Original Article

A Randomized Controlled Study Comparing the Efficacy of DIY Spacer and the AeroChamber in Children with Uncontrolled Asthma

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Background: A pressurized metered-dose inhaler (pMDI) attached to a valved holding chamber with mask has been widely used for delivering pressurized drug aerosol for asthma treatment in young children. Although many commercial valved holding chambers with mask are available in the market but they are quite expensive or unavailable in some developing countries. DIY Spacer is a low-cost, do-it-yourself (DIY) plastic bottle with syphon pump which can be used as an alternative to the commercial valved holding chamber with mask. The main advantage of DIY Spacer is that it can be made easily with simple and inexpensive materials found around the house. However, there is no scientific study to evaluate its treatment effectiveness.

Objective: The aim of the present study is to compare the treatment effectiveness and the caregiver's drug compliance, the accuracy of inhalation techniques and the caregivers' satisfaction with the spacers between the DIY Spacer and the AeroChamber.

Materials and Methods: A randomized, two-consecutive-month, two-sequence crossover study was conducted on 30 children with uncontrolled asthma aged less than or equal 6 years who received an inhaled therapy using a pMDI attached to a valved holding chamber with mask for the first time. The patients were randomly assigned to receive treatment using the pMDI with either a DIY Spacer or an AeroChamber (15 patients each) as a first spacer for two-consecutive months. Afterwards, a crossover treatment was employed in which the patients switched to use another spacer for the next two-consecutive months. As a result, each patient would administer each spacer for two-consecutive months. The level of control, the caregiver's drug compliance and the accuracy of inhalation techniques were evaluated every month during the treatments, whereas, the caregivers' satisfaction with the spacers was evaluated after each treatment.

Results: The comparing results of the level of control, the caregiver's drug compliance and the accuracy of inhalation techniques between the DIY Spacer and AeroChamber were not significantly different ($p>0.05$). However, there were significantly different ($p<0.05$) on the satisfaction of the pMDI drug administration in which the AeroChamber received a higher satisfaction.

Conclusion: For inhaler therapy in young children with uncontrolled asthma, the treatment with the pressurized metered-dose inhaler (pMDI) with DIY Spacer is as effective as the treatment with AeroChamber in terms of the level of asthma control and caregiver's drug compliance and the accuracy of inhalation techniques.

Keywords: Valved Holding Chamber with Mask, Spacer, Asthma, Pressurized metered-dose inhaler, DIY spacer

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Asthma is a common and potentially serious disease and its prevalence has increased worldwide. In Thailand, the overall prevalence of childhood asthma has been reported varying at 6.8 to 14.1%[1,3-7]. Many patients with asthma use asthma inhalers to help with their breathing. The widely used inhaler is a pressurized metered-dose inhaler (pMDI). The pMDI is used with a reservoir called "spacer", a cone-shaped one-way valve, to control the direction of airflow and keep the high level of drug aerosol. The spacer is also called a valved holding chamber or a one-way valve spacer[2].

Although many commercial valved holding chambers with mask (e.g. AeroChamber) are available in the market, but they are quite expensive, approximately 42 to 45 USD, or unavailable in some developing countries. The Thammasart University Hospital asthma care team headed by Prof. Dr. Orapan Poachanukoon has collaborated with the National Metal and Materials Technology Center (MTEC) to design a simple and effective valve holding spacer called DIY Spacer, a low-cost, do-it-yourself (DIY) plastic bottle with syphon pump, which can be used as an alternative to the commercial valved holding chamber with mask (Figure

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Figure 1. Image of DIY spacer.

1). The cost of DIY Spacer is as low as 2 USD.

DIY Spacer received several awards such as and a gold medal from International Exhibition of Invention, Geneva, Switzerland, Lastly, it received and excellent award in medical innovation from Thailand Nation Research Council during the Inventors' day 2014. However, there is no scientific study to evaluate its treatment effectiveness.

The objective of this research is to test the hypothesis that there is no difference in asthma treatment DIY Spacer and AeroChamber by comparing the level of asthma control, the caregiver's drug compliance, accuracy scores of inhalation's techniques and the caregiver's satisfaction of the pMDI with spacer administration.

Materials and Methods

The present study is a cross over experimental study performed in the same experimental unite (30 participants) who were treated by pMDI combined with both types of spacer DIY spacer and AeroChamber in different time periods. Later, the participants were interviewed to evaluate effects in many aspects and the results from each group were compared to each other. This study was approved by the Human Ethics Committee of Thammasat University (the second committee).

Participants

There were young patients at 6 years old or under who were diagnosed as an uncontrolled asthma patient or an uncontrolled asthma patient with other complications and were treated with inhaled corticosteroids (ICS) or corticosteroid + long acting beta-2- agonists (ICS+LABA), Pressurized Metered Dose Inhalers (pMDIS) type by administrating the medications with mask spacer in the first time. Informed consents were obtained from the patients' parent prior to enrollment.

Procedures sampling

The participants were divided into two groups and each group consisted of 15 patients. The first group was started with an AeroChamber then shifted to a DIY spacer later, while the second group was started with a DIY spacer and then shifted to an AeroChamber. Initially, we used sequence randomization method for both spacers in order to reduce sequences of treatments from using different kinds of spacers. The time periods for each spacers treatment were 2 months. Eventually, the researcher would evaluate the effects in many aspects every month. After that, the participants were switched to another type of spacers. This study was not included a wash out period after using the first type of spacer because a spacer is a device assisting a pressurized metered-dose inhaler (pMDI) which did not have any carry over effects or residual effects which could interrupt the treatments.

Data collection

In the first meeting, the researchers interviewed caregivers who have been taking care of an asthma patient about general information of both patients and caregivers. Later in the second to fifth meeting, the patients and caregivers were evaluated in many aspects as follows:

Level of control:

To assess the effectiveness of treatments, The blinded investigators evaluated the patients according to the GINA Pediatric Guidelines GINA 2019 which can divided into 3 levels namely controlled, partly controlled and uncontrolled according to Table 1.

Patients' compliance:

The caregivers were interviewed by the researchers using the compliance evaluation form consisted of 13 questions and each question has rating scales from 0 to 2 that can be interpreted as follows: 2 = every time or always, 1 = sometimes, 0 = never or uncertain and the total score

Table 1. GINA assessment of asthma control in children 5 year and younger

A. Level of asthma symptom control			
In the past 4 weeks, has the child had:	Well controlled	Partly controlled	Uncontrolled
Daytime asthma symptoms for more than a few minutes, more than once a week? Yes O No O Any activity limitation due to asthma? (Runs/play less than other children, tires easily during walks/playing?) Yes O No O Reliever medication needed* more than once a week? Yes O No O Any night waking or night coughing due to asthma? Yes O No O	None of these	1 to 2 of these	3 to 4 of these
B. Future Risk for poor asthma outcomes			
Risk factors for asthma exacerbations within the next few months Uncontrolled of asthma symptoms One or more exacerbations (ED attendance, hospitalization, or course of OCS) in previous year The start of child's usual 'flare-up' season (especially if autumn/fall) Exposure: tobacco smoke; indoor or outdoor air pollution; indoor allergens (e.g. house dust mite, pets, mold), especially in combination with viral infection Major psychological or socio-economic problems for child or family Poor adherence with controller medication, or incorrect inhaler technique Outdoor pollution (NO2 and particles) *Risk factors for fixed airflow limitation* Severe asthma with several hospitalizations History of bronchiolitis *Risk factors for medication side-effects* Systemic: Frequent courses of OCS, high-dose and/or potent ICS Local: moderate/high-dose or potent ICS; incorrect inhaler technique; failure to protect skin or eyes when using ICS by nebulizer or spacer with face mask			

* Excludes reliever taken before exercise
ICS = inhaled corticosteroids; OCS = oral corticosteroids

was 26.

The accuracy of inhalation technique:

The researchers asked the caregivers and patients to demonstrate the way they always used to take (inhale) the medications. Consequently, the researchers evaluated the accuracy of the inhalation technique by giving scores to 8 questions.

The scores were interpreted by 1 = correct techniques, 0 = incorrect techniques and the total score was 8.

The caregivers' satisfaction with the spacers:

The researchers interviewed the caregivers about satisfaction with the spacer by using the satisfaction evaluation form which focused on 4 aspects. The questions were a rating scale in accordance with Likert scale. The score rating criteria was divides into 5 levels as follows: 5 = very satisfied, 4 = satisfied, 3 = uncertain, 2 = unsatisfied, 1 = very unsatisfied and the total score was 25.

The steps of sampling and data collection are shown in the figure 2.

Data analysis

The results were presented by using descriptive statistics that showned general information of the patients and caregivers. In case the data had a normal distribution, the researchers used Chi-square test to compare the level of control in both groups between uncontrolled group and controlled group (including partly controlled and controlled group). However, if the data did not have a normal distribution, the McNemar test would be used instead. As for the comparison of the caregivers' satisfaction between both two groups used Paired t-test if the data had a normal distribution and used Wilcoxon signed ranks test when the data did not have a normal distribution.

Results

The Demographic data of the patients are shown in Table 2. There were no imbalances between groups in

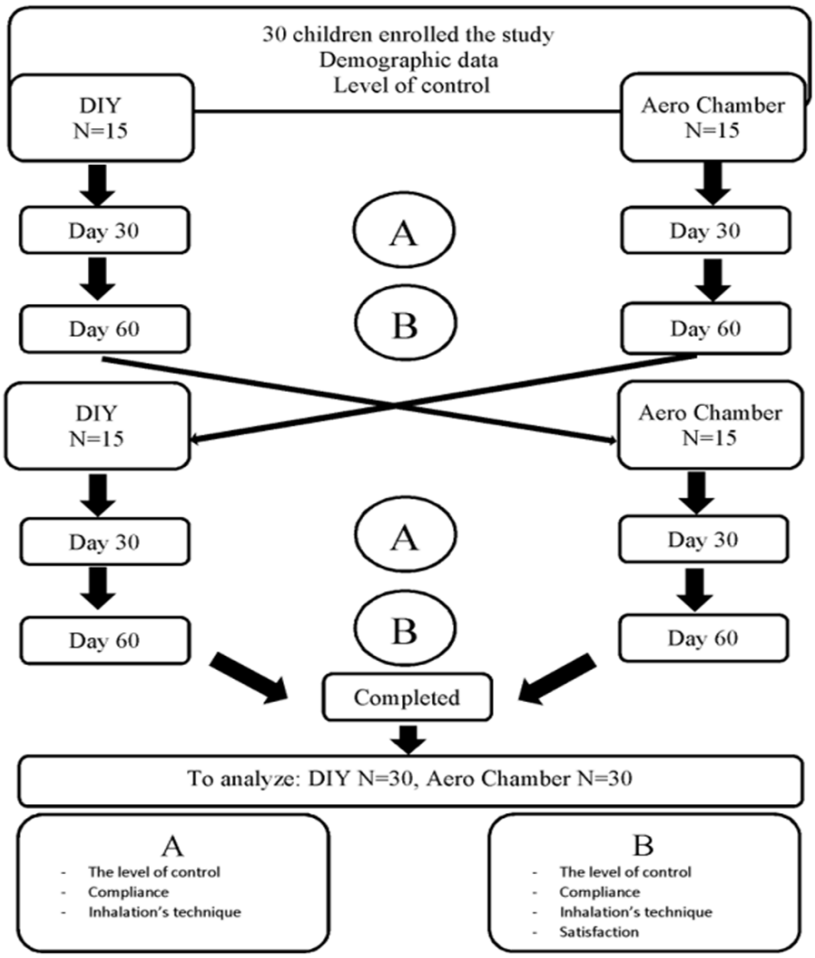

Figure 2. Flow diagram of the study.

Table 2. Demographic data of patients

Demographic data	Number of patients (%)	n = 30
Gender	Male	15 (50.00)
	Female	15 (50.00)
Age (year)	1 to 2	3 (10.00)
	2 to 3	6 (20.00)
	3 to 4	5 (16.67)
	4 to 5	5 (16.67)
	5 to 6	11 (36.67)
Level of asthma control	Controlled	0 (0.00)
	Partly controlled	5 (16.67)
	Uncontrolled	25 (83.33)
ER visit event before entering the research project for 6 months	Mean ± SD	0.80±0.997
Hospital admission events before entering the research project for 6 months	Mean ± SD	0.33±0.547

general data that could affect the comparison according to the present study is a cross-over experimental study conducted in the same sample group.

Level of asthma control

The result of the present study reveals that most patients can control asthma. The comparative results in the

Table 3. The comparison table of outcome parameters between DIY Spacer and AeroChamber

Parameter	Type of spacer	
	DIY	AeroChamber
Numbers of Control Case (%)[#]		
Day 30	29 (96.7)	29 (96.7)
Day 60	29 (96.7)	30 (100.0)
Scores of Caregiver's drug Compliance (Mean ± SD)[$]		
Day 30	23.13±3.884	22.33±4.294
Day 60	22.53±4.321	21.13±5.117
Accuracy Scores of Inhalation's Techniques (Mean ± SD)[$]		
Day 30	7.40±0.855	7.40±0.855
Day 60	7.53±0.86	7.73±0.45
Caregiver's Satisfaction with the spacers (Mean ± SD)[$]		
Day 60	16.67±2.975	18.99±1.561*

[#] McNemar test, [$] Wilcoxon signed ranks test, * $p<0.05$

level of control of asthmatic patient between the group of patients used the DIY spacer and the AeroChamber were not significantly different ($p>0.05$). Statistics for analysis is McNemar Test between two groups of patients were control group (control group included partly control group) and uncontrolled group.

Patients' compliance

The 2 evaluations have found that the average score of caregiver's drug compliance in using the DIY spacer and AeroChamber were not significantly different ($p>0.05$).

The accuracy of inhalation techniques

The two evaluations reveals that the average of accuracy scores of inhalation's technique of patients and their caregivers between DIY spacer and AeroChamber were not significantly different ($p>0.05$).

The caregivers' satisfaction with the spacers

The caregiver's satisfaction scores used pMDI with DIY Spacer were significantly different ($p<0.05$). The results of the present study reveal that the average scores of AeroChamber's satisfaction are more than DIY spacer.

All outcome parameters are shown in Table 3.

Discussion

The comparing results of the level of control and Asthma exacerbation events between the DIY Spacer and AeroChamber were not significantly different ($p>0.05$). So that, the authors have concluded that effective treatment DIY Spacer and AeroChamber were not significantly different 0.05. As well as the study of randomized controlled trial of the efficacy of a metered dose inhaler with bottle spacer for bronchodilator treatment in young children with acute obstruction of the lower airways[11]. And correlated with the study a 500-ml plastic bottle: An effective spacer for children with asthma[8-11]. The reason that caregivers have less satisfaction towards DIY spacer than AeroChamber is because, during the research period, the caregivers will receive both types of spacer free of charge. However, in real situations, if patients want to use AeroChamber, they have to pay approximately 1,200 Baht (non-reimbursable medical supplies); while patients using DIY Spacer will receive it free from the hospital (its cost is about 40 Baht). This should affect the satisfaction because AeroChamber has the higher unit price.

Conclusion

For inhaler therapy in young children with uncontrolled asthma, the treatment with the pressurized metered-dose inhaler (pMDI) with DIY spacer is as effective as the treatment with AeroChamber in term of the level of asthma control, the accuracy of inhalation techniques and caregiver's drug compliance.

What is already known on this topic?

The research of "A 500-ml plastic bottle: An effective spacer for children with asthma" found that a modified 500-ml plastic bottle which is an effective spacer; modification and use of this device should be incorporated into international guidelines for the management of children with asthma[8].

What this study adds?

This research found that inhaler therapy in young children with uncontrolled asthma, the treatment with the pressurized metered-dose inhaler (pMDI) with DIY Spacer is as effective as the treatment with AeroChamber in term of the level of asthma control, the accuracy of inhalation techniques and caregiver's drug compliance.

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Potential conflicts of interest

The authors declare no conflict of interest.

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การศึกษาเปรียบเทียบประสิทธิภาพ ระหว่างกระบอกกักยาที่ประดิษฐ์ด้วยตนเอง (DIY spacer) กับกระบอกกักยาที่จัดจำหน่ายในเชิงพาณิชย์ (AeroChamber) ในผู้ป่วยเด็กโรคหืดที่ควบคุมอาการไม่ได้

ปิยรัตน์ ปรีดียานนท์, อรพรรณ โพชนุกูล

ภูมิหลัง: ผู้ป่วยเด็กที่ต้องใช้ยาพ่นประเภท Pressurized Metered Dose Inhaler (pMDI) ควรใช้ร่วมกับกระบอกกักยา (Spacer) ชนิดที่มีลิ้นและหน้ากากที่แนบหน้า (valved holding chamber with mask) เพื่อให้พ่นยาได้ง่ายขึ้นและเพิ่มปริมาณยาการตกสะสมของยา แต่ spacer ชนิดนี้ที่มีราคาค่อนข้างสูง จึงได้มีการประดิษฐ์ spacer ทำจากขวดพลาสติกและไซฟ่อนปั๊มขึ้นมาทดแทนเรียกว่า DIY (Do-It-Yourself) spacer ที่สามารถทำได้ด้วยตัวเองอย่างง่ายจากวัสดุหาวัสดุที่หาได้ตามครัวเรือนและราคาถูก อย่างไรก็ตามยังไม่มีการศึกษาเปรียบเทียบถึงประสิทธิผลระหว่าง spacer ทั้งสองชนิด

วัตถุประสงค์: เพื่อศึกษาถึงระดับการควบคุมโรคของผู้ป่วยโรคหืด ความร่วมมือในการใช้ยา และความพึงพอใจของผู้ดูแลผู้ป่วยเด็กโรคหืด ในการบริหารยา pMDIs ร่วมกับ Spacer โดยเปรียบเทียบระหว่างกลุ่มผู้ใช้ DIY Spacer กับกลุ่มผู้ใช้ AeroChamber

วัสดุและวิธีการ: เก็บรวบรวมข้อมูลโดยใช้กลุ่มวิจัยเดียวกันจำนวน 30 คน แต่แบ่งเป็นช่วงที่ใช้ยาร่วมกับ DIY Spacer และช่วงที่ใช้ยาร่วมกับ AeroChamber กลุ่มวิจัยเป็นผู้ป่วยเด็กโรคหืด อายุน้อยกว่าหรือเท่ากับ 6 ปีที่รับการรักษาที่โรงพยาบาลธรรมศาสตร์ฯ ด้วยยากลุ่ม ICS หรือ ICS+LABA ประเภท (pMDI) ใช้ร่วมกับ spacer โดยแบ่งผู้ป่วยเป็น 2 กลุ่มๆ ละ 15 คน โดยในช่วงต้นการวิจัย กลุ่มแรกใช้ AeroChamber กลุ่มสอง ใช้ DIY Spacer เป็นระยะเวลา 2 เดือน หลังจากนั้นสลับให้กลุ่มแรกมาใช้ DIY Spacer และกลุ่มสองจะใช้ AeroChamber ต่อเนื่องอีก 2 เดือน ระหว่างนั้นมีการประเมินผลเดือนละครั้งในหัวข้อระดับการควบคุมโรคของผู้ป่วยโรคหืด, ความร่วมมือในการใช้ยาตามสั่ง, ความถูกต้องของเทคนิคการสูดพ่นยา และความพึงพอใจต่อกระบอกกักยา (Spacer)

ผลการศึกษา: ระดับการควบคุมโรคของผู้ป่วยโรคหืด, ความร่วมมือในการใช้ยาตามสั่ง และความถูกต้องของเทคนิคการสูดพ่นยาของผู้ป่วยเด็กโรคหืด ระหว่างกลุ่มผู้ป่วยที่ใช้กระบอกกักยา DIY Spacer กับ AeroChamber ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ส่วนความพึงพอใจต่อ AeroChamber ดีกว่า DIY อย่างมีนัยสำคัญทางสถิติ

สรุป: การบริหารยาสูดพ่นประเภท pMDI ร่วมกับ DIY Spacer ในการรักษาผู้ป่วยเด็กโรคหืดอายุน้อยกว่าหรือเท่ากับ 6 ปีพบว่ามีประสิทธิผลเทียบเท่ากับกระบอกกักยา AreoChamber ในแง่ระดับการควบคุมโรคของผู้ป่วยโรคหืดและความร่วมมือในการใช้ยาตามสั่ง