designed by the Dutch Lung Foundation. Afterwards, feedback on inhalation technique was provided to the child and his/her parent(s). Six weeks later their inhalation technique was re-evaluated.

**Results:** Significantly more children carried out a perfect inhalation technique (67.0% vs. 36.3%,  $p < 0.001$ ) and significantly less children showed one, two or three errors (31.5% vs. 63.7%  $p < 0.001$ ) 6 weeks after instruction. Significantly more children failed to shake their inhaler 6 weeks after instruction (16.9% vs. 6.6%,  $p = 0.035$ ).

**Conclusion:** Although we observed a significant improvement in inhalation technique six weeks after instruction with tailored feedback, more young asthmatic children failed to shake their inhaler. We recommend that reinforcement on essential steps that are performed correctly should be highly emphasized.

**Keywords:** Childhood asthma; Inhalation technique; Evaluation; Feedback; Children; Inhalation errors

### Abbreviations

pMDI/s: pressurized Metered Dose Inhaler with spacer; C-ACT: Childhood Asthma Control Test

### Introduction

Asthma is the most common chronic illness among children and is featured by inflammation of the lower airways [1]. Inhaled corticosteroids are the cornerstone of treatment for persistent childhood asthma due to their potent anti-inflammatory effects and are recommended for daily use [2]. Correct use of inhalation devices is a prerequisite for successful drug treatment of asthma. Unfortunately inhaler technique is inadequate in many asthmatic children as well as medication adherence in general (50-60%) [3,4]. Even after inhalation instruction many children use their inhalers devices too poorly to result in reliable drug delivery [5,6].

Kamps et al. showed in newly referred asthmatic children, that a single inhalation instruction session is insufficient to maintain appropriate use of daily used inhaled medication, and recommended to repeat instruction at every clinical follow-up [5]. Current international guidelines recommend repeated comprehensive

inhalation instructions every 3-6 months to improve inhalation technique [5,7,8]. However, the sustained effect over time of a single inhalation instruction on inhaler technique in young children (4-8 years) using a pressurized metered dose inhaler in conjunction with a spacer (pMDI/s) is not known.

The aim of this study was to investigate inhalation technique 6 weeks after a single instruction in young asthmatic children who are regularly reviewed by a pediatrician, using a pMDI/s.

### Methods and Materials

#### Patients

From October 2012 till March 2013, 91 children (aged 4-8 years) with a doctor's diagnosis of asthma and a prescription of inhalation corticosteroids were recruited from the outpatient clinic of the paediatric departments of three hospitals (Medisch Spectrum Twente, Enschede (MST) and Ziekenhuisgroep Twente (ZGT), Hengelo and Almelo. Subjects were enrolled in our standard asthma care program which includes instruction of inhalation technique twice a year i.e. a demonstration of the child's inhalation technique with feedback on the specific items as mentioned in the checklist in Table 1. They were included to participate in the IMPACT study (NL 40615.044.12) to assess the impact of a discussed exercise challenge test on adherence and medication beliefs of parents. Adherence was electronically

measured for six weeks before and after the discussed exercise challenge test.

### Study design

Children and parents were asked to show their habitual inhalation technique with a pMDI/s i.e. with or without parental supervision to simulate real-life inhalation technique. The majority of the children were helped or supervised by their parents during inhalation in the home situation. These parents were asked to do so during the demonstration as well.

Errors in inhalation technique were scored by the investigator on an inhaler specific standardized checklist designed by the Dutch Lung Foundation [5]. Inhalation technique was demonstrated and scored by 8 items of which 5 were considered to be essential for reliable drug delivery (Table 1). Items were scored as correct or not correct (error). Immediately afterwards the investigator reviewed the technique with the child and his/her parent(s) and a tailored instruction of approximately 5 minutes was provided. Six weeks later their inhalation technique was demonstrated and scored again by the same investigator using the same checklist.

		Baseline (N=91)	Follow-up (N=89)
1	Shake the inhaler*	6 (6.6%)	15 (16.9%)
2	Correct assembly of the spacer device and MDI*	0 (0%)	0 (0%)
3	Sit or stand upright	24 (26.4%)	1 (1.1%)
4	Place mouthpiece between teeth and lips/ facemask over nose and mouth and form a seal*	2 (2.2%)	0 (0%)
5	Hold the spacer in a horizontal position	42 (46.2%)	13 (14.6%)
6	Activation of the canister*	0 (0.0%)	0 (0%)
7	Inhale at least five times	8 (8.8%)	7 (7.9%)
8	Check that spacer valve is moving*	0 (0%)	0 (0%)
* Essential steps			

**Table 1:** Inhaler checklist for pMDI/s with number (%) of children making errors at baseline and follow-up.

Note that a child can make more than one error.

Number of children	91
Median age, years	5.8 (5.4-6.8)
Gender, boys	51 (56%)
Disease duration (years)	1.8 (0.4-3.2)
Maintenance medication	
fluticasone	72 (79.1%)
beclomethasone	11 (12.1%)
salmeterol+fluticasone	8 (8.8%)
C-ACT ≤ 19	15 (16.5%)
C-ACT score	22.2 ± 2.8
Data expressed as mean values ± standard deviation, median (interquartile ranges) or numbers (percentage). Disease duration: years of pediatrician care, C-ACT = Childhood-Asthma Control Test: a score ≤19 indicates uncontrolled asthma [10].	

**Table 2:** Baseline characteristics.

### Questionnaire

Asthma control was assessed before the first inhaler technique demonstration by the Childhood Asthma Control Test (C-ACT, total score 3 – 27) [9]. The C-ACT is especially designed to measure asthma control in asthmatic children 4-11 years old and consists of 7 questions; 4 questions for the child (scores 0-3) and 3 for their parents

(scores 1-5). Scores of all questions were summed (range 3-27) and a C-ACT score of ≤19 indicates poor asthma control.

### Statistical analyses

Continuous variables were expressed as means with standard deviations or medians with interquartile ranges, depending upon the

normality of the data. Categorical variables were expressed as numbers with corresponding proportions.

The percentage of children demonstrating errors before and 6 weeks after instruction was analyzed with a McNemar test.

The association between age or asthma control and inhalation technique was analyzed by a chi square test (categorical variables) or Kruskal Wallis test (not normally distributed continuous variables). A 2 sided value of  $P < 0.05$  was considered statistically significant. All analyses were performed using SPSS for Windows, version 20.0.

		Number of errors at follow up (N, %)					Total
		0	1	2	3	Missing	
Numbers of errors at baseline	0	23 (25.3)	9 (9.9)	1 (1.1)	0	0	33 (36.3)
	1	27 (29.7)	8 (8.8)	0	0	2 (2.2)	37 (40.6)
	2	9 (9.9)	4 (4.4)	4 (4.4)	1 (1.1)	0	18 (19.8)
	3	2 (2.2)	0	1 (1.1)	0	0	3 (3.3)
Total		61 (67.0)	21 (23.1)	6 (6.6)	1 (1.1)	2 (2.2)	91 (100)

**Table 3:** Number of errors at baseline and follow up (N, %).

### Ethical Considerations

This study was approved by the hospital ethics review board. All parents provided written informed consent to participate in this study.

### Results

Ninety-one children of whom 51 boys, 4-8 years of age, were asked to demonstrate their inhalation technique with their metered dose inhaler. Eighty-eight children had only used a pMDI/s before the

study; three children had switched within a year prior to the study from a pMDI/s to a breath actuated inhaler. In the context of the IMPACT study these children were reverted to a pMDI/s. All children and parents had been given inhalation instructions at the time of prescription. Table 2 summarizes all baseline characteristics.

Two children were lost during follow up, one patient due to illness, and one patient due to a long travel time to the hospital due to moving house.

		Follow up		Total
		No errors	Errors	
Baseline	No errors	69	12	81
	Errors	5	3	8
Total		74	15	89

**Table 4:** Number of children making essential errors at baseline and follow up.

### All Errors

Table 1 shows every step of the inhaler checklist with errors at baseline and follow up of our population. Table 3 shows the number of errors at baseline and follow up. Of the 91 children 33 (36.3%) carried out all steps correctly at baseline and 61 (67.0%) at follow up ( $p < 0.01$ ). At baseline the most common mistake (46.2%) was not holding the spacer in a horizontal position, while at follow up the most common mistake was failing to shake the inhaler (16.9%).

### Essential errors

At baseline, eight children made at least one essential error (8.8% of the total patient group). Six of these eight children failed to shake their inhaler, while two did not place the facemask correctly over their nose and mouth (Table 1). At follow up, fifteen children made at least one essential error (16.9%). All these children failed to shake their inhaler. Three children persistently did not shake their inhaler, so there were 12 new children who failed to shake their inhaler at follow up. The

increase in the number of children making at least one essential error was not significant ( $p = 0.14$ , Table 4), however the increase in the number of children who failed to shake their inhaler was significant ( $p = 0.04$ ).

### Age and asthma control

There was no association between age ( $p = 0.79$ ) or asthma control as measured with the C-ACT ( $p = 0.46$ ) and number of errors in inhalation technique.

### Discussion

The results of this study demonstrate that 6 weeks after a single inhalation instruction significantly more children (69.7% vs. 36.3%) carried out a perfect inhalation technique. However, of those who did not perform a perfect technique significantly more children made an essential error, with failing to shake their inhaler being the main error (6.6% at baseline, 16.9% six weeks after the single instruction).

We are not aware of any studies investigating the short term effect (6 weeks) of a single inhalation instruction on inhalation technique in outpatient asthmatic children. Kamps et al. showed in a similar study that with at least two consecutive instructions in a 4 week period 93% of children carried out all essential steps correctly when reviewed 6 weeks after the last instruction [5]. However, in daily clinical practice this seems to be too great a burden for patients and health care resources.

Focusing on essential errors, we found 6 weeks after instruction already a decline of 91% to 83% of children who carried out all essential steps (i.e. shake the inhaler) correctly. Although, our inhalation instruction regarding not shaking the inhaler was effective in half of the children (3/6), we found twelve new children failing to shake their inhaler at follow up.

Guidelines recommend to monitor inhalation technique in asthmatic children every 3-6 months [8]. According to our observations this interval is too long to prevent the appearance of new essential errors.

Deerojanawong et al. studied outpatient children of the same age using a pMDI/s and observed a perfect inhalation technique in 47.1%. However, they used the checklist based on the recommendations of the National Institute of Health (NIH) which does not incorporate body posture [10]. Excluding the body posture error in our study group we found the same amount of children (46.2%) demonstrating a perfect inhalation technique. Hagmolen of ten Have et al. found 49% of the children demonstrating a perfect inhalation technique using the same checklist of the Dutch Lung Foundation as we did. They studied outpatient asthmatic children with a mean age of 10.5 years old, suggesting better inhalation technique in older aged children [11].

Children in our study showed few essential errors in inhalation technique at baseline (8.8%) compared to 16-40% in other studies among outpatient children using a pMDI/s [5,10,12]. In line with other studies, we observed that failing to shake the inhaler was the most frequent essential error at baseline (6.6%). In the studies of Kamps et al. 19.6% of clinical outpatients and 29% of newly referred children failed to shake their inhaler [5,12]. Not shaking the inhaler reduces the output of the pMDI/s with approximately 35% [13].

Deerojanawong et al. showed a high percentage of essential errors (39.2%) compared to our study but used the NIH checklist that classifies the step of taking 5-6 deep and slow breaths as essential [10]. When using the NIH checklist in our study population, 17.6% showed an essential error at baseline.

We showed no association between asthma control as measured with the C-ACT and number of errors in inhalation technique. Previous studies are not conclusive about the relation between asthma control and errors in inhalation technique. Most of these studies measured asthma control with clinical study end-points in contrast to the C-ACT used in our study. Probably this discrepancy is also caused by differences in study population and adherence [2,11,12,14].

We hypothesize that the low number of essential errors in our study group compared to other studies is a consequence of the organization of our asthma care. In our clinic, comprehensive asthma management consists of frequent follow up visits every 4 months alternately to a pediatrician and a dedicated asthma nurse who extensively checks inhalation technique.

We were surprised to find more children failing to shake their inhaler 6 weeks after inhalation instruction. This shows that

reinforcement of essential steps which previously were performed correctly should be emphasized. When the investigator confronted children and parents with this essential error, they responded they did shake their inhaler at home.

The main strengths of our study include the homogenous group of young asthmatic children using the same device in a narrow age range. The same investigator evaluated all children.

A limitation of our study is that demonstrated inhalation technique observed by parents and health care professionals may not correspond well with inhalation technique in daily life. Although we provided each patient with a structured feedback about their inhalation technique, an investigator bias may have been introduced in these discussions as in any patient-doctor contact.

Furthermore, inhalation technique may have improved due to the use of electronic loggers during the IMPACT study. However, subjects were aware that the loggers could measure adherence, but not inhalation technique.

Further studies could investigate the effect of monitoring the inhalation technique of asthmatic children with modern internet technology, visualizing inhalation technique at home.

Although we observed a significant improvement in perfect inhalation technique six weeks after instruction with tailored feedback, more young asthmatic children failed to shake their inhaler. We recommend that reinforcement on essential steps that are performed correctly should be highly emphasized.

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