EFFECTS OF ADAPTED SMALL VOLUME JET NEBULIZER ON DEAD VOLUME AND DURATION OF AEROSOL THERAPY IN 1-5 YEAR OLD ASTHMATIC CHILDREN

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ABSTRACT

This study was experimental research that aimed to compare the amount of dead volume and the duration of aerosol therapy in 1-5 year old asthmatic children who receive bronchodilators with the conventional small volume jet nebulizer or with the adapted small volume jet nebulizer. The samples focused on 64 asthmatic children who were attending the Pediatric Outpatient Department at Srisaket hospital, Srisaket province, Thailand, from September to November 2014. And selected by purposive sampling according to the inclusion criteria and divided randomly into a control group and an experimental group with 32 cases in each group. The control group used the conventional small volume jet nebulizer, whereas the experimental group used the adapted small volume jet nebulizer. Descriptive statistics, Chi-square test, Independent t – test, and ANCOVA were utilized in data analysis.

The results revealed that 1-5 asthmatic children who received aerosol bronchodilators with the adapted small volume jet nebulizer were not statistically significant different from the amount of dead volume from those who used the conventional small volume jet nebulizer in the control group (0.989 ± 0.3681 cc. vs. 1.190 ± 0.406 cc. ; $p > .05$), and the durations of the aerosol therapy between the adapted and the conventional small volume jet nebulizers were not different with a statistical significance (12.76 ± 1.95 mins. vs. 12.96 ± 2.39 mins. ; $p > .05$).

Even though the adapted small volume jet nebulizer was theoretically adapted to use as an effective equipment for aerosol therapy for 1-5 year old asthmatic children. But, there was a problem about significant difference in age distribution in the samples, that the mean age of subjects in the control group was 27.44 months, whereas the mean age of subjects in the experimental group was 40 months. It was noticeably that, during aerosol therapy, younger children did not cooperate well like older children. They cried, held their breath, and squirmed all along the treatment, so the true effect of the adapted small volume jet nebulizer might not be revealed. It is recommended that further research is needed by study with the same age groups within 1-5 year of age, whose tidal volume are the same amount as in the reservoir of the adapted equipment to get the adequate result. To find out which age group will get the benefit from this adapted small volume jet nebulizer.

KEY WORDS: ASTHMATIC CHILDREN / ADAPTED SMALL VOLLUME JET NEBULIZER / DEAD VOLUME / DURATION OF AEROSOL THERAPY

100 pages

ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ 1-5 ปีที่เป็นโรคหืด

EFFECTS OF ADAPTED SMALL VOLUME JET NEBULIZER ON DEAD VOLUME AND DURATION OF AEROSOL THERAPY IN 1-5 YEAR OLD ASTHMATIC CHILDREN

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บทคัดย่อ

การวิจัยครั้งนี้เป็นการวิจัยเชิงทดลอง (Experimental research) โดยมีวัตถุประสงค์เพื่อเปรียบเทียบปริมาณของของเหลวที่เหลือค้างในกระเปาะ (dead volume) หลังการพ่นฝอยละออง และระยะเวลาที่ใช้ในการพ่นฝอยละออง ระหว่างการใช้อุปกรณ์แบบดัดแปลง กับอุปกรณ์แบบปกติ ในเด็กอายุ 1-5 ปี ที่เป็นโรคหืดจำนวน 64 ราย ที่ได้การรักษาด้วยการพ่นยาขยายหลอดลมชนิดซัลบูตามอล ในแผนกผู้ป่วยนอกกุมารเวชกรรมโรงพยาบาลศรีสะเกษ จังหวัดศรีสะเกษ ระหว่างเดือนกันยายน ถึงพฤศจิกายน พ.ศ. 2557 คัดเลือกกลุ่มตัวอย่างแบบเฉพาะเจาะจงตามคุณสมบัติที่กำหนด แบ่งกลุ่มตัวอย่างออกเป็นกลุ่มทดลอง และกลุ่มควบคุม กลุ่มละ 32 คน โดยวิธีการสุ่ม กลุ่มทดลองได้รับการพ่นยาด้วยอุปกรณ์แบบดัดแปลง และกลุ่มควบคุมได้รับการพ่นยาด้วยอุปกรณ์แบบปกติ วิเคราะห์ข้อมูลโดยใช้สถิติเชิงบรรยาย ไคสแควส์ Independent t-test และ ANCOVA

ผลการศึกษาพบว่า มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติของอายุระหว่างกลุ่มตัวอย่างที่ $p < .05$ ทำให้ต้องนำตัวแปรอายุเข้าเป็นตัวแปรร่วมในการทดสอบสมุติฐาน ซึ่งพบว่า ปริมาณของเหลวที่เหลือค้างในกระเปาะหลังการพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในกลุ่มเด็กเล็กที่ได้รับการพ่นยาด้วยอุปกรณ์แบบดัดแปลงไม่แตกต่างจากกลุ่มที่ได้รับการพ่นยาด้วยอุปกรณ์แบบปกติอย่างมีนัยสำคัญทางสถิติ ($p > .05$)

ถึงแม้ว่าในทางทฤษฎีอุปกรณ์แบบดัดแปลงน่าจะใช้ได้ผลดีในเด็กช่วงอายุ 1-5 ปี แต่เนื่องจากมีปัญหาเรื่องความแตกต่างกันในเรื่องอายุ ซึ่งพบว่ากลุ่มควบคุมมีอายุเฉลี่ย 27.44 เดือน ขณะที่กลุ่มทดลองมีอายุเฉลี่ยมากกว่า คือ 40.00 เดือน จากการสังเกตพบว่า ระหว่างการบำบัดรักษาด้วยฝอยละออง เด็กเล็กมักจะร้อง กลั้นและดิ้นรนต่อต้านมากกว่าเด็กโต ทำให้ผลการศึกษาไม่อาจพิสูจน์ประสิทธิภาพที่แท้จริงของอุปกรณ์แบบดัดแปลงได้ ซึ่งต้องการการศึกษาต่อไป โดยควรจำแนกศึกษาช่วงอายุเดียวกันในระหว่างอายุ 1-5 ปี ซึ่งเป็นช่วงอายุที่มีปริมาตรความจุปอดใกล้เคียงกับปริมาตรความจุที่เก็บกักฝอยละอองในอุปกรณ์แบบดัดแปลง เพื่อได้ผลที่แน่นอนว่าอุปกรณ์ดังกล่าวสามารถใช้ได้ผลดีกับเด็กตั้งแต่ช่วงอายุใด

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CHAPTER I
INTRODUCTION

Background and Significance of the Problem

Aerosol therapy is an effective treatment of respiratory diseases, particularly when used with patients who have asthma and chronic pulmonary diseases (Helms & Christie, 1999). The aerosolized fluids or medication can directly penetrate into the respiratory tract and effect within similar duration as the medication administered intravenously, but a smaller amount and has considerably fewer side effects (Aroonwan Preutthipan, B.E. 2546). However, the physiology of the respiratory tract and breathing patterns of young children are different from those of older children and adults, there often experience about the effectiveness of aerosol therapy. Moreover, young children are likely to be uncooperative with the treatment and reject the aerosol therapy equipment. They tend to cry and hold their breaths during administration, causing most of the aerosolized medication spread in the air, hence reducing the amount of the aerosolized medication that goes into the lower respiratory tract (Thitida Chaisumongkollarp, B.E. 2550). As a result, the effectiveness of the treatment is diminished. Therefore, the modification of the aerosol therapy equipment that suit to young children is deemed necessary to help aerosolized medication to penetrate into their lower airway, and then increase in effectiveness of aerosol therapy (Amirav & Newhouse, 2008).

"Aerosol therapy" refers to the delivery of drug to the body via the airway by delivering it in an aerosolize form to treat respiratory diseases (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544; Khilnani & Banga, 2008). Whether aerosol therapy is effective or not depends on the amount of the aerosolized particles that enter the lower respiratory tract, which determines responses to the aerosolized medication (Labiris & Dolovich, 2003). In fact, effectiveness of aerosol therapy depends on two main factors—use of effective equipment and cooperation of the patients (Thitida

Chaisupmongkollarp, B.E. 2550; Supitcha Sangchote & Nualchan Prapphal, B.E. 2544; Bisgaard, 1999; Hess, 2008).

Effective equipment used in aerosol therapy consists of a small volume jet nebulizer or a standardized nebulizer which can produce suitable sizes of aerosolized medication that can easily penetrate into the lower respiratory tract, ranging from 1 to 5 microns in size (Hess, 2008). In order to produce aerosolized spray in preferred sizes, the gas induction tube has to be connected and the flow rate of the gas is approximately 6 to 8 liters per minute (Moore, Phipps, & Marcer, 1985; Rubin & Fink, 2003). The mask needs to be in an appropriate size that closely covers the face, and with round openings on both sides for the aerosolized spray to be released (Hess, 2008). The volume of the mask for adults is about 145 milliliters, while that of the mask for children is about 80 milliliters. Beside from the effective equipment for aerosol therapy, the other important factor is cooperativeness of the patients (Amirav & Newhouse, 2012). During aerosol therapy, the patients have to inhale deeply and slowly and hold their breath for at least four seconds before exhaling. They have to repeat this until all the aerosolized particle is gone (Thitida Chaisupmongkollarp, B.E. 2550; Khilnani & Banga, 2004), so as to allow time for aerosolized particles, attached to different parts of the bronchioles and aveoli (Thitida Chaisupmongkollarp, B.E. 2550).

During each session of aerosol therapy, about 4-5 milliliters of medication or fluid (Hess, 2008) is filled into the small volume jet nebulizer. After that, the nebulizer is connected to the mask, with the gas tube being connected to the other side of the nebulizer. The compressor is turned on with the gas flow rate of 6-8 liters per minute. The aerosolized particles about 1 to 10 microns in diameters will be released as a white fume at the rate of 0.25 to 0.30 milliliters per minute. The fume will be trapped inside the mask, ready to be inhaled by the patients. Part of it will be inhaled and enter the lower respiratory tract, another part will hit the face and become condensed, turning into droplets and fall into the nebulizer below, and the remaining will be sprayed into the atmosphere through the large round openings on both sides of the mask (Thitida Chaisupmongkollarp, B.E. 2550). The condensed medication that falls into the nebulizer, will be aerosolized and sprayed one more time. This cycle goes on until there is no more aerosolized particle left, with the sputtering sound

coming out of the nebulizer (Elliott & Dunne, 2011; Galvin, Dunne, Kallstrom, & Gregory, 2011). After the aerosol therapy is completed, there should be only a minimum amount of medication left in the nebulizer, which means that most of the fluid or medication has already entered the patients' respiratory tract (Chatburn & McPack, 2007).

The duration of aerosol therapy in children is extremely crucial because young children are unable to withstand the process for too long. They feel that their activities are restricted and they have lost their self-control, which leads to rebellious behaviors and lack of cooperation (McCallion, Taylor, Bridges, Thomas, & Taylor, 1996). In general, each session of aerosol therapy is approximately 10 to 15 minutes (Aroonwan Preutthipan, B.E. 2546). A previous study has reported that when the quantity of fluid or medication used in each session of aerosol therapy was increased, the patients had a chance to receive more medication, as well as, the duration for the aerosol therapy session would become longer (Hess, 2000). After each session, there is always some fluid left in the nebulizer. In fact, the amount of the remaining fluid, called dead volume, should be as minimal as possible; about 1 to 3 milliliters (Hess, 2000). The amount of the remaining fluid is part of the criteria used to assess the effectiveness of aerosol therapy (Dennis, 1998). If the dead volume is large, it means less aerosolized medication goes to the patients' respiratory tract. On the other hand, if the dead volume is small, it means more aerosolized medication goes to the patients' respiratory tract (Chatburn & McPack, 2007).

Aerosol therapy used in young children has some limitation. Even though the children who have regular breathing, only 1.3% to 4.6% of the aerosolized medication can enter to their lower respiratory tract (Nikander, Berg, & Smaldone, 2007), due to their inability to hold their breaths. Also, their respiratory rate and inspiration flow rate are fast, and their tidal volume is low as about 80 to 150 milliliters, that make their breathing cannot keep up with the quick and huge speed of the aerosolized medication, which is generated from the nebulizer, causing most of the medication left in the nebulizer, tube, and mask, while some is lost into the atmosphere during exhalation (Fink, 2012). Besides this, if the children are crying during aerosol therapy, their exhalation will be longer but their inhalation will be shorter and faster, further causing the aerosolized medication to be blown out of the

mask rather than be inhaled into the lower respiratory tract (Thitida Chaisupmongkollarp, B.E. 2550; Aroonwan Preutthipan, B.E. 2546; Iles, Lister, & Edmunds, 1999). As a result, the effectiveness of the treatment is reduced, and the symptoms of the disease do not improve or even become worse.

The equipment currently used in aerosol therapy is in fact manufactured for adults. It consists of a small volume jet nebulizer with a face mask which generates about 0.25-0.3 milliliters of aerosolized medication per minute. The aerosolized medication will float within the face mask, which is large, and with a tidal volume of approximately 145 milliliters. Therefore, the face mask is like a reservoir which could help to collect the large amount of the aerosolized medication that generate from the small volume jet nebulizer. Moreover, adults have a higher inspiration flow rate and a larger tidal volume, about 500 milliliters, so they can sufficiently inhale the aerosolized medication into their lower respiratory tract. Thus, the amount of aerosolized medication that is lost into the outside atmosphere and hit to the face and face mask is lower. However, when it is used with young children, which volume of the child's face mask is about 80 milliliters, the nebulizer is still generate the same amount and speed of aerosolized medication, so it is impossible for the mask to hold all that particles. Moreover, young children's inspiratory flow rate and tidal volume are low, so they are unable to breathe at the same speed as the speed of the aerosolized medication (Aroonwan Preutthipan, B.E. 2546; Rubin & Fink, 2003). When the aerosolized medication is jetted into a small face mask, some will hit the children's face, face mask, and sprayed through the ventilation holes on both sides of the face mask, while others will become condensed and changed into small droplets that eventually fall into the nebulizer, hence get more dead volume and longer duration of aerosol therapy (Ahrens, 2005).

A review of related literature on modification of a small volume jet nebulizer has shown that different kinds of equipment used in aerosol therapy have been designed and modified to ensure their suitability for young children and to increase their effectiveness. For example, the breath-enhanced nebulizer sucks outside air in during inhalation, so the size of the aerosolized medication is smaller and there is more aerosolized medication produced during inhalation. In addition, the breath-actuated nebulizer produces the aerosolized medication only during inhalation, hence

less loss of aerosolized medication during exhalation (Thitida Chaisupmongkollarp, B.E. 2550; Aroonwan Preutthipan, B.E. 2546). But, such equipment is expensive, and there are no studies conducted with young children to confirm the effectiveness of such equipment when used with young children (Thitida Chaisupmongkollarp, B.E. 2550). Furthermore, other small volume jet nebulizers have been adapted to enhance effectiveness of medication therapy such as by connecting the external reservoir with the reservoir tube or bag to the small volume jet nebulizer with the T-piece connector between the nebulizer and the face mask or the mouth piece. This supplementary equipment can hold the aerosolized medication during exhalation, so it is kept within the tube or the bag, thus lessening the amount of the aerosolized medication lost into the atmosphere. This enables the patients to get more aerosolized particles during inhalation (Chatburn & Mcpeck, 2007; Pitance, Vecellio, Leal, Reycher, Recher, & Liisto, 2010).

It is worth noting that previous studies were mostly conducted for developmental and experimental purposes in the laboratory and the number of clinical research studies is very small, particularly the studies in children. The findings from studies carried out in adults need to be applied with children due to previously discussed restrictions. In addition, evaluation of the effectiveness of aerosol therapy varies, and evaluation methods are complicated and costly such as scintigraphy technique (Amirav, Balanov, Gorenberg, Groshar, & Luder, 2003), radioimmunoassay (Iles et al., 1999), and lung capacity measurement (Wiparat Manuyakorn, B.E. 2545). According to the researcher's professional experience, aerosol therapy in young children is difficult to administer due to lack of cooperation, so they do not receive sufficient amount of medication and the treatment has to be repeatedly administered. Moreover, the duration of the treatment is longer, and there is always a larger dead volume in the nebulizer. Therefore, the researcher was interested in adapting the aerosol therapy equipment to better suit young children so as to increase the amount of medication that could penetrate to the lower respiratory tract to promote effectiveness of the treatment. This was done by connecting the corrugate tube 6 inches in length and 22 millimeters in diameter. According to Bernoulli's principle, which contends that when the cross-sectional surface of the flow is increased, the speed of the flow will be reduced, and the air flow theory, which, according to Robert Boyes, posits that

when the volume is increased, the gas pressure will be reduced (Chaisawad Tianwibul, B.E. 2548). When a corrugate tube was added, the cross-sectional surface of the tube was increased. Therefore, the speed of the aerosolized medication that was jetted to the face, the face mask, and the tube wall would be reduced. This, coupled with additional 6 inches of the length of the tube, increased the total volume by 70 milliliters. Therefore, the gas pressure will be reduced. The corrugate tube would slow down the speed of the aerosolized medication and also acted as a reservoir that keep the aerosolized particles. Therefore, the speed of the aerosolized medication that was jetted to the face, the face mask, and the tube wall would be reduced, ensuring that there would be sufficient aerosol for young children to inhale into their lower respiratory tract. The combined volume from the increased volume of the adapted corrugate tube and the volume of the face mask was close to the tidal volume of young children, ensuring that young children increase the amount of the aerosolized medication that enters the respiratory tract, hence a lower dead volume and a shorter duration of aerosol therapy.

Conceptual Framework of the Study

In this study, the scientific knowledge related to the anatomy and physiology of the respiratory tract of children and knowledge of aerosol therapy with the small volume jet nebulizer were employed as the conceptual framework of the study.

Aerosol therapy is commonly used in children with respiratory diseases. When young children are treated at the hospital, the small volume jet nebulizer which consists of the oxygen tube, the nebulizer, and the face mask, is usually used. In order to get effective treatment, the aerosolized particle has to be attached to the lower respiratory tract. This depends on two major factors—use of effective equipment and cooperation of the patients to inhale the aerosolized medication (Thitida Chaisupmongkollarp, B.E. 2550; Supitcha Sangchote & Nualchan Prappal, B.E. 2544; Bisgaard, 1999; Hess, 2008).

The principle of aerosol therapy is that when the compressor is turned on, the gas goes through the oxygen tube to the small volume jet nebulizer at the speed of

6-8 liters. The negative pressure that results from the gas that travels at a very high speed will suck the liquid at the bottom of the nebulizer to be exposed to the gas, so the liquid will be aerosolized into tiny droplets that look like white fume (Khilnani & Banga, 2008). The suitable size of aerosolized particles to penetrate to the lower respiratory tract is 1-10 microns, produced at the rate of 0.25-0.3 milliliters per minute. The duration of each aerosol therapy is 10 to 15 minutes (Wipa Reechaipichitkul, B.E. 2542). After there is no aerosol generate from the nebulizer, there will always be some liquid left in the nebulizer, called the dead volume, which is about 1-3 milliliters (Hess, 2000). Tapping lightly on the side of the nebulizer during the session of aerosol therapy can reduce the dead volume.

Effective aerosol therapy requires standardized equipment that produces the aerosol size of the particles small enough to get in to the lower respiratory tract. Moreover, the size of the face mask has to be suitable with the face of young children, and closely cover their face to protect the loss of aerosolize particles. The small holes on both side of the face mask are needed to ventilate the exhaled air (Aroonwan Preutthipan, B.E. 2546; Chatburn & Mcpeck, 2007). In addition, other designs or modifications of the small volume jet nebulizer can increase the effectiveness of the therapy (Wipa Reechaipichitkul, B.E. 2542). According to Chatburn and Mcpeck (2007), a conserving device can be used to prevent loss of aerosol and slow down the aerosol speed, and made more aerosols to enter the lower respiratory tract. A corrugate tube, 6 inches in length, 22 millimeters in diameter with 70 milliliters in volume, can be used as its capacity is close to the tidal volume of young children. This reservoir tube is placed between the nebulizer and the face mask because young children have less inhaling force and their breathing pattern is not consistent. When the gas passes the nebulizer into the corrugate tube, it may satisfy the need to accommodate the young children's flow demand. Therefore, the young children would get more aerosolize particles during inhalation.

Another important factor for successful aerosol therapy is the patients themselves. During the therapy session, the children have to inhale and exhale normally. In fact, they should inhale deeply and hold their breaths for at least four seconds, done this until there is no aerosol left (Wipa Reechaipichitkul, B.E. 2542; Khilnani & Banga, 2004) so as to give time for the aerosol particles to deposit to

different parts of the trachea and the alveoli. However, in general, young children tend not to cooperate during the therapy session. They struggle and resist, breathe rapidly and inconsistently, and are unable to hold their breaths or control their breathing pattern. Therefore, most of the aerosol falls onto the upper respiratory tract, with little aerosol entering the lower respiratory tract, hence less effectiveness of the therapy (Thitida Chaisuppamongkollarp, B.E. 2550; Baillie, 2001).

The anatomy and physiology of the respiratory system of children are different from those of adults. From birth to five years of age, children's breathing pattern is fast and their inspiration flow rate and tidal volume are low (Amirav & Newhouse, 2012; Bennett & Zerma, 1998; Xu & Yu, 1986). In addition, the airway resistance of children is five times higher than that of adults (Zahraa, 2012). In five year old children, their tidal volume is about 150 milliliters, whereas the tidal volume of adults is about 500 milliliters. During the aerosol therapy, it can be seen that adults will get the maximum amount of aerosol during inhalation because their inspiration flow rate is faster than the speed of the aerosol produced by the nebulizer. On the contrary, in young children, their tidal volume is smaller and their inspiration flow rate is slower than that of the speed of the aerosol produced, so they can inhale only part of the aerosol into their lower respiratory tract (Aroonwan Preutthipan, B.E. 2546). Most of the aerosol is lost to the atmosphere through the ventilation holes on the sides of the face mask or sticks to the face and the face mask.

The researcher was interested in adapting the aerosol therapy equipment by connecting the corrugate tube, 6 inches in length, 22 millimeters in diameter, and 70 milliliters in volume, between the nebulizer and the face mask, with a total around of 80 milliliters in volume of face mask. The combined volume of the corrugate tube and the face mask is similar to the tidal volume of young children which is around 80 to 150 milliliters, and this can prevent re-breathing and carbon dioxide retention (Chatburn & Mcpeck, 2007). The corrugate tube would slow down the speed of the aerosol and reserve the aerosol produced by the small volume jet nebulizer, ensuring that there would be sufficient aerosol for young children to inhale into their lower respiratory tract, hence less loss through the ventilation holes on the sides of the face mask and a lower dead volume. The total duration of aerosol therapy was also shortened. The adapted small volume jet nebulizer is illustrated in Figure 1.1 below.

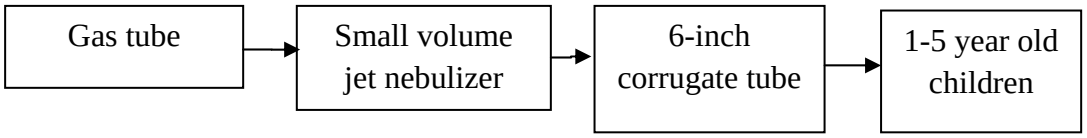

Figure 1.1: Components of the adapted small volume jet nebulizer

In the present study, the researcher was interested in examining the effects of the adapted small volume jet nebulizer, based on the aforementioned theoretical concepts. It was anticipated that the aerosol therapy with the adapted small volume jet nebulizer would increase the amount of the aerosol that entered the lower respiratory tract, reduce the dead volume in the nebulizer, and shorten the duration of the aerosol therapy session. The conceptual framework of this study is illustrated in Figure 1.2 below.

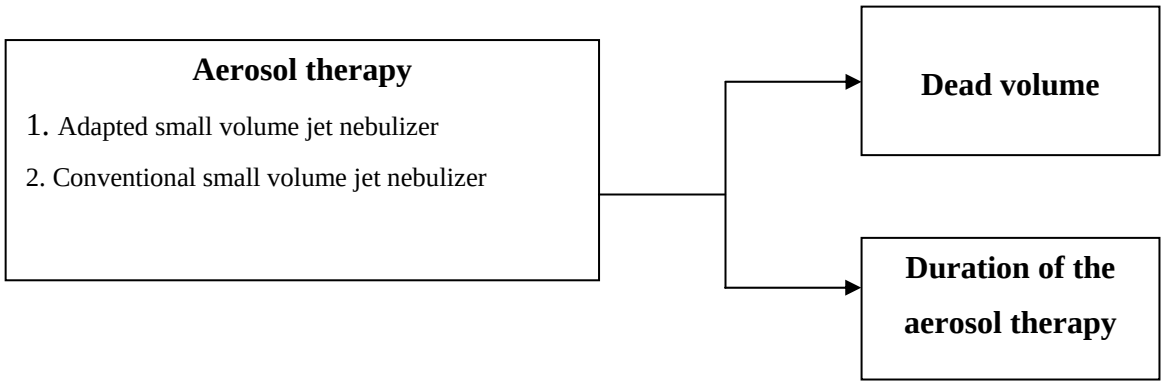

Figure 1.2: Conceptual framework of the study

Research Questions

1. Is there any difference in the amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer and a conventional small volume jet nebulizer in 1-5 year old children?

2. Is there any difference in the duration of aerosol therapy with an adapted small volume jet nebulizer and a conventional small volume jet nebulizer in 1-5 year old children?

Research Objectives

1. To compare the difference in the amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer and a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

2. To compare the difference in the duration of aerosol therapy with an adapted small volume jet nebulizer and a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

Expected Outcomes and Benefit

Nurses can use the adapted small volume jet nebulizer that was tried out in the present study to administer aerosol therapy in young children so as to increase the effectiveness of the treatment.

Research Hypotheses

1. The amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer was less than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

2. The duration of aerosol therapy with an adapted small volume jet nebulizer was shorter than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

Definition of Variables

Aerosol therapy with a conventional small volume jet nebulizer referred to administration of an aerosolized bronchodilator called Salbutamol with the equipment generally used at the hospital consisting of the gas tube and small volume jet nebulizer connected to the face mask for children.

Aerosol therapy with an adapted small volume jet nebulizer referred to administration of an aerosolized bronchodilator called Salbutamol with the equipment

adapted by the researcher consisting of the gas tube, small volume jet nebulizer connected with a corrugate tube which was 6 inches in length and 22 millimeters in diameter and the face mask for children.

Dead volume referred to the amount of fluid that remained in the nebulizer after tapping the nebulizer when the fume began to thin out and the sputtering noise is heard from the nebulizer until the noise stopped and there was no fume of the aerosol left to be seen. The amount of dead volume was a difference weight of the fluid between before and after aerosol therapy session, measured by using a highly sensitive electronic balance. The measurement was done by weighing the conventional small volume jet nebulizer composed of the nebulizer and the face mask sealed in a zip lock bag or the adapted small volume jet nebulizer composed of the nebulizer, the corrugate tube 6 inches in length and 22 millimeters in diameter, and the face mask sealed in a zip lock bag before the aerosol therapy session and deducting the weight by the weight of both types of equipment after the aerosol therapy session.

Duration of the aerosol therapy referred to the total amount of time spent in one aerosol therapy session, as measured in minutes with a timer. The timer was started as soon as the oxygen gas was turned on, and the timing continued until the therapy was completed—when there was no more sputtering sound in the nebulizer and none of the white fume of the aerosolized medication or aerosol was left to be seen.

CHAPTER II
LITERATURE REVIEW

The present study aimed at investigating the effects of an adapted small volume jet nebulizer on dead volume and duration of aerosol therapy in young asthmatic children. In this chapter, related textbooks, documents, and research studies are reviewed in the following topics:

2.1 Asthma in children.

2.2 Aerosol therapy.

2.2.1 Treatment with aerosol therapy.

2.2.2 Factors related to aerosol therapy.

2.2.3 Development and adaptation of aerosol therapy equipment.

2.2.4 Evaluation of effectiveness of aerosol therapy.

2.3 Anatomy and physiology of children's respiratory system.

2.3.1 Anatomy and physiology of children's respiratory tract.

2.3.2 Differences in anatomy and physiology of children's and adults respiratory systems.

2.3.4 Problems with aerosol therapy in children.

2.1 Asthma in children

Asthma is a commonly found disease in childhood. It is one of the causes of a chronic illness in children. Asthma occurs because of chronic inflammation of the bronchiole, which causes the bronchial tissues to become hyperresponsive to allergens and the environment, leading to bronchospasm, narrowing bronchiole, and airway inflammation. More phlegm is also secreted, hence obstruction of the airway (Paisal Lertrudeeporn, B.E. 2550). At present, the incidence rates of asthma range from 0% to 30%, and the incidences tend to rise all over the world (Paisal Lertrudeeporn, B.E.

2550). The symptoms of asthma include chest tightness, breathlessness, wheezing, and dyspnea, especially at night or early morning. Such symptoms immediately occur when the patients are exposed to the allergens or stimuli, and they will disappear when the bronchodilator is administered (Somchai Soontornlohanakul, B.E. 2545).

The mechanism of onset of asthma results from the repeated inflammation of the airway, leading to a process called remodeling of the airway. There are more fibrosis and brachial plexus in the airway, hence abnormal thickening of the airway, which, in turn, causes it to lose its flexibility. As a result, chronic obstruction of the respiratory tract continues due to four major processes of acute bronchoconstriction, swelling of the airway, chronic mucus and plague formation, and airway remodeling) (Paisal Lertrudeeporn, B.E. 2550; Viboon Boonsarngsuk, B.E. 2551).

There are two causes of childhood asthma—internal factors and environmental factors. Internal factors that stimulate the onset of asthma include heredity, gender, and ethnicity; environmental factors that have an effect on the onset of asthma include allergens, such as dust mites, dead skin cells of pets, pollens, cigarette smoke, or food, as well as the factors that stimulate asthmatic symptoms such as respiratory infections, allergen exposure, strenuous exercises, weather changes, and emotional changes (Paisal Lertrudeeporn, B.E. 2550). Changes in emotions may result in rapid breathing and excessive air ventilation, which causes the body to have too much carbon dioxide, hence narrowing of the airway (Mutita Trakultivakorn, B.E. 2544).

Diagnosis of asthma in children requires data from elicitation of the patients' history, examinations of physical conditions and clinical symptoms, laboratory examinations, and lung capacity tests. The diagnosis in children younger than three years old is rather complicated and restricted as there may be some diseases whose symptoms are similar to those of asthma and which well respond to anti-inflammation agents or bronchodilators such as milk inhalation, cystic fibrosis, and congenital heart disease, which cause children to have chronic coughing and wheezing (Nual-anong Wisitsoontorn, B.E. 2545; Pakit Wichayanon, B.E. 2543; Paisal Lertrudeeporn, B.E. 2550).

As regards severity of asthma in children, according to the treatment guideline of GINA Global Strategy for Management and Prevention 2014, severity of

asthma is assessed retrospectively from the level of treatment required to control symptoms and exacerbations, that after patient has been on controller treatments for several months. The categories of asthma severity can be divided into the following three levels (GINA, 2014):

- Mild asthma: well controlled with steps 1 or 2 (as-needed SABA or low dose ICS)
- Moderate asthma: well-controlled with step 3 (low-dose ICS/LABA)
- Severe asthma: requires 4/5 (moderate or high dose ICS/LABA ± add-on uncontrolled despite this treatment)

The goal of treatment of asthma is to control the disease, to minimize its symptoms, reduce the use of bronchodilator when there are relapses, and promote the patients' lung capacity to be close to the normal level as much as possible. Therefore, the treatment emphasizes avoidance of exposure to allergens and other risk factors. When there are relapses of symptoms, the $ß_2$ agonist bronchodilator is used with other groups of medication such as systemic steroids. The patients' symptoms need to be periodically assessed and followed-up as well (Paisal Lertrudeeporn, B.E. 2550).

In conclusion, childhood asthma is a major health problem. Correct diagnosis and appropriate treatment are important to reduce mortality rates and complications. Aerosol therapy is a pharmacological management that constitutes a significant component in treatment of asthma in children, particularly when there are exacerbations or asthma attacks because the medication can directly reach the organs that have the pathology. The medication used in aerosol therapy is the β 2 agonist bronchodilators and anti-inflammatory agents called corticosteroid (Wipa Reechaipichitkul, B.E. 2542). In addition, aerosol therapy moisturizes the respiratory tract and increases the efficiency of the mucociliary elevator. It also enhances the efficiency of phlegm expulsion (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544).

In the present study, the study sample consisted of children aged 1 to 5 years old who had been diagnosed asthma in mild or moderate severity of asthma exacerbation. Their treatment guideline included use of aerosol therapy with an aerosolized bronchodilator called Salbutamol.

2.2 Aerosol Therapy

2.2.1 Treatment with aerosol therapy

Aerosol therapy is used to treat pediatric patients who have either acute or chronic lower respiratory infections such as bronchitis, bronchiolitis, pneumonia, asthma, and bronchiectasis, etc.

Aerosol therapy refers to administration of medication or fluid in the form of aerosol. The medication can be either solid molecules or liquid molecules suspended in the air or gas, and it enters the respiratory tract and the lungs to treat the respiratory tract (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544). The term 'aerosol' refers to fluid or liquid or minute solid suspended in the air or gas that can be seen when it is exposed to light, resembling mist or fog (Thitida Chaisupmongkollarp, B.E. 2550; Supitcha Sangchote & Nualchan Prapphal, B.E. 2544). The goal of aerosol therapy is to allow the medication or fluid in the desired amount to enter the respiratory tract without causing any harm to the respiratory tract or the lungs and with no or minimum side effects. In fact, the objectives of aerosol therapy are as follows (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544):

1. To increase the efficiency of the mucociliary elevator
2. To moisturize the phlegm retained in the respiratory tract, making it easier to be expelled (Pakit Wichayanon, B.E. 2535)
3. To stimulate expulsion of phlegm and enhance coughing efficiency
4. To moisturize air or gas that is inhaled into the respiratory tract
5. To administer the medication into the respiratory tract and the lungs which have pathology by relieving bronchospasm and swelling of the respiratory tract.

Aerosol therapy is popularly used to treat respiratory diseases because the medication can directly take effects at the respiratory tract, so a smaller dose of medication is required and its effect lasts as long as oral intake or intravenous administration of the medication. Aerosol therapy also has fewer side effects due to a smaller dose required, and it is not as painful as an injection (Thitida

Chaisupmongkollarp, B.E. 2550; Aroonwan Preutthipan, B.E. 2546; Le Brun, De Boer, Heijerman, & Frijlink, 2000). At present, there are different kinds of equipment for aerosol therapy, which vary in terms of special means of use (Ari & Fink, 2011; Labiris & Dolovich, 2003). For example, a pressurized metered dose inhaler (pMDI) is a cylinder with minute suspended medication molecules that can be aerosolized, a pMDI with spacer has a supplementary spacer, a dry powder inhaler (DPI) is a cylinder like the pMDI but the medication molecules are solid rather than liquid, a small volume nebulizer (SVN), and a large volume nebulizer (LVN). However, the amount of medication the patients receive and the efficiency of the medication depends on the administration techniques and selection of the type of the equipment to suit the patients (Thitida Chaisupmongkollarp, B.E. 2550; Hess, 2008).

A small volume jet nebulizer is popularly used with young children who control their own breathe, particularly those who do not cooperate with the treatment, who have difficulty breathing, and who are unable to inhale deeply or hold their breaths because oxygen can be administered during the aerosol is produced (Aroonwan Preutthipan, B.E. 2546; Suchada Sritippayawan, B.E. 2554; Ari & Fink, 2011; Ari & Restreppo, 2012). The small volume jet nebulizer consists of a gas tube, nebulizer, and aerosol face mask. The production of aerosol is based on the Bernoulli principle or the Venturi principle. That is, the air compressor pressurizes air or oxygen through the liquid in the nebulizer. When the high pressure gas goes through the capillary tube, there will be negative pressure at the end of the tube, so the liquid around the tube in the nebulizer will be drawn up the tube to the area where there is negative pressure. The gas pressure will turn the liquid into aerosol that floats into contact with the baffles placed inside the nebulizer. Thus, large-sized aerosols fall back down to the reservoir, while the small aerosols flow with the gas into the respiratory tract of the patients, as depicted in Figure 2.1 below (Hess, 2008).

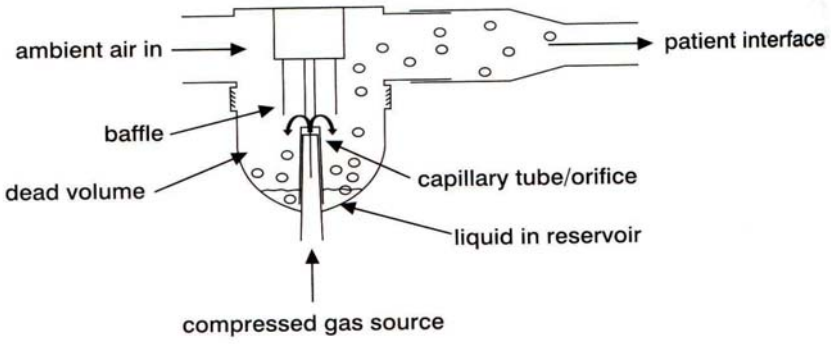

Figure 2.1: Functioning of a small volume jet nebulizer (Elliott & Dunne, 2011: 9)

Administration of medication with the small volume jet nebulizer involves sucking the aerosols into the mouth with a mouth piece or with an aerosol face mask. If a mouth piece is used, aerosols can more effectively go to the lower respiratory tract than the face mask. However, it has been documented that there is no difference between responses to administration of bronchodilators with a mouth piece and with a face mask. Therefore, the equipment should be chosen based on the preference of the patients (Thitida Chaisupmongkollarp, B.E. 2550; Wipa Reechaipichitkul, B.E. 2543). The small volume jet nebulizer consists of a gas tube, nebulizer, and a face mask for children or a mouth piece, as illustrated in Figures 2.2 and 2.3.

Figure 2.2: A small volume jet nebulizer and a face mask for children (http://www.thefind.com/beauty/info-volume-nebulizer-case, Retrieved September 23, 2013)

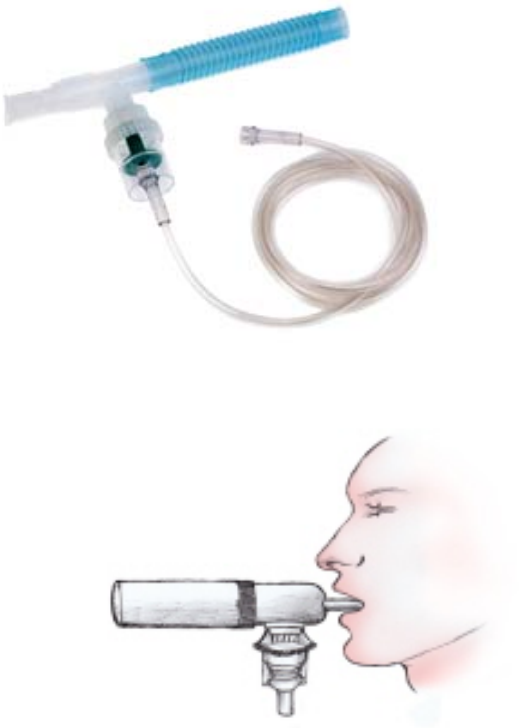

Figure 2.3: A small volume jet nebulizer and a mouth piece
(Source: http://emedicine.medscape.com/article/1413366-overview,
Retrieved September 23, 2013)

The sizes and density of the aerosol vary depending on the type of the nebulizer, though they produce aerosols that are almost similar in size. It has been found that the aerosols that are 1-5 microns in size are most suitable as they can penetrate the lower respiratory tract after they are inhaled, or are respirable (Coates & Ho, 19998; Hess, 2008). Aerosols that are different in sizes will enter and fall onto different levels of the respiratory tract. Large aerosols, with diameters larger than 10 microns, tend to fall onto the oropharynx, while those 5 to 10 microns in size tend to fall onto the upper respiratory tract, and those about 1 to 5 microns in size are able to get into the small bronchiole in the alveoli. However, the aerosols that are too small such as those whose diameter is 0.3 to 0.6 microns tend to leave the respiratory tract during exhalation, so they are not beneficial for the treatment. The locations where

aerosols are able to enter the respiratory tract are shown in Figure 2.4 below (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544).

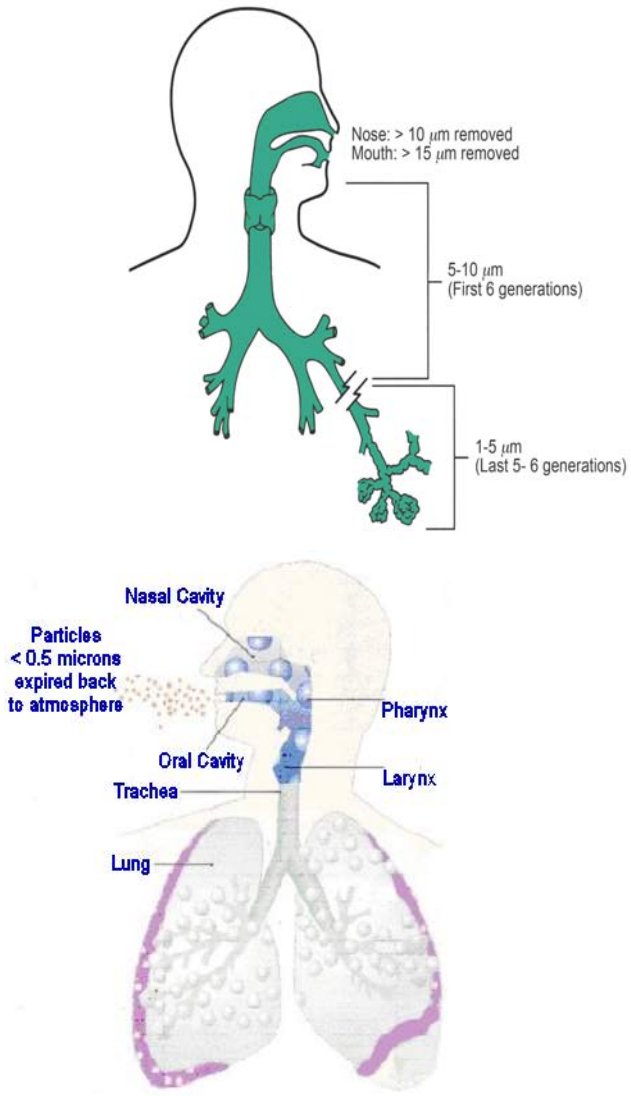

Figure 2.4: Image depicting the locations where aerosols enter the respiratory tract

(Source: Elliott & Dunne, 2011: 9
http://diagimaging.co.uk/smartvent_particle_size.htm**,** Retrieved September 25, 2013)

The size of aerosols depends on the chemical and physical structures of the medication and its component. The aerosol which is a needle-shaped solid can

penetrate the respiratory tract more deeply, but in practice, the shape of most aerosols is circular. In addition, it has been found that the aerosol particles will be larger if they go through the gas which is high in humidity due to hygroscopic particles. Moreover, medication at room temperature can vaporize better, hence smaller aerosols that can more effectively go into the respiratory tract (Thitida Chaisupmongkollarp, B.E. 2550; McCallion, Taylor, Bridges, Thomas, & Taylor, 1996).

In conclusion, aerosol therapy is considered an important treatment that is widely used to treat respiratory diseases. Small-sized aerosols can directly enter the lungs in a sufficient amount to take effect at the bronchiole, with fewer side effects from the medication absorbed into the bloodstream.

2.2.2 Factors related to aerosol therapy

Effectiveness of aerosol therapy with a small volume jet nebulizer depends on two major aspects: the equipment and the patients.

Equipment

Selection of the equipment is one of the factors that determine the effectiveness of aerosol therapy. The equipment used has to be standardized with good quality. When selecting the equipment, pathology and prognosis of the diseases should be taken into consideration to ensure suitability for each patient. The equipment that is popularly used with pediatric patients at the hospital is a small volume jet nebulizer which consists of a gas tube, a nebulizer, and a face mask or a mouth piece.

A nebulizer produces the aerosols by aerosolizing the liquid in the nebulizer using the pressure from the air or oxygen in the air compressor. Different nebulizers produce different sizes of aerosols with different efficiency. Some have to be constantly vertical position so as to be able to produce the aerosols, while others can be horizontal position during the therapy session, during which the nebulizer has to be tightly sealed. This is because leakage can affect the quantity and quality of the aerosols. Therefore, during aerosol therapy, the characteristics of the aerosols being produced need to be observed (Aroonwan Preutthipan, B.E. 2546). A good nebulizer has to be able to produce the aerosols in appropriate sizes to go into the respiratory

tract and fall onto the lower respiratory tract (Hess, 2000). The amount of aerosols produced should be consistent, approximately 0.5 milliliter per minute so as to accurately calculate the dose of the medication the children receive (Pakit Witchayanon, B.E. 2543). Johnson, Newman, Bloom, Talaee, & Clarke (1996) conducted a study to compare the function of two nebulizers—a turret nebulizer and an inspiron nebulizer with the medication called albuterol at 250, 250, 500, and 1,000 micrograms and ipratropium bromide at 50, 50, 100, and 200 micrograms, with the oxygen flow rate of 12 and 7 liters per minute. After that, the amount of medication that entered different parts of the respiratory tract was measured. The study findings showed that the turret nebulizer was able to produce more aerosols that entered the lower respiratory tract than the inspiron nebulizer with statistical significance ($p < 0.01$). In addition, there was an experiment carried out at a laboratory to measure the sizes of aerosols produced by four types of nebulizers manufactured by different companies at room temperature and at the temperature that was 10 degrees Celsius lower. Each nebulizer was filled with Salbutamol, and there were two nebulizers that were filled with budesonide, with the oxygen flow rate of 7 liters per minute. The results showed that the sizes of aerosols produced by all four types of nebulizers were different, and they became larger when the temperature was lower, with statistical significance ($p < 0.05$) (Zhou, Ahuja, Irvin, Kracko, McDonald, & Cheng, 2005). Based on such study findings, it could be concluded that different nebulizers produce different sizes of aerosols. Thus, a small volume jet nebulizer to be used in aerosol therapy should be selected from a reliable company, with high quality, which is able to produce aerosols regardless of whether it is vertical position, horizontal position, or tilted (Aroonwan Preutthipan, B.E. 2546).

The flow rate that produces aerosols in an appropriate size for aerosol therapy is 6 to 8 liters. The higher the flow rate, the smaller the size of the aerosols, hence more aerosols to go into the respiratory tract. Moor, Phipps, and Marcer (1985) conducted a study with chronic asthma patients using a small volume jet nebulizer nebulizer with 5 ml. of a bronchodilator called rimiterol. The oxygen flow rate was 4 and 8 liters per minute. It was found that when the oxygen flow rate was increased, the size of the aerosols became smaller and the patients got more aerosolized medication. Furthermore, Coates, MacNeish, Meisner, Kelemen, Thibert, MacDonald,

and Vadas (1997) conducted an experiment with two types of nebulizers—Hudson 1720 nebulizer and Hudson 1730 nebulizer. The first one was filled with 2 ml. of tobramycin and 0.5 ml. of Salbutamol mixed with 0.9% saline solution totaling 3 or 4 ml. The second one was filled with 2 ml. of tobramycin mixed with 1 or 2 ml. of 0.9% saline solution, with the flow rate of 6 and 8 liters per minute. The results revealed that when the gas flow rate was increased, the aerosols would be smaller and more aerosols could get into the respiratory tract. However, when the gas flow rate was too fast, the aerosols became minute and would be expelled during inhalation (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544; Hess, 2008). Therefore, aerosol therapy with a jet nebulizer should be used with an appropriate gas flow rate of 6 to 8 liters per minute so as to obtain aerosols in an appropriate size to enter the lower respiratory tract.

The fill volume of the aerosol therapy is about 4-5 ml. of the medication mixed with saline solution, which is considered the most appropriate amount (Fink, 2003). This is because after the therapy is done until there is no mist or fog left, there is always some fluid left in the nebulizer in the consistent amount. For example, if the amount of fill volume is 2 ml., there is always 1 ml. of fluid left in the nebulizer. This means that only 50% of the total amount of medication is aerosolized. However, if the fill volume is 4 ml. and there is 1 ml. of fluid left in the nebulizer, it means that 75% of the medication is aerosolized (Aroonwan Preutthipan, B.E. 2546; Fink, 2003). A study finding has shown that an increase in the amount of fill volume in aerosol therapy means an increase in the amount of aerosolized medication the patients will receive, but it also means the therapy session will be longer as well (Hess, 2000). Hess, Fisher, Williams, Pooler, and Kacmarek (1996) conducted a laboratory experiment with 17 types of nebulizers from different companies using 0.5 ml. of Salbutamol bronchodilator together with 2.5 ml., 3.5 ml., and 4.5 ml. of 0.9% saline solution with the oxygen flow rate of 6, 8, and 10 liters per minute. The findings revealed that the amounts of fluid left in the nebulizer differed with statistical significance ($p < 0.001$), depending on the types of nebulizer. When increasing the amount of fill volume, the amount of aerosolized medication that go into the respiratory tract and the duration of the aerosol therapy increased. Likewise, when reducing the oxygen flow rate, the duration of the aerosol therapy increased with

statistical significance ($p < 0.001$). Hess et al. (1996) have concluded that the larger the amount of precursory fluid, the longer the aerosol therapy session.

A face mask has an opening hole on both sides of the nose to allow the medication mist to leave into the outside atmosphere to prevent too much retention of the aerosolized medication in the mask. This is because when the aerosols come into contact with one another, they will be condensed into droplets that stay on the face, around the eyes, or become larger aerosols that cannot get into the lower respiratory tract (Aroonwan Preutthipan, B.E. 2546). When selecting a face mask for pediatric patients, the face mask with an appropriate size to perfectly fit the children's face should be chosen. There are previous studies which support selection of a face mask with ventilation holes closer to the eyes to prevent aerosols to get into the children's eyes and with an appropriate size that is not too tight. For instance, Sangwan, Gurses, and Samaldone (2004) conducted a study with a child-sized mannequin with the ventilator set to resemble natural breathing of children aged two years old, with the tidal volume of 50 ml. and the respiratory rate of 25 breaths per minute. Two ml. of 0.9% NSS was mixed with technitium (^{99m}Tc) and two different types of nebulizers were used with seven types of face masks. In this study, the amount of aerosols at different places on the face was measured using a gamma camera. It was found that aerosols that were produced from different nebulizers varied in terms of sizes and amounts. Also, the amounts of aerosols that went into the respiratory tract and that were left on the face differed, depending on the types of face masks used. Thus, it was concluded that the types of face masks had an effect on the amount of aerosolized medication left on the face and eyes of the patients.

In addition to inspiration of aerosols through the face mask, in older children who can control their own breathing, aerosolized medication can be inhaled through a mouth piece, which results in a larger amount of medication intake. This is because when breathing through the nasal cavity, aerosols larger than 2 microns in size will be filtered. On the contrary, when breathing through the oral cavity, there is no such filtration (Thitida Chaisupmongkollarp, B.E 2550). There is a study which was undertaken to compare aerosol therapy with a face mask and a mouth piece. A comparison between a face mask and a mouth piece showed that when a mouth piece was used, a larger amount of aerosols could get into the lower respiratory tract than the

mask. The study was conducted with asthmatic children aged eight to 15 years old who received aerosol therapy with 0.5 ml. Salbutamol bronchodilator mixed with 2 ml. of 0.9% saline solution, with the oxygen flow rate of 3.5 liters per minute. The face mask and the mouth piece were used. At 15 minutes and 30 minutes after the aerosol therapy ended, their lung capacity was assessed. It was found that the effects of aerosol therapy with a face mask and a mouth piece were different with statistical significance ($p < 0.05$). In particular, the aerosol therapy with a mouth piece, the FEV_1 increased, with the means of 56.4 ± 32.6% and 28.9 ± 19.1%, respectively. Moreover, the FVC measured when the mouth piece was used was higher than that measured when the face mask was used, with the means of 30.7% ± 27.0% and 9.3% ± 15.3%, respectively, at 15 minutes after aerosol therapy and 34.4% ± 26.4% and 7.5% ± 14.9%, respectively, at 30 minutes after aerosol therapy (Kishida, Suzuki, Kabayama, Koshibu, Izawa, Takashita, Kurita, Okada, Shinomiya, & Aoki, 2002). Therefore, it could be concluded that aerosol therapy with a mouth piece results in a larger amount of aerosolized medication intake than aerosol therapy with a face mask.

However, there are certain restrictions of aerosol therapy with a mouth piece when used with young children. This is mainly because young children tend not to cooperate with the treatment. Furthermore, they do not know how to breathe properly or hold their breaths. Mellon, Leflein, Walton-Bowen, Cruz-River, Fitzpatrick, and Smith (2000) compared clinical outcomes of aerosol therapy with a face mask and that with a mouth piece in infant and young children with asthma who were treated with 0.25, 0.5, and 1 ml. of steroid called budesonide by measuring responses to the treatment. They found that both groups of children who received aerosol therapy with a face mask and aerosol therapy with a mouth piece had similar clinical outcomes. Based on such findings, it could be concluded that even though aerosol therapy with a mouth piece results in a larger amount of aerosolized medication intake, aerosol therapy with a face mask yields similar clinical outcomes. Therefore, when aerosol therapy is used with young children who are unable to control their breathing through the mouth or do not cooperate with the therapy, a face mask should be used instead of a mouth piece (Thitida Chaisupmongkollarp, B.E. 2550; Supitcha Sangchote & Nualchan Prapphal, B.E. 2544; Ari & Fink, 2011).

In summary, to ensure effectiveness of aerosol therapy with a small volume jet nebulizer in young children, equipment should be of a high quality and standardized, and the face mask should be carefully chosen to make sure that it perfectly fits the children's face (Aroonwan Preutthipan, B.E. 2546; Rubin & Fink, 2003). The oxygen flow rate is 6-8 liters per minute, so that the aerosolized medication will be in a size that is appropriate for inspiration into the lower respiratory tract (Hess, 2008).

Patient factors

In addition to equipment factors, patient factors are also important for successful administration of aerosol therapy to ensure that aerosols go into the lower respiratory tract.

As regards breathing patterns, the breathing pattern that can increase the amount of aerosols to go into the lower respiratory tract and the lungs is deep and slow breathing at 0.2-0.5 liters per second, with the breath held for at least four seconds, to allow the aerosol particles to penetrate to different parts the lungs before exhaling (Thitida Chaisupmongkollarp, B.E. 2550; Supitcha Sangchote & Nualchan Prapphal, B.E. 2544).,

It can be seen that a larger tidal volume can increase the amount of aerosols that go into the lower respiratory tract. The tidal volume can be increased when the breathing is slow and deep (Smaldone, 2005). However, this is not always possible in young children younger than five years of age (Marguet, Couderc, Roux, Jeabbot, Lefay, & Mallet, 2001) whose tidal volume and inspiration flow tend to be low and breath holding time tends to be short (Supticha Sangchote & Nualchan Prappal, B.E. 2544; Ari & Fink, 2011). Therefore, the amount of aerosolized medication that goes into the lower respiratory tract is lower. Barry and O'Callaghan (1998) conducted a study to compare the amount of medication received from three types of nebulizers using respiratory models of patients aged six months old and one, three, five, ten, and 16 years old, with the tidal volumes (V_t) of 50, 75, 125, 150, 225, and 600 ml., respectively, and the respiratory rates of 30, 28, 24, 20, 16, and 16 breaths/minute, respectively. Two milliliters of budesonide was used, with the vacuum pump set at 20 or 60 liters/minute and the therapy session of five minutes. It

was found that the amounts of aerosolized medication produced by these three instruments varied, with the amount received when the tidal volume was equal to 50 milliliters the lowest. In addition, when further analyzing the tidal volumes and oxygen flow rates, it could be seen that when the tidal volume increased from 50 milliliters to 400 milliliters and the flow rate was increased from 4 liters to 8 liters, the amount of aerosolized medication intake increased from 34% to 79%, or by 2.2 to 3 times (Everad et al., 1992). Thus, it could be concluded that patients who have a larger tidal volume will receive more aerosolized medication.

Pediatric patients younger than five years of age generally tend to resist the treatment, and this can result in abnormal breathing patterns (Marguet et al., 2001). Children tend to have longer exhalation followed by rapid and short inhalation, causing most of the aerosolized medication to fall onto the oral cavity and the larynx, while some aerosols are lost into the atmosphere during exhalation (Amirav, 2004). Iles, Lister, and Edmund (1999) carried out a study with 15 infants aged nine to 13 months old with broncospasm who were in a calm state compared to those who were crying and had increased respiratory rates during aerosol therapy sessions with 20 mg. of sodiumcromoglycate mixed with 4 ml. of 0.9% saline with oxygen flow rate of 6 liters/minute. The amount of medication intake was assessed from their urine. It was found that the amount of medication in urine of the infants in a calm state was 0.43%, while that of the infants who were crying was 0.11%, which was different with statistical significance ($p < 0.001$). Thus, they concluded that children who were crying during aerosol therapy had less medication that fell onto the lungs and was absorbed into their system compared to children who were in a calm state. Therefore, aerosol therapy should be carried out when children are in a calm state or are sleeping.

In fact, nose breathing may not be as effective as mouth breathing to let the aerosolized medication go into the lower respiratory tract. This is because nose breathing involves more resistance than mouth breathing. In addition, the nose will filter the aerosols which are larger than 2 microns, so to ensure sufficient medication intake, mouth breathing should be used instead. However, young children do not know how to control their breathing through the mouth (Thitida Chaisupmongkollarp, B.E. 2550), so aerosol therapy with a face mask is necessary. Chua, Collis, Newbery, Chan, Bower, Sly, and Souof (1994) compared infants who were sleeping with

children aged 6.3-18 years old who had cystic fibrosis and received aerosolized 0.9% saline solution which was radiolabelled. The infants inhaled the aerosols through their nose, while older children inhaled the aerosols through the nose and the mouth. The research results indicated that the amount of aerosols that fell onto the lungs of the infants was smaller than that of older children. However, differences in the amounts of aerosols inhaled through the mouth and the nose were found in children aged 6.3-18 years old. Thus, it could be concluded that children who breathe through the nose receive a smaller amount of aerosolized medication than those who breathe through the mouth. Besides this, young children have a narrow respiratory tract, and they are more susceptible to respirator inflammation, swelling of the respiratory tissues, and obstructive respiratory tract due to phlegm, all of which prevent the aerosols from effectively entering the lower respiratory tract and the lungs (Amirav, 2012). Previous studies have revealed that clearing the airway before administering aerosol therapy can increase the amount of aerosolized medication that reach the lower respiratory tract (Edsbacker et al., 2008 cited in Woraruethai Kamlungharn, B.E. 2555).

Face-mask seal is an important factor that affects the amount of aerosolized mediation intake. To achieve effective aerosol therapy, the mask has to perfectly fit the face of the infants. However, young children tend to lack cooperation and resist the therapy by screaming or thrashing around, so the mask may not be properly put in place and more aerosols can be lost into the outside atmosphere, hence less medication intake. A previous study has reported that when the face mask was only 1 cm. away from the face of children, the amount of aerosolized medication that entered the respiratory tract was reduced by as much as 50% (Everard et al., 1992). Therefore, so as to prepare the children for aerosol therapy, caregivers should try to make children accept the treatment such as by using games or toys to make them feel relaxed and cooperate (Amirav & Newhouse, 2008). Lin, Restrepo, Gardenhire, and Rau (2007) conducted a study to measure the amount of aerosolized medication when three different methods of face mask use. A model was used with the simulated respiratory rates of young children, with a tidal volume of 60 ml., the respiratory rate of 20 beats per minute, and the inspiratory-expiratory ratio of 1:3. Three types of face mask use were compared—with the lower edge of the face masks placed further away from the chin for 0, 1, and 2 cm. Three milliliters of salbutamol bronchodilator was

used, with the oxygen flow rate of 8 liters per minute. It was found that the amounts of aerosolized medication that entered the respiratory tract were different with statistical significance ($p < 0.001$), with the amount largest when the face mask was 0 cm. away from the chin and the amount smallest when the face mask was 2 cm. away from the chin. Thus, it could be concluded that the further away the face mask is from the face, the less aerosolized medication that go into the lower respiratory tract.

Diseases or conditions that have an effect on the anatomy of the respiratory system constitute another major factor. The respiratory structure that is narrow or the congenital defective respiratory system, together with obstruction caused by phlegm, can prevent aerosols to get into the desired parts of the respiratory tract (Thitida Chaisupmongkollarp, B.E. 2550). However, factors that result from abnormality of the respiratory tract and respiratory diseases do not have an effect on the total amount of aerosolized medication that goes into the respiratory tract, but they affect the medication's penetration into the desired parts of the respiratory tract. For example, patients who have respiratory diseases have high respiratory resistance, so most of the aerosols that go into the respiratory tract tend to fall onto the upper respiratory tract. However, a correct method of aerosol therapy can ensure that aerosols will fall into the lower respiratory tract, making the treatment effective (Khinani & Banga, 2008). Amirav and Newhouse (2008) and Amirav (2012) reviewed research studies related to lung deposition in infants with different respiratory diseases, though there were not many studies conducted due to restrictions in research ethics. They found that the amount of lung deposit in children with bronchiolitis was not different from that in children with other obstructive bronchia. The location of lung deposit is mostly central deposition. It was also found that the older the children become, the more the amount of lung deposition, increasing by 5.4% in children aged two to four years old and 11.1% in children five to seven years old, which was equal to the amount of lung deposition in adults, but in adults lung deposition is mostly found in the peripheral airway.

In conclusion, aerosol therapy in young children should take different aforementioned factors into consideration to maximize its efficiency. However, some of the factors are difficult to control such as diseases or conditions that affect the anatomy of the respiratory tract. Healthcare professionals should realize the

significance of selection of the nebulizer with a high quality and correct techniques of aerosol therapy administration so as to increase the clinical outcomes of the treatment.

2.2.3 Development and adaptation of a small volume jet nebulizer

Instruments that are used in aerosol therapy have been developed and improved for years to increase the amount of aerosolized medication that go into the respiratory tract. Existing instruments are adapted, and new technology is used to increase efficiency of aerosol therapy and effectiveness of the treatment.

Adaptation of the original nebulizer to maximize effectiveness can be done by connecting the T-piece connector with a corrugate tube or reservoir bag to keep the aerosols during exhalation and prevent loss of the aerosols into the outside atmosphere during exhalation (Hess, 2012). Corcoran, Dauber, Chigier, and Iacono (2002) conducted a study in a laboratory to compare the amount of aerosols when the Hudson Micromist nebulizers with and without a reservoir bag were used, with different gas flow rates. It was found that when the gas flow rate was increased, the size of the aerosols would be smaller. Also, the Hudson Micromist nebulizer with a reservoir bag could increase the amount of aerosols by 28% compared to the same nebulizer without a reservoir bag, even though some aerosols could still be found in the reservoir bag. As such, it was concluded that a nebulizer with a reservoir bag could increase the amount of aerosols that entered the respiratory tract.

In 2007, Chatburn and Mcpack adapted the nebulizer by connecting a reservoir to the existing nebulizer. The reservoir worked by containing the aerosols that came out during exhalation to prevent loss of aerosols into the atmosphere and to slow down the speed of the aerosols by retaining the exhaled aerosols for subsequent inhalation. The adaptation was easy to do by connecting a flexible tube to a T-piece connector, with one side left open into the atmosphere or connected to the nebulizer to allow the aerosols to flow into the patients. The size and length of the tube depended on the amount of aerosols to contain. If the tube was long, more aerosols would be contained. However, when the tube was longer, ventilatory dead space would be increased, and this had an effect on expulsion of carbon dioxide. Moreover, the nebulizer could be adapted by adding a valve that could be opened or closed to separate inhalation and exhalation, hence an increase in the amount of aerosolized

medication the patients received. In young children with a small tidal volume, however, the equipment could be adapted by connecting the reservoir as part of the nebulizer, above the nebulizer and next to the face mask, so that the aerosols could flow into the patients with the pressure from the gas flow (Chatburn & Mcpack, 2007).

Adaptation with a reservoir or a tube should be used to increase the efficiency of the treatment as it ensures that the patients receive more aerosolized medication, hence more effective medication management. Pitance, Vecellio, Leal, Reycher, Recher, and Liisto (2010) assessed the effectiveness of three types of nebulizers—an original nebulizer, an adapted nebulizer with a 110-cc corrugate tube connected to it, and a vibrating mesh nebulizer. It was found that the patients with whom the vibrating mesh nebulizer was used received the highest amount aerosolized medication. Therefore, it was concluded that a vibrating mesh nebulizer increase the effectiveness of aerosol therapy. Whereas, comparing between the original nebulizer and the adapted nebulizer which connected a corrugate tube to the nebulizer. It was found that the adapted nebulizer could increase the amount of aerosolized nebulizer by as much as 33% compared to the regular one. Therefore the adapted nebulizer could increase the effectiveness of aerosol therapy. In addition, there is adaptation by adding a valve to allow outside air to mix with the aerosols during inspiration, hence more and smaller aerosols. Some nebulizers such as the breath-enhanced nebulizer and the breath-actuated nebulizer produce the aerosol only during inhalation, reduction in loss of aerosols during exhalation (Thitida Chaisupmongkollarp, B.E. 2550). There are a number of studies which support that adapted nebulizers can increase the amount of aerosols in the lungs (Hess, 2008).

Bisgaard who is a pediatric professor at a National University Hospital in Copenhagen, Denmark, has proposed a guideline on development of nebulizers for children. According to him, in addition to an increase in the amount of aerosols that go into the respiratory tract and lungs, nebulizers for children need to be patient-friendly. They should be something that children like, such as having a warning signal when the medication almost runs out. They should also be practical and involve the use of new technology. However, at present, nebulizers are improved with technology, but the children have to adapt themselves to the nebulizers instead of the other way round (Bisgaard, 1999).

Amirav, Newhouse, Minocchieri, Castro-Rodriguez, and Schuepp (2010) have pointed out that development of nebulizers for young children has to make sure that the aerosols are in a size that is appropriate for the respiratory tract of young children, are child-friendly, and do not cause fear or resistance in children. Moreover, the nebulizers should create satisfaction in children's caregivers. Based on such a concept, a child-friendly nebulizer has been adapted with aerosols jetted through the oxygen hood to reduce direct exposure to the children's face so as not to cause anxiety or fear, which can lead to crying and resistance (Amirav, 2004; Amirav & Newhouse, 2008; Amirav, Newhouse, Minocchieri, Castro-Rodriguez, & Schuepp, 2010). In 2003, Amirav, Balanov, Gorenberg, Groshar, & Luder conducted a study to compare the amount of lung deposits in 14 children aged one to 19 months who had wheezing sound when breathing. A nebulizer with a face mask or an oxygen hood was used with Salbutalmol bronchodilator, and the gamma scintigraphy was employed to measure the amount of aerosols. The results showed that the lung deposit of aerosolized medication in children who received aerosol therapy with a face mask was 2.4%, while that in children who received aerosol therapy with an oxygen hood was 2.6%. Furthermore, clinical outcomes in both groups of children showed improvement, and the caregivers of the children were more satisfied with the nebulizer with an oxygen hood than the nebulizer with a face mask.

In 2005, Amirav, Oron, Tal, Cesar, Ballin, Houri, and Mandelberg carried out a study with 49 children aged one to 24 months old who had virus-induced bronchiolitis. The nebulizer with a face mask and the nebulizer with an oxygen hood to cover the children's face instead of a face mask were used. The results showed that clinical outcomes in both groups of children improved, with the clinical severity scores increased after three days of aerosol therapy during hospital admission with statistical significance ($p < 0.001$) (Hood group: 15%, 15.4%, and 16.4%, respectively; Mask group: 17.5%, 12.1%, and 12.7%, respectively). Also, the children's caregivers were more satisfied with the oxygen hood than the face mask by 80% (Amirav, Oron, Tal, Cesar, Ballin, Houri, & Mandelberg, 2005). In addition, some types of child-friendly nebulizers have been invented to ensure children's pleasure during the therapy session. For instance, Infamed Company Limited in Australia has manufactured an instrument called a Funhaler spacer which consists of a toy ball with a spinner inside.

The spinner is connected to a whistle, which, in turn, is connected to a spacer with valve that can be opened or closed to prevent contamination from the outside air. When children inhale the aerosols with a sufficient air volume, during inhalation, the air in the reservoir will push the object in the toy ball to spin, and the air that passes through the tube will make a whistling sound, which can entertain the children during the therapy session. There was a study undertaken to compare the use of the Funhaler with the Breath-a-tech, the most widely used tradition spacer in Australia in children aged one to five years old who received continuous aerosol therapy at home. It was found that the children accepted aerosol therapy more when the Funhaler was used and their parents were more satisfied with the Funhaler than the traditional spacer (Watt, Clements, Devadoson, & Chaney, 2003).

In addition to adaptation of nebulizers, technology has also been used to develop nebulizers to suit young children. Modern technology began to play a role in the 1990s, when a nebulizer called the adaptive aerosol delivery system (AAD) was invented to reduce the loss of aerosols into the outside atmosphere, so the patients receive an appropriate amount of the aerosolized medication. It is suitable for patients who are unable to control their own breathing. It contains a microship which controls and records its functioning during the aerosol therapy session. The medication is aerosolized when there is breathing through the face mask, and the aerosols are produced in accordance with the patients' breathing patterns. Thus, it is observable whether the face mask is properly put in place. Furthermore, during the therapy session, the patients can pause without having to lose the aerosols into the outside atmosphere, and the total amount of aerosolized medication the patients receive is constantly recorded (Denyer & Nikander, 2010). In their study, Nikander, Arheden, Denyer, and Cobos (2003) tried out the use of the adaptive aerosol delivery system (AAD) connected to the ventstream jet nebulizer with a face mask in 155 children aged seven months to six years old who suffered from asthma. The results revealed that 91.3% of the children accepted the aerosol therapy, 90.4% accepted the adaptive aerosol delivery system (AAD), and 90% of the caregivers were able to more correctly put the face mask on the face of the children and were satisfied with the system. As a consequence, it was concluded that the adaptive aerosol delivery system (AAD) could actually be used to treat asthma, particularly in patients who are young children.

Based on the aforementioned discussion, it can be seen that studies on development and adaptation of nebulizers for children have been continuously conducted overseas, with an aim to improve the equipment to reduce loss of aerosols and increase lower respiratory tract and lung deposits, as well as to make children accept aerosol therapy more. However, there are not many such studies in Thailand. For instance, Woraruthai Kamlangharn (B.E. 2555) conducted a study to investigate the effects of jet nebulizers on acceptance behavior and four aspects of clinical outcomes in young children with bronchospasm and received aerosol therapy with salbutamol using a modified small volume jet nebulizer wrapped in cartoon-printed wool. The study findings showed that the children with whom the modified small volume jet nebulizer had more acceptance behavior of aerosol therapy compared to those with whom a regular one was used with statistical significance. However, their clinical outcomes were not statistically significantly different. Such findings indicated that even though a modified small volume jet nebulizer has not yielded a significant effect on clinical outcomes of pediatric patients as expected, and further research is required, it can generate more acceptance in children because it is more child-friendly and suitable for the developmental stages of young children. In addition to adaptation of the nebulizer to suit patients who are young children, healthcare team members should be equipped with the knowledge on how to correctly use the nebulizer and how to transfer such knowledge to caregivers of the children and the children themselves, using teaching, demonstration, or practices to ensure that they are also able to correctly utilize the equipment (Fink, 2012).

A review on related literature on development and adaptation of nebulizers has shown that there are still not many studies on adaptation of nebulizers to suit young children. Only one study was found in Thailand. For this reason, the researcher was interested in adapting the small volume jet nebulizer using a corrugate tube to connect the nebulizer and the face mask to prevent loss of aerosols into the outside atmosphere (Chatburn & Mcpack, 2007; Hess, 2012). A flexible corrugate about 6 inches in length and 22 millimeters in diameter, which was a standard size easily available and generally used at a hospital, was used. The capacity of the tube was 70 milliliters, so when it was connected to the nebulizer and the face mask, which had a volume of about 80 millimeters, the combined volume would be close to the

tidal volume of young children. It also did not cause rebreathing or carbon dioxide leakage (Chatburn & Mcpeck, 2007). The corrugate tube helped contain the aerosols to prevent unnecessary loss and increase the amount of aerosols during children's inhalation. The equipment used in the aerosol therapy is illustrated in Figure 2.5 below.

Figure 2.5: A corrugate tube connecting the nebulizer and the face mask

2.2.4 Evaluation of effectiveness of aerosol therapy

Evaluation of effectiveness of aerosol therapy can be done by measuring the amount of lung deposit that is sufficient to take effect to control clinical symptoms of the patients such as using radiolabelled drugs and a gamma camera. In the past, radiolabelled drugs were not popularly used, because it was believed that it may not be safe and because of consideration of research ethics. However, at present, this method is more popularly used (Everard, 1996).

Single-photon emission computed tomography (SPECT) is a radiography technique using gamma ray to assess the characteristics and locations of the aerosol deposits in the respiratory tract. It is similar to the original radiography, but the

original yields two-dimensional horizontal photos, while this new technique yields three-dimensional photos, so the amount of aerosol deposits can be more accurately determined. In addition, the scintigraphy technique can also be used by aerosolizing the radiolabelled 99m Technetium (^{99m}TC) before using a gamma camera to take photos to assess the locations of the aerosol deposits in the respiratory tract and estimate the amount of aerosolized medication the patients have received.

The amount of medication excreted with urine can also be used to calculate the amount of the aerosolized medication absorbed into the body using the radioimmunoassay technique, which is a radiological examination mostly used with the sodium glomoglycate bronchodilator.

In addition assessment of the amount of lung deposits, evaluation of effectiveness of aerosol therapy in young children can also be done using lung capacity assessment and clinical symptoms, which can be described as follows:

Assessment of lung capacity (Aroonwan Preutthipan, B.E. 2550)

1. Spiromethy refers to assessment of the flow and volume that result after the patients have inhaled up to the maximum lung capacity before abruptly and fully exhaling. The assessment of total lung capacity and residual volume will be compared to the normal values and reported in percentage of the predicted value derived from the assessment of normal healthy persons whose age, height, gender, and ethnicity are similar to those of the patients. This technique cannot be used with young children.

2. Peak expiration flow rate is done by blowing the peak flow in short and powerful bursts. This can be done with young children aged four to six years old.

3. Bronchial challenge test stimulates the bronchia to constrict, and it is generally used with patients who are suspected to have bronchial hyperactivity, using different stimulation techniques such as exercises or breathing cold air.

4. Lung volume measurement is a measurement of the input air volume in the lungs. Two instruments can be used in the measurement—the whole body plethysmography and gas dilution.

5. Respiratory muscle pressure measurement assesses the power of the muscles used in breathing, particularly during inhalation.

Follow-ups of clinical symptoms

In young children whose lung capacity cannot be measured, the severity of the diseases is determined by evaluating their clinical symptoms using the modified pulmonary index scores. In general, six aspects of clinical symptoms are measured—oxygen saturation, accessory muscle use, inhalation-exhalation ratio, heart rate, respiratory rate or respiration/minute, and wheezing. The evaluation of each aspect of clinical symptoms yields scores ranging from 0 to 3 points, and the total scores of six aspects are combined, ranging from 0 to 18 points. The severity of bronchospasm caused by asthma in young children can be divided into three levels—the scores of 0 to 5 points refer to mild asthma, the scores of 6 to 11 points refer to moderate asthma, and the scores of 12 to 18 points refer to severe asthma, as shown in Table 2.1 below.

Table 2.1: The Modified Pulmonary Index scores

Category	Score			
	0	**1**	**2**	**3**
Oxygen saturation (%)	> 95	93-95	90-92	< 90
Accessory muscle use	Not using	Slight constriction of accessory muscles	Moderate constriction of accessory muscles	Moderate constriction of accessory muscles
Inhalation-exhalation ration	2:1	1:1	1:2	1:3
Heart rate (beat/min)				
< 3 years	< 120	120-140	141-160	> 160
≥ 3 years	< 100	100-140	121-140	> 140
Respiratory rate (beat/min)				
< 6 years old	≤ 30	31-45	46-60	> 60
≥ 6 years old	≤ 20	21-35	36-50	> 50
Wheezing	None	end expiratory	Aspiratory and expiratory wheeze, good aeration	Aspiratory and expiratory wheeze, decreased aeration

Source: Carroll, Anand, Sekaran, and Tru (2005)

In conclusion, the evaluation of the effectiveness of aerosol therapy varies**.** Hence, the choices of the method of aerosol therapy evaluation have to consider the limitations of each method .

2.3 Anatomy and physiology of children's respiratory system

2.3.1 Anatomy and physiology of children's respiratory tract

Growth and development of the respiratory system begin when the fetus is still in its mother's womb and continue well after delivery until a child becomes an adolescent. It has been documented that at the age of eight years old, the number of air sacs is 300 to 600 millions, similar to that in adults. Therefore, the respiratory system of infants and young children does not function as well as that of adults. When young children have respiratory or pulmonary diseases, the severity of the diseases is much greater compared to those in adults (Harutai Kamalaporn, B.E. 2550). For this reason, knowledge and understanding of the anatomical and physiological characteristics of the respiratory system in children is deemed vital for treatment of respiratory diseases in young children.

The anatomy of the respiratory tract of children can be divided into two parts—the upper and the lower respiratory tract. The upper respiratory tract consists of the nose, mouth, pharynx, and larynx. It functions to bring the outside air into the lower respiratory tract without any gas exchange. In the upper respiratory tract, there are soft tissues that have more compliance and function to prevent foreign objects and germs into the respiratory tract, adjust humidity and warmth of the incoming air to suit the body temperature in the oral and nasal cavities, contains the sinus that is light in weight and acts as an air ventilation cavity, and produces mucus for the nasal cavities (Harutai Kamalaporn, B.E. 2550). The lower respiratory tract begins with the windpipe (trachea) and within the lungs, the bronchi, bronchioles, and alveoli. It functions to bring the air in the bronchiole to the lungs and exchange gas to send oxygen to nurture different parts of the body. The gas exchange takes place at the 17^{th} to 19^{th} respiratory bronchioles onwards (Phongthara Vichitvejpaisal, B.E. 2539; Harutai Kamalaporn, B.E. 2550).

The functioning of the respiratory system in children consists of the physiological structures and adaptation as follows:

1. The bronchiole of children is very narrow, and in approximately 80% of the infants and children, the diameter of their bronchiole is less than 1 mm. Thus, even slight obstruction caused by phlegm, swelling of the bronchiole, or constriction of the smooth muscles of the bronchiole walls can easily either completely or incompletely block the airway.

2. As regards functioning of the respiratory muscles, infants and young children use the muscles of the diaphragms which are most important for breathing. The type I fatigue resistance muscle fibers in the diaphragms are not found until the children are about eight years old when they begin to develop. Therefore, the diaphragm muscles can easily become fatigued. It has also been found that the tidal volume in young children mostly results from functioning of the diaphragm muscles. This goes on until they are five to seven years old when their ribs begin to function more. In addition, it is found that there are fewer channels for collateral ventilation, so collapsed lungs can easily occur in that position.

3. The position of the ribs in young children is more horizontal, and their chest is rather round than oval shape, so the expansion of the ribs is reduced, causes less expansion of the chest and lungs.

4. Lung compliance in young children is higher. Such an abnormally high compliance requires more energy expenditure, particularly during inhalation.

5. With regards to metabolism of the respiratory system, young children have a high rate of metabolism. There are also more heat production and fluid expulsion, which causes higher respiratory rates. The respiratory muscles, therefore, have to work harder to maintain the oxygen level to ensure sufficiency with the functioning of the body. When the children have respiratory or pulmonary diseases, the condition can be worsened. This is because pulmonary diseases in young children do not affect any bodily function in particular, but they affect the total functioning system of the body. As a result, pathology of pulmonary diseases in young children is different from that of pulmonary diseases found in adult

Anatomical and physiological considerations of young children are the upper airway are quite different from adults, especially in infants. The larynx is situate much higher, the epiglottis, which is rather narrow and floppy, is located nearer palate. During the infancy the volume of the lung parenchyma enlarges more relative to airway volume. Thus, the conductance in infant lungs is greater than in older lung. In addition, young children have lower inspiration flow rate and tidal volume.

2.3.2 Differences in anatomy and physiology of children's and adults respiratory systems

Treatment and care of pediatric patients who have respiratory problems requires consideration of many important factors to ensure the best treatment outcomes possible to save life and prevent possible disabilities (Suparee Suwanjutha, B.E. 2531). One of the major factors is the anatomical and physiological factor of the respiratory system of children. This is because anatomical and physiological development varies along age groups, and it can affect the effectiveness of the treatment. The differences in terms of physiological structures and adaptation are as follows:

1. Children have a large tongue compared to the size of their oral cavity, and the position of the larynx is closer to the front and higher than that of adults. Thus, the top of the larynx closure is next to the back of the palate, causing young children to become obligate nose breathers (Ari & Fink, 2011; Fink, 2012).

2. The narrowest part of the respiratory tract of children younger than 10 years of age is located lower than the vocal cords, which cannot be expanded, so the larynx is funnel shaped. On the contrary, the larynx of adolescents and adults is cylinder shaped (Wanida Pao-in & Apassorn Watanasomsiri, B.E. 2544).

3. The structures of the respiratory cartilages, muscles, and tissues of young children are rather soft. They are not yet strong and can easily collapse compared to those of adults (Dusit Sathavorn, B.E. 2544; Sorasak Lojindarat, B.E. 2544; Everand, 1996).

4. The bronchiole of children is shorter in length and the diameter is shorter compared to that of adults (Harutai Kamalaporn, B.E. 2550). Thus, when it is inflamed, it can be more easily swollen and narrowed. When the diameter

of the airway is shorter, there is more airway resistance, so more energy expenditure is needed during breathing (Wanida Pao-in & Apasson Wattanasomsiri, B.E. 2544).

5. Young children have airway resistance in the respiratory tract more than adults. In general, the airway resistance during oral breathing in young children is about 7 liquid centimeters/liter/second, while that of adults is 0.5-1.5 liquid centimeters/liter/second. When there is narrowing of the airway due to swelling, spasm, or blockage caused by phlegm, the airway resistance can substantial increased (Suparee Suwanjudha, B.E. 2531).

6. Breathing patterns of young children tend to be inconsistent due to incomplete development of the nervous system that controls breathing. The respiratory rate is about 20-60 breaths per minute. Moreover, the chest volume of children is lower than that of adults, and this has an effect on pulmonary functioning and responses of the respiratory tract when the children have respiratory diseases (Suparee Suwanjudha, B.E. 2531).

7. When children are crying, their breathing will be a turbulent flow which increases the airway resistance in a reverse proportion of the radius of the respiratory tract to the power of five, which substantially increases the resistance and the energy needed in breathing (Wanida Pao-in & Apassorn Watanasomsiri, B.E. 2544). This can affect the aerosol therapy, so young children undergoing aerosol therapy should be taken care of until they are in a calm state of mind.

8. Pulmonary compliance and expansion in children are less than those of adults because in adults, their ribs and chest bones support the expansion of the lungs. When the diaphragm muscles and the muscles between the ribs constrict, the lungs can expand. In children, on the other hand, the ribs are much more flexible, so they cannot equally support the lungs' expansion (Wanida Pao-in & Apassorn Watanasomsiri, B.E. 2544). In addition, the ribs of infants are more horizontally lined than those of adults, and their chest is rounder, not oval like that of adults', so the expansion of the ribs is reduced, hence less expansion of the chest and the lungs (Amirav & Newhouse, 2008).

9. The tidal volume of children is lower than that of adults. This is because in children, the diaphragm muscles work more than the ribs, until they reach the age of 5-7 when the ribs began to function more. Moreover, there are fewer

channels of collateral ventilation, particularly at the right upper lobe (RUL) and the right middle lobe (RML), so collapsed lungs are more common at those locations (Prasard & Hussey, 1995).

10. Young children have faster inhalation and respiratory rate, and their inspiration airflow is lower than that of adults (Thitida Chaisupmongkollarp, B.E. 2550; Amirav & Newhouse, 2008).

Based on the aforementioned description, it can be seen that the anatomy and physiology of the respiratory system of children are different from that of adults. From childhood to adulthood, there are changes in characteristics and sizes of the respiratory tract, respiratory rates, tidal volumes, breathing patterns, and lung capacity. The respiratory system of children will begin to function like adults' when they are about 12 years old (Ari & Fink, 2011). Knowledge and understanding of such changes can be applied to provide care and treatment to pediatric patients who have respiratory problems to maximize effectiveness of the treatment and safety of patients (Suparee Suwanjudtha, B.E. 2550).

Aerosol therapy to treat respiratory diseases in young children is complicated and challenging. This is because young children aged 1-5 years old have anatomy and physiology of the respiratory system that is different from that of adults. There are also restrictions in intellectual development which prevents them from cooperating with aerosol therapy. As a result, the amount of aerosolized medication they receive is smaller than that of the adults. In general, in young children aged six months to one year old, the respiratory volume is almost the same as the volume of the air produced by the small volume jet nebulizer, with the oxygen flow rate of 6-8 liters per minute. Thus, they are unable to inhale the aerosol fast enough, and most of the aerosol is left in the upper respiratory tract such as the oral cavity, nose, and some is lost through the ventilation holes. As such, there is less chance that the reservoir will enter the lower respiratory tract. However, when patients are older, there is more likelihood that the reservoir will go into the lower respiratory rate (Amirav, Newhouse, Minocchieri, Castro-Rodriguez, & Schuepp, 2010). There is one study which has reported that only 1% of the aerosol enters the lower respiratory tract of young children (Rubin & Fink, 2003), as most of the aerosol falls in the upper respiratory tract. On the other hand, adults receive 8% to 22% of the aerosol produced

by the small volume jet nebulizer (Rubin & Fink, 2003). Janssens, Krijgsman, Verbraak, Hope, de Jongste, & Tiddens (1999) conducted an experiment in a laboratory to compare the amounts of aerosol in the simulated respiratory tracts of children and adults. They found that more aerosol was found in the simulated adult respiratory tract than in the simulated child respiratory tract. In other words, the amount of aerosol in the upper respiratory tract decreases with age. It could be explained that children's breathing has a lower tidal volume, and their respiratory rate is faster and more intense, particularly when breathing through the nose. Consequently, there is less aerosol that enters the lower respiratory tract and more that enters the upper respiratory tract.

2.3.3 Problems with aerosol therapy in children

There are many restrictions of aerosol therapy when used with young children, both anatomically and physiologically. Moreover, young children tend to lack cooperation and resist the treatment, hence less chance for the aerosolized medication to go into the lower respiratory tract compared to adults.

Crying and resistance in young children receiving aerosol therapy tend to result from fear and discomfort when their movements are restricted. A study has reported that about half of the children cry when they are undergoing aerosol therapy. In the past, it was believed that if children were crying, more aerosols would go into the respiratory tract due to deeper breathing. However, in fact, when children are crying, their exhalation will be extended but their inhalation will be faster and shorter, with a higher frequency. As a result, most of the aerosols are deposited in the upper respiratory tract. An academic paper written by Amirav and Newhouse (2012) which reviewed four research studies on acceptance behavior of aerosol therapy compared to the amount of deposits in infants has shown that when children are crying and resisting the treatment, fewer aerosols can go into the lower respiratory tract and more in the gastrointestinal tract. This is because the children would swallow the aerosolized medication in the upper respiratory tract into the gastrointestinal tract. Moreover, crying not only affects changes in breathing patterns, but it also makes it impossible to perfectly fit the mask on the children's face. Marguet, Couderc, Roux, Jeannot, Lefay, and Mallet (2001) conducted a study on acceptance of aerosol therapy in 94 children

younger than five years of age who received aerosol therapy with MDIs with a spacer conducted by their own caregivers. It was found that 78% of the children cooperated with the treatment, but 22% gave in with difficulty. Also, 38% of the children were crying during the session, particularly those who were younger than others. It was concluded, therefore, that crying of children had an effect on acceptance of aerosol therapy, making it more difficult to put the face mask on, and repeated crying during the therapy was the most commonly found problem in young children, so solutions to such problems needed to be found.

With regard to duration of aerosol therapy, generally each session of aerosol therapy lasts 10 to 15 minutes, which is considered too long for young children to withstand (Aroonwan Preutthipan, B.E. 2546). Young children feel that their activities are restricted, and they lose freedom to control themselves (Supitcha Sangchote & Nualchan Prapphal, B.E. 2544; Aroonwan Preutthipan, B.E. 2546). They may resist the treatment, struggle, and reject the treatment (Amirav et al., 2010). Even though there are a number of research studies which recommend that aerosol therapy be administered while children are sleeping, in practice it is difficult to do so because during the therapy there is a loud noise which is caused by the functioning of the nebulizer, which can wake up the children. Moreover, the duration of aerosol therapy is long, so children can wake up in the middle of the session (Amirav, 2004). In addition, during aerosol therapy, there is a white mist that floats inside the mask, which can cause fear in children and make them have more resistance behavior. Therefore, design and selection of the equipment that suits the patients and that is satisfactory for the caregivers can help increase the efficiency of the treatment (Ari & Fink, 2011).

The dead volume, which remains in the nebulizer after there is no more mist left, is about 1 to 3 ml. (Hess, 2011). The amount of dead volume can be reduced by frequently tapping the nebulizer during the therapy session so as to let the aerosols that are stuck on the sides of the nebulizer to fall down to the bottom and be aerosolized. The nebulizer may be made into a conical shape to reduce the internal surface as well (McCallion, Taylor, Bridges, Thomas, & Taylor, 1996). Everard, Evans, & Milner (1994) conducted a laboratory experiment by using a ventilator and a model with a simulated breathing pattern of children with a tidal volume of 50 ml. and

the respiratory rate of 32 breaths per minute. Two and 4 ml. of 1% sodium cromoglycate was used with the gas flow rate of 8 liters per minute. The duration of the therapy session was five minutes, after which the amount of dead volume in the nebulizer and the amount of aerosolized medication that entered the respiratory tract were measured to determine the difference between tapping and not tapping the nebulizer. It was found that when the nebulizer was tapped at one minute and 30 seconds after the therapy started, which was the time when the medication almost ran out, could result in more aerosolized medication produced by 38%. Also, when measuring the concentration of the dead volume, it was found that the precursory amount of 2 ml. had higher concentration than the precursory amount of 4 ml. Furthermore, it was found that when the medication in the nebulizer almost ran out, there were sputtering sounds that lasted for a while, which indicated a decrease in the amount of aerosols produced (Randolph, Malone, Hollie, Glynn-Barnhart, & Nelson, 1993). Thus, based on this experiment, it could be concluded that tapping the nebulizer during aerosol therapy sessions enables the aerosols to enter the respiratory tract more effectively. However, based on the researcher's experience, when a small volume jet nebulizer is used with young children, they tend not to cooperate with the treatment, and some do not allow the nebulizer to be tapped, probably due to unfamiliarity with the sounds that occur as a result of the tapping. As a consequence, the duration of aerosol therapy lasts longer and the amount of dead volume that remains in the nebulizer increases, less aerosolized medication that enters their respiratory tract.

At present, a small jet nebulizer is generally used with a face mask, rather than a mouth piece, when it is used with young children because of young children's inability to control their own breathing (Amirav & Newhouse, 2008; Ari & Fink, 2011; Everad, 1996). Even though studies have shown that the use of a mouth piece results in more aerosolized medication that enters the respiratory tract, a face mask is preferred because, in addition to inability to control breathing, young children tend to lack cooperation with the treatment and resist aerosol therapy. Previous studies have revealed that the use of a face mask has an effect on deposits on the face and eyes of children. This is because the pressure that produces aerosols pushes the aerosols into the face mask, and the aerosols that leak around the sides of the nose can go directly to

the eyes of children (Hess, 2008; Mitchell, 2008). In their academic paper, Brodie and Adalat (2006) found that 19-month-old children who received aerosol therapy with a face mask using salbutamol and ipratropium bromind had a dilated left pupil that did not constrict in response to light due to side effects of ipratropium bromind that leaked from the face mask and went to their eyes.

Based on study findings, new methods of aerosol therapy have been designed particularly for children such as use of ultrasonic or vibrating mesh which help increase the effectiveness of the treatment but which are more costly (Mitchell, 2008). A technique called "blow-by" can be used with children who put up a lot of resistance to aerosol therapy by putting the tube close to the children's face without using a face mask. However, this method results in a great loss of the aerosols into the atmosphere, so it should not be used (Rubin & Fink, 2003). Similarly, Nikander, Berg, and Smandone (2007) found that when the "blow-by" technique was used, the amount of medication that entered the respiratory tract was reduced due to the distance from the face. In addition, a new type of face mask has been designed to reduce the deposit of the aerosols on the face and eyes, with ventilation holes on both sides of the mask to prevent the aerosols to go directly to the children's eyes (Smaldone, Sangwan, & Shah, 2007). However, there are still problems with loss of the aerosols into the atmosphere through the ventilation holes.

In conclusion, aforementioned problems with aerosol therapy mean further studies are needed to develop and improve the instruments to be used with young children and to find correct and suitable aerosol therapy techniques that best suit young children to maximize the effectiveness of the therapy.

CHAPTER III
METHODOLOGY

This study was an experimental research and control groups with posttest design. The purpose of this study was to compare the amount of dead volume and the duration of aerosol therapy in 1-5 years old asthmatic children who receive aerosolized bronchodilators with the conventional small volume jet nebulizer or with the adapted small volume jet nebulizer.

Population and Sampling

Population

The population in this research was 1-5 year old children, both male and female, who had been diagnosed by a physician as asthma, and need aerosolized bronchodilator therapy.

Sampling

The sample of this research was 1-5 year old children who had been diagnosed by a physician as asthma and were treated with aerosolized bronchodilator therapy at the pediatrics out-patient department at Srisaket hospital, Srisaket province.

The sample was selected by purposive sampling method according to the inclusion and exclusion criteria as follows:

Inclusion criteria

1. They had been diagnosed by physician as asthma and treated with the aerosolized salbutamol bronchodilator.

2. The exacerbation severity is mild or moderate, which categorized by performing the modified pulmonary index score, include oxygen saturation, heart rate,

respiratory rate, accessory muscle use, inhalation-exhalation ratio, and wheezing (carroll et al., 2005).

3. Parents accept to allow children to participate in the research project.

Exclusion criteria

1. Patients with congenital anomaly of respiratory system.

2. Patients with foreign body or large amounts of secretion occluded the airway

3. Patients with severe wheezing symptom having difficult to breathe or symptoms such as tissue cyanosis including an oxygen saturation less than 90 %.while receiving aerosol nebulization.

4. Patients who are difficulty in accepting aerosol nebulization such as excessive crying, squirming and rejection of the device.

Sample size

Sample size was calculated by using the table of Independent t-test in Testing Hypotheses employed by Cohen's concept (Cohen, 1988) at .05 significance level. A 0.80 a conventional level of power of test and a large effect size of 1.68 were used as suggested for nursing or social science research (Polit & Beck, 2012), made the sample size match to 26 samples per group and took into account an average attrition rate of 20%, which equal to 32 samples per group. Thus, this study was conducted with a total of 64 asthmatic children.

In this study, the samples were selected by purposive sampling according to the criteria and randomly assigned by simple random sampling with the labels as control or experimental group until completely sampled. There were 32 subjects in each group.

Settings

The study was conducted during September 2014 – November 2014 at pediatrics out-patient department in Srisaket hospital, that is a tertiary care hospital. The pediatrics out-patient department is operated on Monday to Friday from 08.00 a.m. to 08.00 p.m. The asthma clinic is performed on Friday from 08.00 a.m. to 16.00 a.m. The asthmatic patients were examined by physician. During the examination, the physician would give instructions about the use of the inhale medicine and child care. If the asthmatic children had bad control of disease with wheezing, they would be treated with the aerosolized salbutamol bronchodilator promptly. The follow – up visit and home medications are scheduled based on symptoms by physician's decision.

Research instruments

Research instruments that used in this study composed of two parts as followed:

1. The Experimental instrument.

1.1 A conventional small volume jet nebulizer. This is a regular device that commonly used in general hospital.

1.2 An adapted small volume jet nebulizer. This is a device that designed to add a corrugate tube, 6 inches in length, and 22 millimeters in diameter in a conventional system by attached between the small volume jet nebulizer and the pediatric face mask.

1.3 The protocol for aerosol therapy with small volume jet nebulizer. This is a new procedure that was constructed by the researchers based on the literature reviews.

2. The data collection instruments.

2.1 The demographic assessment was consisted of gender, age, diagnosis, and severity level

2.2 The treatment data was composed of three sections included the following :

The first section consist of type of device.

The second section consist of weight of device.

The third section consist of duration of aerosol therapy.

2.2 An electronic balance.

2.3 A stopwatch.

Validation of Research Instruments

Content validity

In this research, the protocol for aerosol therapy with small volume jet nebulizer was validated by three experts in the field of respiratory disease as followed:

- One pediatric respiratory physician.
- Two clinical nurse specialist in pediatric respiratory care.

The researcher modified the content of the protocol according to the experts' comments and recommendations prior to pilot study, the Content Validity Index was 0.90.

Reliability

1. All of the samples in this study used a brand-new small volume jet nebulizer that had been prof by the company.

2. An electronic balance and a stopwatch, those had been inspected and calibrated prior to the research.

Protection of human rights of the participants

The researcher submitted research proposal to the Institutional Review Board of the Faculty of Medicine, Ramathibodi hospital and Srisaket Hospital Institutional Review Board on Human Research for agreement of ethical research in human subjects. Researcher explained the research objectives, benefits, data collection procedures, and potential risks and inconvenience which might occur to the parents for

an acceptance to be a participant in the study. Parents were informed that they could allow their children to participate or refuse to participate in this study anytime without any negative effects on the medical treatment. The consent form was signed if the parents accepted. The research outcomes would be presented as an overall result without identification of the subjects.

Data collection

The data was obtained by the researcher in the following:

1. Researcher submitted research proposal to the Institutional Review Board of the Faculty of Medicine, Ramathibodi hospital to obtain the certification of ethical research in human subjects.

2. Researcher submitted research proposal to Srisaket Hospital Institutional Review Board on Human Research.

3. After receiving the permission from the Institutional Review Board of the Faculty of Medicine, Ramathibodi hospital, the letter of introduction issued to request for a permission from the Graduate School of Mahidol University was sent to Srisaket hospital for permission to collect data.

4. Once receiving a permission, researcher introduced herself to the head of the nursing division, the head nurse of pediatrics out-patient department, Emergency department and the personnel of those area, explained the research objectives and the process of data collection, and asked for a co-operation in data collection.

5. Researcher selected asthmatic children who met the inclusion criteria and randomly the sample group into two groups: control and experimental group. A control group would receive conventional small volume jet nebulizer for aerosol therapy and an experimental group would receive adapted small volume jet nebulizer for aerosol therapy.

6. Researcher introduced herself to the parents, describes research objectives, expected outcomes and benefits, and data collection procedures, potential risks and inconvenience which might occur. The parents' right to participate or not in

this study. The research outcomes would be presented as an overall result without identification of the subjects. The consent form was signed if the parents accepted to participate in this study.

7. Research assistant is a pediatric nurse who has at least 3 year experiences and was well-trained to collect data about the duration of aerosol therapy.

8. Researcher explained the process of aerosol therapy to the participants and collected the demographic data.

9. Researcher determined a severity of an asthma exacerbation by performing the modified pulmonary index score, include oxygen saturation, heart rate, respiratory rate, inhalation-exhalation ratio, accessory muscle use, and wheezing. Then, the patients received the treatment followed by the protocol for aerosol therapy with small volume jet nebulizer with the following steps:

Control group

- Weigh a conventional small volume jet nebulizer by putting all the equipment, which compose of a small volume jet nebulizer and pediatric face mask in a zip lock bag and weigh using electronic balance.
- Put the medication in the nebulizer while adding the amount of saline solution up to 4 ml.
- Explain the protocol to the parents.
- Comfort patient into upright position.
- Connect one end of the oxygen tubing to the nebulizer and the other to oxygen pipe line.
- Place the mask over the child's nose and mouth. Make sure that it fits comfortably on the child's face at all time of aerosol therapy.
- Turn on the oxygen flow 8 liters per minute, research assistant start the timer.
- Encourage the children to breath normally and observe the possible side effects and inhalation reactions
- Trap the nebulizer when the fume begins thin out and sputtering noise is heard from the nebulizer until noise stops and there is no fume of the aerosol left to be seen, the research assistant stop a timer.

- Weigh the conventional small volume jet nebulizer again when the treatment is completed putting all the equipment, which compose of a small volume jet nebulizer and pediatric face mask in a zip lock bag and weigh using electronic balance.

Experimental group

- Weigh an adapted small volume jet nebulizer by putting all the equipment, which compose of a small volume jet nebulizer, a corrugate tube 6 inches in length, and 22 millimeters in diameter, and pediatric face mask in a zip lock bag and weigh using electronic balance.
- Put the medication in the nebulizer while adding the amount of saline solution up to 4 ml.
- Explain the protocol to the parents.
- Comfort patient into upright position.
- Connect one end of the oxygen tubing to the nebulizer and the other to oxygen pipe line.
- Place the mask over the child's nose and mouth. Make sure that it fits comfortably on the child's face at all time of aerosol therapy.
- Turn on the oxygen flow 8 liters per minute, research assistant start the timer.
- Encourage the children to breath normally and observe the possible side effects and inhalation reactions
- Trap the nebulizer when the fume begins thin out and sputtering noise is heard from the nebulizer until noise stops and there is no fume of the aerosol left to be seen, the research assistant stop a timer.
- Weigh the adapted small volume jet nebulizer again when the treatment is completed putting all the equipment, which compose of a small volume jet nebulizer, a corrugate tube 6 inches in length, and 22 millimeters in diameter, and pediatric face mask in a zip lock bag and weigh using electronic balance.

10. After completion of the data collection, researcher thanked the participants for their participation.

11. All data were inspected, analyzed, and interpreted statistically.

Data analysis

The data were analyzed by using a computer program as followed:

1. Demographic characteristics of patients including gender and severity of asthma exacerbation were analyzed with descriptive statistics of frequency and percentage. The data regarding age of the participants were analyzed in terms of mean, and standard deviation.

2. Difference of demographic characteristics between the control and experimental groups were analyzed by using the Chi-square test and Independent t-test

3. The assumptions were tested by using Komogorov-Smirnov test and Levene's test.

4. Comparisons of the amount of the dead volume between the control group and the experimental group were analyzed by using Analysis of Covariance (ANCOVA).

5. Comparisons of the duration of aerosol therapy between the control group and the experimental group were analyzed by using Analysis of Covariance (ANCOVA).

CHAPTER IV
RESULTS

This study was an experimental research, control groups posttest design. The purpose of this study were to compare the mean of the amount of dead volume and duration of aerosol therapy between the experimental group who received aerosolized bronchodilator with the adapted small volume jet nebulizer and the control group who received aerosolized bronchodilators with the conventional small volume jet nebulizer.

The sample was selected by purposive sampling method who were 1-5 years old asthmatic children, both male and female at the pediatrics out-patient department at Srisaket hospital in Srisaket province. Seventy patients were met the criteria. However, six patients were not participated in this study, due to crying, squirming and rejection of the device during the treatment. The participants remained in this study were 64 patients.

The results of data analysis were presented in four sections as followed:

Section 1: The demographic characteristics of sample groups.

Section 2: The amount of dead volume.

Section 3: The duration of aerosol therapy.

Section 4: The result of hypothesis testing.

Section 1: The demographic characteristics of sample groups.

A total of subjects in this study were 64 asthmatic children. There were thirty- two subjects in each group. The mean age of subjects in the control and the experimental groups were 27 months (S.D. = 12.43) and 40 months (S.D. = 15.01), respectively. The majority of age in the control group and experimental group was 12-36 months (24 cases, 75.00 %) and 37-60 months (18 cases, 71.90 %), respectively. The most subjects were male (18 cases, 56.30 %) equally between the control group

and the experimental group. The majority of the subjects in the control group has been classified as moderate asthma exacerbation (20 cases, 62.50 %), while the experimental group was equally between mild and moderate asthma exacerbation (16 cases, 50 %).

In summary, The demographic characteristics of asthmatic children were compared in both groups. Independent t-test was used to compare age of sample between the control group and the experimental group, and Chi-square test was used to compare gender and severity of asthma exacerbation of sample in both groups. There was statistically significant differences of age between the control group and the experimental group ($p < .05$), as present in table 4.1, whereas gender and severity of asthma exacerbation were not significant differences in both groups, as present in table 4.2.

Table 4.1 Comparison of age between the control and experimental groups

Variable	Control gr. (n = 32)			Experimental gr. (n = 32)			t	p
	Frequency (case)	Percentage (%)	$\overline{X}$	Frequency (case)	Percentage (%)	$\overline{X}$		
Age (month)								
12-36	24	75.00	27.44	14	43.75	40.0	-3.645	.001
37-60	8	25.00		18	56.25			

Table 4.2 Comparison of gender and severity of asthma exacerbation between the control and experimental groups

Variable	Control gr. (n = 32)		Experimental gr. (n = 32)		χ^2	p
	Frequency (case)	Percentage	Frequency (case)	Percentage		
Gender						
male	18	56.30	18	56.30	1.00	.317
female	14	43.80	14	43.80		
Severity of asthma exacerbation						
mild	12	37.50	16	50.00	1.00	.317
moderate	20	62.50	16	50.00		

Section 2: The amount of dead volume.

After completion of aerosol therapy, the mean of the amount of dead volume of subjects in the control group and experimental group were 1.190 cc. (S.D. = 0.406) and 0.989 cc. (S.D. = 0.368), respectively. The lowest of the amount of dead volume in the control group and the experimental group were 0.627 cc. and 0.348 cc., respectively. The highest of the amount of dead volume in the control group and the experimental group were 2.568 cc. and 1.739 cc., respectively, as show in table 4.3.

Table 4.3 The amount of dead volume between the control group and the experimental group. (N = 64)

Group	Frequency (case)	Dead volume (cc)		
		Min-Max	Mean	S.D.
Control gr.	32	0.627-2.568	1.190	0.406
Experimental gr.	32	0.348-1.739	0.989	0.368

Section 3: The duration of aerosol therapy.

The mean duration of aerosol therapy in the control group and the experimental group were 12.96 minutes (S.D. = 2.39) and 12.76 minutes (S.D. = 1.95), respectively. The minimum duration in the control group and the experimental group were 9.07 minutes and 10.21 minutes, respectively. Whereas, the maximum duration in the control group and the experimental group were 19.22 minutes and 17.19 minutes, respectively, as show in table 4.4.

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Table 4.4 The duration of aerosol therapy between the control group and the experimental group. (N = 64)

Group	Frequency (case)	Duration (minute)		
		Min-Max	Mean	S.D.
Control gr.	32	9.07-19.22	12.96	2.39
Experimental gr.	32	10.21-17.19	12.76	1.95

Section 4: The result of hypothesis testing.

Research hypothesis

This study has two hypothesis as follow:

1. The amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer was less than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

2. The duration of aerosol therapy with an adapted small volume jet nebulizer was shorter than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

The result of hypothesis were presented as follow:

Hypothesis 1: The amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer was less than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

The base line of dependent variables (dead volume) were tested with Komogorov-Smirnov test and Levene's test. It was found that the amount of dead

volume was a normal distribution, and there was a positive relationship between the amount of dead volume and age (F = .001, p = 12.956). Consequently, the Analysis of Covariance (ANCOVA) was applied to compare the mean of the amount of dead volume between the control group and the experimental group. The result showed that mean of the amount of dead volume in the experimental group was not different statistically significant from the control group (F = 2.291, p = .592), as present in table 4.5. The result of research hypothesis indicated that the amount of dead volume of aerosol therapy in 1-5 year old asthmatic children who used the adapted small volume jet nebulizer in the experimental group did not differ from the one who used the conventional small volume jet nebulizer. Therefore, this hypothesis was not supported. (Table 4.5)

Table 4.5 Comparison of the amount of dead volume between the control and experimental groups by ANCOVA (N = 64)

Source of Variation	Sum of Squares	df	Mean square	F	p
Age	1.633	1	1.633	12.956	.001
Group	.037	1	.037	.291	.592
Error	7.688	61	.126		
Total	9.964	63			

Hypothesis 2: The duration of aerosol therapy with an adapted small volume jet nebulizer was shorter than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

The base line of variables (duration) were tested with Komogorov-Smirnov test and Levene's test, it was found that the duration was normal distribution, and there was no relationship between the duration and age (F = .555, p = .459). The Analysis of Covariance (ANCOVA) was applied to compare the mean of duration between the control group and the experimental group. The result appeared that, there were no statistically significances difference among this data between the control group and experimental group (F = 1.597, p = .211), as present in table 4.6. The result

of research hypothesis showed that the duration of aerosol therapy in 1-5 asthmatic children who used the adapted small volume jet nebulizer in the experimental group did not differ from the one who used the conventional small volume jet nebulizer in the control group. Therefore, the research hypothesis was not supported. (Table 4.6)

Table 4.6 Comparison of the duration of the aerosol therapy between the control and experimental groups by ANCOVA. (N = 64)

Source of Variation	Sum of Squares	Df	Mean square	F	p
Age	7.548	1	7.548	1.597	.211
Group	2.621	1	2.621	.555	.459
Error	283.604	60	4.727		
Total	295.966	63			

In conclusion, this research found that the amount of dead volume and the duration of aerosol therapy in 1-5 year old asthmatic children who used the adapted small volume jet nebulizer in the experimental group did not differ from the control group who used the conventional small volume jet nebulizer.

CHAPTER V
DISCUSSION

The present study aimed at investigating the effects of an adapted small volume jet nebulizer by comparing the differences in the amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer used with the subjects in the experimental group and a conventional small volume jet nebulizer used with the subjects in the control group. The total number of subjects was 64, with 32 subjects being assigned into the experimental group and the other 32 being assigned into the control group. In this chapter, the study findings were discussed.

Demographic Characteristics of the Subjects

A comparison of the data regarding demographic characteristics of the subjects in both groups revealed that they were not statistically significant difference in terms of gender, and severity of asthma exacerbation, while age was difference in both group. When considering the data regarding the age of both groups, it could be seen that the subjects in the control group were mostly younger than those in the experimental group. Almost two-thirds of the subjects in the control group, or 65.60%, were between 24 and 30 months old, while nearly three quarters of the subjects in the experimental group, or 71.90%, ranged in age from 31 to 60 months old. Because of the problems about age distribution between 2 groups, it seemed to have some effect on the effectiveness of the therapy. During data collection, it was noticeable that aerosol therapy could be done appropriately at all times in children aged 3 years old and older, because they could cooperate well without crying and fighting. On the other hand, when the aerosol therapy was done with the children younger than three years of age, they could not cooperate well. Almost all of them cried, squirmed, and refused to get the aerosol treatment. Face mask could not be fitted

to children's face, the breath was held from time to time, these could had an effect on the amount of the aerosolized medication that entered the respiratory tract.

The amount of dead volume

Hypothesis 1: The amount of dead volume in the nebulizer after aerosol therapy with an adapted small volume jet nebulizer was less than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

The study findings showed that the dead volume of aerosol therapy with an adapted small volume jet nebulizer used with 1-5 year old asthmatic children in the experimental group was not statistically significant difference from that of those in control group, who used a conventional small volume jet nebulizer at the 0.05 level ($F = 2.291$, $p = .592$). The study findings revealed that the mean dead volume of the experimental group was equal to 0.99 (S.D. = 0.37), while that of the subjects in the control group was equal to 1.19 (SD = 0.40). Therefore, Hypothesis 1 was not accepted.

Base on the principles and the theory of air flow, Robert Boyes (1627-1692) posited that when the volume is increased, the gas pressure will be reduced, and the Bernoulli's principle, which contends that when the cross-sectional surface of the flow is increased, the speed of the flow will be reduced (Chaisawad Tianwibul, B.E. 2548). In this study, when a corrugate tube 22 millimeters in diameters was added, the cross-sectional surface of the tube was increased. This, coupled with additional 6 inches of the length of the tube, increased the total volume by 70 milliliters. Therefore, the speed of the aerosolized medication that was hit to the face, the face mask, and the tube wall would be reduced. So the condensation would be decreased that occurred as a result of this. The combined volume from the increased volume of the adapted corrugate tube and the volume of the face mask was close to the tidal volume of young children, so they were able to inhale more aerosolized medication into their respiratory tract, hence less loss of the aerosolized particles into the outside

atmosphere during exhalation (Chatburn & McPeck, 2007; Hess, 2000), and the amount of dead volume should be reduced.

Even though the adapted small volume jet nebulizer was theoretically adapted to use as an effective equipment for aerosol therapy for young children as the reason above. But there was a problem about significant difference in age distribution in the samples as in a discussion earlier, so researcher had to consider to put age as a covariate variable in hypothesis testing. Therefore, the Analysis of Covariance (ANCOVA) was applied to compare the mean of the amount of dead volume between the control group and the experimental group, and a statistically significant analysis could not be achieved. In conclusion, in this study, if age distribution of the two groups was sampling appropriately and was not significant difference, the result should reveal the true effect of the adapted small volume jet nebulizer on dead volume. Future research is still needed to explore the effectiveness of this adapted small volume jet nebulizer due to the scientific reason as in the above discussion.

In previous study, there is no study that has been conducted to study the dead volume on any kind of adapted small volume jet nebulizer. However, there are some studies which indirectly examined the adaptation of a small volume jet nebulizer by adding the reservoir to increase the amount of aerosolized particle into the respiratory tract. Based on the aforementioned discussion of principles and theories, it could be concluded that an addition of a corrugate tube into a regular small jet volume nebulizer can increase the amount of the aerosolized particle that enters the respiratory tract of patients while simultaneously should reduce the dead volume left after the aerosol therapy is completed. For example, Chatburn and McPeck (2007) have proposed a concept of an additional aerosol reservoir which is added into the regular equipment to contain the aerosolized particle and prevent it from losing into the outside atmosphere during exhalation, hence a larger amount of aerosolized medication that enters the respiratory tract. Furthermore, Corcoran, Dauber, Chigier, and Iacono (2002) compared the amount of aerosolized medication from a regular small volume jet nebulizer and an adapted small volume jet nebulizer with a reservoir bag added at the end of the nebulizer. They found that the adapted small jet volume nebulizer could increase the amount of aerosolized particle that entered the respiratory tract by 28% with statistical significance at $p < 0.05$. This was because the reservoir

bag worked to keep the aerosolized particle and prevented them from losing to the outside atmosphere, hence an increase in the amount of the medication that entered the respiratory tract. Likewise, Pitance, Vecellio, Leal, Reychler, Reychler, and Liistro (2010) compared the effectiveness of aerosol therapy in adults using a regular nebulizer, an adapted small volume jet nebulizer, and a vibrating mesh nebulizer. The adapted small volume jet nebulizer was adapted by adding a 110-cc corrugate tube into the nebulizer. It was found that the adapted small nebulizer could increase the amount of aerosolized nebulizer by as much as 33% compared to the regular one ($p < 0.05$). This was because the added corrugate tube could help restore the aerosolized particles that came out with the exhalation, so it was not lost to the outside atmosphere. Moreover, when the nebulizer was tapped on, the aerosolized particle that fell to the inside of the tube and face mask became condensed and turned into droplets that fell into the nebulizer, hence more aerosolized medication to enter the patients' respiratory tract. Therefore, connecting an additional corrugate tube into the regular nebulizer to slow down the speed and to restore aerosolized particles can reduce the loss of aerosolized medication, moreover, the corrugate tube with a length of 6 inches reduce the equipment noise that promoted young children to relax during the aerosol therapy, hence more medication to go into the respiratory tract and possibility to decrease the amount of dead volume in the nebulizer.

Duration of Aerosol Therapy

Hypothesis 2: The duration of aerosol therapy with an adapted small volume jet nebulizer was shorter than that of aerosol therapy with a conventional small volume jet nebulizer in 1-5 year old asthmatic children.

According to the result of data analysis by applying the analysis of covariation (ANCOVA), the duration of aerosol therapy of the experimental group with an adapted small volume jet nebulizer was not different from the duration of the aerosol therapy of the control group with a conventional small volume jet nebulizer with statistical significance at the 0.05 level ($F = 1.597$, $p = .211$). The study findings revealed that the mean duration of aerosol therapy of the subject in the experimental

group was 12.76 (S.D. = 1.95), while that of the subjects in the control group was equal to 12.96 (S.D. = 2.39). Therefore, Hypothesis 2 was rejected.

In fact, the factors that have an effect on duration of aerosol therapy are the amount of fill volume and the gas flow rate used during the therapy (McCallion et al., 1996; Steckel & Eskandar, 2003). If the amount of the fill volume is larger, the duration will be longer. By the same token, if the gas flow rate is faster, the duration of aerosol therapy will be shorter (Hess et al., 1996). Generally, in each aerosol therapy, the amount of fill volume is 4 milliliters and the gas flow rate is 6 to 8 liters per minute, resulting in the aerosolized particles with a diameter of 1 to 10 microns, which is considered the most appropriate size. A small volume jet nebulizer can produce small-sized aerosolized particles that can effectively go into the lower respiratory tract, lasting 10 to 15 minutes (Fink, 2003). Thus, if the amount of fill volume is small, but the gas flow rate is stable at 6 to 8 liters per minute all through the therapy session, the duration of aerosol therapy should be shorter.

The analysis of the study findings showed that when comparing the mean durations of aerosol therapy between the experimental group and the control group (Table 4.4), the mean duration of the experimental group ($\overline{X}$ = 12.76) was shorter than that of the control group ($\overline{X}$ = 12.96). This could be explained that the corrugate tube which was 6 inches in length and 22 millimeters in diameter that connected the face mask and the nebulizer could keep the aerosolized particles inside the mask and the tube, ready for the young patients to inhale it. In so doing, it reduced the fall of the aerosolized medication onto the face, face mask, and tube wall, as well as the condensation of the aerosolized medication that was changed into droplets and fell again into the nebulizer. For these reasons, the mean duration of aerosol therapy of the experimental group was shorter than that of the control group. However, the amount of fill volume was 4 milliliters., which was very small, so a statistically significant analysis could not be achieved. A study conducted by Corcoran, Dauber, Chigier, and Iacono (2002) to determine the effectiveness of nebulizers in the laboratory by comparing the amounts of aerosolized medication intake when a regular small volume jet nebulizer and an adapted small volume jet nebulizer with a reservoir bag added into the end of the nebulizer. They reported that the adapted nebulizer with

an added reservoir bag could increase the amount of aerosolized mediation intake by as much as 28% without increasing the duration of the aerosol therapy session. Therefore, such findings led to a conclusion that adaptation of the nebulizer by adding a conserving device did not result in a longer duration of aerosol therapy.

Based on the findings of the present study, it could be concluded that when an adapted small volume jet nebulizer was used with 1-5 year old asthmatic children, the dead volume in the nebulizer was not statistical significant difference from that of a conventional small volume jet nebulizer ($p > .05$), and the durations of the aerosol therapy between the adapted and the conventional small volume jet nebulizers were not statistical significant difference ($p > .05$).

CHAPTER VI
CONCLUSIONS & RECOMMENDATIONS

The purpose of this study was to compare the amount of dead volume and the duration of aerosol therapy in 1-5 years old asthmatic children who receive bronchodilators with the conventional small volume jet nebulizer or with the adapted small volume jet nebulizer. The conclusions and the recommendations as follows:

Conclusions

This study was an experimental research with posttest design. The purpose of this study was to compare the amount of dead volume and the duration of aerosol therapy in 1-5 year old asthmatic children who receive aerosolized bronchodilators with the conventional small volume jet nebulizer or with the adapted small volume jet nebulizer. In this study, the scientific knowledge related to the anatomy and physiology of the respiratory tract of children and knowledge of aerosol therapy with the small volume jet nebulizer were employed as the conceptual framework of the study. The samples were 1 year to 5 years asthmatic children, both males and females, who had been diagnosed by a physician, and were treated at the pediatric outpatient department at Srisaket hospital, Srisaket province. The samples were selected by purposive sampling according to the criteria and randomly assigned by simple random sampling with the labels as control or experimental group until completely sampled.

Research instruments that used in this study composed of two parts as followed:

1) The Experimental instrument.

1.1 A conventional small volume jet nebulizer. This is a regular device that commonly used in general hospital.

1.2 An adapted small volume jet nebulizer. This is a device that designed to add a corrugate tube, 6 inches in length, and 22 millimeters in

diameter in a conventional system by attached between the small volume jet nebulizer and the pediatric face mask.

1.3 The protocol for aerosol therapy with small volume jet nebulizer. This is a new procedure that was constructed by the researchers based on the literature reviews.

2) The data collection instruments.

2.1 The demographic assessment was consisted of gender, age, diagnosis, and severity level

2.2 The treatment data was composed of three sections included the following:

The first section consist of type of device.

The second section consist of weight of device.

The third section consist of duration of aerosol therapy.

2.3 An electronic balance.

2.4 A stopwatch.

All the data were analyzed by the statistical computer program. The difference of demographic characteristics between the control and experimental groups were analyzed by using the Independent t-test and the Chi-square test. The comparisons of dead volume and duration of aerosol therapy between the control group and the experimental group were analyzed by using Analysis of Covariance (ANCOVA).

The result of study

1. The amount of dead volume in 1-5 year old asthmatic children who used the adapted small volume jet nebulizer in the experimental group did not differ from the control who used the conventional small volume jet nebulizer ($p > .05$).

2. The duration of aerosol therapy in 1-5 year old asthmatic children who used the adapted small volume jet nebulizer in the experimental group did not differ from the control who used the conventional small volume jet nebulizer ($p > .05$).

Limitation of the Study

According to an observation conducted during data collection, it was noticeable that during the experiment with young children older than three years of age, their position could be adjusted so that the aerosol therapy could be conducted appropriately. That is, the corrugated tube that was between the face mask and the nebulizer was in a straight line and did not bend. On the other hand, it could be observed that when the aerosol therapy was conducted with children younger than three years of age, it was more difficult to put them in the correct position. Some of the children were tiny and had a very low body weight. Thus, during the therapy session with the adapted small volume jet nebulizer, the corrugate tube that connected the face mask and the nebulizer was bended and not in a straight line, and this could have had an effect on the amount of the aerosolized medication that entered their respiratory tract. In addition, it was found in this study that the children who were younger than three years old tended to lack cooperation. They cried and resisted the aerosol therapy, so sometimes it was impossible to appropriately cover their face with the face mask. This could have had an effect on the amount of dead volume after the therapy and the duration of the therapy.

Implications and Recommendations

Implications and Applications of Research Finding

1. The study findings revealed that the use of the adapted small volume jet nebulizer did not have any effect on the amount of dead volume in the nebulizer and duration of aerosol therapy, which may have been due to various limitations previously mentioned. Therefore, studies should be conducted to further explore the effectiveness of the adapted small volume jet nebulizer. Nevertheless, nurses working in a clinical setting can still use the small volume jet nebulizer when implementing aerosol therapy with young children with asthma to ensure correct and uniformed nursing care practices.

2. Based on the limitations found in the present study, nurses working in a clinical setting can apply the concept of the adapted small volume jet nebulizer by further adapting or developing the small volume jet nebulizer to ensure suitability when used with young children with asthma.

Further nursing research

Even though the existing principles and theories related to adaptation of the small volume jet nebulizer for young children with asthma yield support to the adaptation with the use of a corrugate tube connected to the reservoir to increase the amount of aerosolized medication that enters the lower respiratory tract, but certain limitations have been identified in the present study and there was a problem about significant difference in age distribution in the samples as in a discussion earlier, thus the study result may not be reveal the true effect outcome. It is recommended that further research should include the subjects who are similar in age or are in the same age group so that the study findings could better determine the effects of the adapted small volume jet nebulizer on the amount of dead volume and the duration of the aerosol therapy.

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APPENDICES

APPENDIX A
PARTICIPANT INFORMATION SHEET

เอกสารชี้แจงผู้เข้าร่วมการวิจัย

(Participant Information Sheet)

ชื่อโครงการวิจัย ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ 1-5 ปีที่เป็นโรคหืด (EFFECTS OF ADAPTED SMALL VOLUME JET NEBULIZER ON DEAD VOLUME AND DURATION OF AEROSOL THERAPY IN 1-5 YEAR OLD ASTHMATIC CHILDREN)

ชื่อผู้วิจัย น.ส.อุไรวรรณ สร้อยอุดม

สถานที่วิจัย โรงพยาบาลศรีสะเกษ จังหวัดศรีสะเกษ

บุคคลและวิธีการติดต่อเมื่อมีเหตุฉุกเฉินหรือมีความผิดปกติที่เกี่ยวข้องกับการวิจัย
น.ส. อุไรวรรณ สร้อยอุดม **หมายเลขโทรศัพท์ที่ติดต่อได้** 081-5450609

ผู้สนับสนุนการวิจัย ไม่มี

ความเป็นมาของโครงการ

การพ่นยาแบบฝอยละออง เป็นวิธีการบำบัดรักษาโรคระบบทางเดินหายใจที่มีประสิทธิภาพ โดยเฉพาะในการรักษาผู้ป่วยที่เป็นโรคหอบหืดและโรคปอดเรื้อรัง โดยฝอยละอองของของเหลวหรือยาจะเข้าสู่ทางเดินหายใจได้โดยตรง ออกฤทธิ์ทันทีในระยะเวลาที่ใกล้เคียงกับการให้ยาฉีดทางหลอดเลือดดำ แต่ใช้ยาในปริมาณที่น้อยกว่า มีผลข้างเคียงน้อยกว่ามาก แต่เนื่องจากสรีรวิทยาของระบบหายใจ และรูปแบบการใจของเด็กเล็กที่มีความแตกต่างจากเด็กโตและผู้ใหญ่ ทำให้การพ่นยาแบบฝอยละอองโดยใช้เครื่องพ่นยาแบบปกติในเด็กเล็กมักพบปัญหาเรื่องประสิทธิภาพในการบำบัดรักษา ประกอบกับเด็กเล็กมักจะร้องไห้กลั้นหายใจเวลาพ่นยา ทำให้ฝอยละอองยาส่วน

ใหญ่ถูกพ่นออกไปสู่บรรยากาศ ส่งผลให้ฝอยละอองยาลงสู่ท่อทางเดินหายใจส่วนล่างลดลง ดังนั้น การประยุกต์อุปกรณ์ที่ใช้ในการพ่นยาแบบฝอยละอองให้มีความเหมาะสมกับเด็กเล็กน่าจะทำให้ประสิทธิภาพในการบำบัดรักษาด้วยการพ่นยาแบบฝอยละอองดียิ่งขึ้น

ดังนั้นผู้วิจัยจึงมีแนวคิดที่จะดัดแปลงอุปกรณ์การพ่นยาแบบละอองฝอยให้มีความเหมาะสมกับเด็ก และสามารถเพิ่มปริมาณฝอยละอองยาสูดเข้าทางเดินหายใจส่วนล่างได้อย่างเพียงพอ ส่งเสริมการรักษาให้มีประสิทธิภาพมากยิ่งขึ้น โดยต่อท่อคอร์รุเกตที่มีความยาวขนาด 6 นิ้ว เส้นผ่านศูนย์กลางประมาณ 22 มิลลิเมตร เชื่อมต่อระหว่างกระเปาะยากับหน้ากาก โดยท่อคอร์รุเกตจะทำหน้าที่เป็นตัวชะลอความเร็ว และเก็บกักฝอยละออง (reservoir) ที่ผลิตขึ้นจากเครื่องกำเนิดฝอยละออง ทำให้ฝอยละอองลอยฟุ้งอยู่ได้ตลอดเวลา เด็กสามารถสูดดมฝอยละอองได้ทัน ฝอยละอองยาเข้าสู่ท่อทางเดินหายใจส่วนล่างได้เพิ่มขึ้น ทำให้ของเหลวที่ค้างอยู่ในกระเปาะพ่นยา (dead volume) ลดลง และระยะเวลาในการพ่นยาน้อยลง

วัตถุประสงค์

1. เพื่อเปรียบเทียบความแตกต่างของปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยา (dead volume) หลังการพ่นฝอยละอองในเด็กเล็กที่เป็นโรคหอบหืด ในกลุ่มที่ได้รับการพ่นฝอยละอองด้วยอุปกรณ์แบบดัดแปลง กับกลุ่มที่ได้รับการพ่นฝอยละอองด้วยอุปกรณ์แบบปกติ
2. เพื่อเปรียบเทียบความแตกต่างของระยะเวลาที่ใช้ในการพ่นฝอยละอองในเด็กเล็กที่เป็นโรคหอบหืด ในกลุ่มที่ได้รับการพ่นฝอยละอองด้วยอุปกรณ์แบบดัดแปลง กับกลุ่มที่ได้รับการพ่นฝอยละอองด้วยอุปกรณ์แบบปกติ

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมการวิจัย

การเข้าร่วมในการวิจัยครั้งนี้เป็นไปด้วยความสมัครใจ มีการแบ่งกลุ่มตัวอย่างเป็น 2 กลุ่ม คือ กลุ่มทดลองคือกลุ่มที่ได้รับการพ่นยาแบบฝอยละอองด้วยอุปกรณ์พ่นยาแบบดัดแปลง และกลุ่มควบคุมที่ได้รับการพ่นยาแบบฝอยละอองด้วยอุปกรณ์พ่นยาแบบปกติ

ขั้นตอนงานวิจัย มีดังต่อไปนี้คือ

- การพ่นยาแบบฝอยละอองนั้นจะดำเนินการเมื่อเด็กเข้ารับการรักษาในหอผู้ป่วยนอกและมีคำสั่งจากแพทย์ให้พ่นยาแบบฝอยละออง

- หลังจากที่ผู้ปกครองยินยอมที่จะเข้าร่วมการวิจัยและลงนามในใบยินยอมแล้ว จากนั้นท่านจะได้รับการบันทึกข้อมูลส่วนบุคคล และผู้วิจัยจะชี้แจงให้ผู้ปกครองทราบถึงวัตถุประสงค์ของการวิจัย และทำความเข้าใจกับผู้ปกครองของกลุ่มตัวอย่างว่าจะทำการพ่นยาด้วยอุปกรณ์ (ตามกลุ่มที่จับสลากได้) แล้วจึงให้ผู้ปกครองลงชื่อยินยอมในแบบฟอร์มเมื่อผู้ปกครองตอบตกลง ผู้วิจัยสอบถามประวัติและลงบันทึกข้อมูลพื้นฐานของกลุ่มตัวอย่างในแบบบันทึกข้อมูลทั่วไป
- สอบถามความพร้อมของเด็กและผู้ปกครองในการพ่นยา นำเด็กและผู้ปกครองเข้าห้องปฏิบัติการพยาบาล ให้คำแนะนำเกี่ยวกับข้อปฏิบัติในการพ่นยา โดยจัดท่าเด็กเล็กนั่งบนตักผู้ปกครอง และหันหน้าไปด้านข้าง ศีรษะแนบกับหน้าอกผู้ปกครอง ให้ผู้ปกครองโอบกอดบุตร
- สำหรับกลุ่มทดลองจะได้รับการพ่นยาแบบฝอยละอองด้วยอุปกรณ์พ่นยาแบบดัดแปลง
- สำหรับกลุ่มควบคุมจะได้รับการพ่นยาแบบฝอยละอองด้วยอุปกรณ์พ่นยาแบบปกติ

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้เข้าร่วมการวิจัย

ผลประโยชน์ที่ผู้เข้าร่วมโครงการจะได้รับคือได้รับการพ่นยาด้วยอุปกรณ์พ่นยาแบบดัดแปลง ซึ่งผู้วิจัยได้มีการทบทวนวรรณกรรม แล้วพบว่าสามารถเพิ่มปริมาณฝอยละอองให้ลงสู่ท่อทางเดินหายใจส่วนล่าง และเพิ่มประสิทธิภาพในการบำบัดรักษา

ผลข้างเคียงที่อาจเกิดขึ้นต่อผู้เข้าร่วมการวิจัยนั้น ที่ผ่านมามีการศึกษาเกี่ยวกับการพ่นยาแบบฝอยละอองในเด็กโดยการประยุกต์อุปกรณ์หรือดัดแปลงให้มีความเหมาะสมกับเด็ก และเปรียบเทียบปริมาณการได้รับฝอยละอองจากการพ่นยาพบว่าอุปกรณ์พ่นยาแบบประยุกต์หรือดัดแปลงที่ใช้ในการศึกษานั้น ไม่ก่อให้เกิดเหตุการณ์ไม่พึงประสงค์ต่อผู้เข้าร่วมวิจัย

หากท่านไม่อนุญาตให้เด็กในปกครองของท่านเข้าร่วมในโครงการวิจัยนี้ สามารถทำได้โดยไม่มีผลต่อการรักษาและพยาบาล ท่านมีสิทธิ์ถอนตัวเด็กในปกครองของท่านออกจากโครงการวิจัยเมื่อใดก็ได้ โดยไม่ต้องแจ้งให้ทราบล่วงหน้า และการไม่เข้าร่วมการวิจัยหรือถอนตัวออกจากโครงการวิจัยนี้ จะไม่มีผลกระทบใดๆ ต่อการบริการและการรักษาที่เด็กในปกครองของท่านสมควรจะได้รับแต่ประการใดและตลอดการดำเนินการวิจัยท่านสามารถซักถามข้อสงสัยเพิ่มเติมได้

การเก็บข้อมูลเป็นความลับ

ข้อมูลส่วนตัวของเด็กในปกครองของท่านจะถูกเก็บรักษาไว้ ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล แต่จะรายงานผลการวิจัยเป็นข้อมูลส่วนรวม ข้อมูลของผู้เข้าร่วมการวิจัยเป็นรายบุคคลอาจมีคณะบุคคลบางกลุ่มเข้ามาตรวจสอบได้ เช่น ผู้ให้ทุนวิจัย, สถาบัน หรือองค์กรของรัฐที่มีหน้าที่ตรวจสอบ, คณะกรรมการจริยธรรมฯ เป็นต้น และหากมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษที่เกี่ยวข้องกับการวิจัยนี้ ผู้วิจัยจะแจ้งให้ทราบโดยรวดเร็วไม่ปิดบัง

ถ้าท่านมีปัญหาข้องใจหรือรู้สึกกังวลใจกับการเข้าร่วมในโครงการวิจัยนี้ท่านสามารถติดต่อกับประธานกรรมการจริยธรรมการวิจัยในคน สำนักงานวิจัยคณะฯ อาคารวิจัยและสวัสดิการคณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี โทร.022011544

APPENDIX B
CONSENT FORM

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

(Informed Consent Form)

วันที่.....เดือน.....พ.ศ. .....

ชื่อโครงการวิจัย ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ 1-5 ปีที่เป็นโรคหืด (EFFECTS OF ADAPTED SMALL VOLUME JET NEBULIZER ON DEAD VOLUME AND DURATION OF AEROSOL THERAPY IN 1-5 YEAR OLD ASTHMATIC CHILDREN)

ชื่อผู้วิจัย น.ส. อุไรวรรณ สร้อยอุดม

ข้าพเจ้าชื่อ.....นามสกุล.....มีความเกี่ยวข้องเป็น.....อนุญาตให้ (เด็กหญิง/เด็กชาย).....อายุ .....ปี……. เดือน เข้าร่วมโครงการวิจัยเรื่อง “ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ 1-5 ปีที่เป็นโรคหืด” ได้รับทราบรายละเอียดและข้อมูลเกี่ยวกับโครงการวิจัย ขั้นตอนการวิจัยและข้อมูลเกี่ยวกับการทำหัตถการ ตลอดจนประโยชน์รวมทั้งความเสี่ยงที่อาจเกิดขึ้นจากผู้วิจัยแล้วอย่างชัดเจน รวมทั้งได้ซักถามข้อสงสัยและทำความเข้าใจเกี่ยวกับการรักษาเป็นที่เรียบร้อยแล้ว และยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้น ข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่เข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ข้าพเจ้าพึงได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นผลสรุปการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ.....(ผู้เข้าร่วมการวิจัย)

.....(พยาน)

.....(พยาน)

วันที่.....

คำอธิบายของผู้วิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยทราบแล้วอย่างชัดเจน โดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ.....

(น.ส. อุไรวรรณ สร้อยอุดม)

ผู้วิจัย

หมายเหตุ: กรณีผู้เข้าร่วมการวิจัยไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือยินยอมฯ นี้ให้แก่ผู้เข้าร่วมการวิจัยฟังจนเข้าใจดีแล้ว และให้ผู้เข้าร่วมการวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวข้างต้นไว้ด้วย

* ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

APPENDIX C
RESEARCH INSTRUMENT

เครื่องมือที่ใช้ในการดำเนินการทดลอง

เครื่องมือที่ใช้ในการดำเนินการทดลอง มี 3 แบบ คือ 1) อุปกรณ์การพ่นยาแบบปกติ 2) อุปกรณ์การพ่นยาแบบดัดแปลง 3) แบบแผนการพ่นยาด้วยเครื่องกำเนิดฝอยละอองขนาดเล็ก

1. อุปกรณ์การพ่นยาแบบปกติ

เป็นอุปกรณ์สำหรับพ่นยาแบบฝอยละอองแบบที่ใช้กันอยู่ทั่วไป ประกอบด้วย ชุดอุปกรณ์กำเนิดฝอยละอองขนาดเล็ก หน้ากากพ่นยาเด็ก และสายนำก๊าซยาว 210 เซนติเมตร (ดังภาพ)

ภาพ 1 รูปภาพอุปกรณ์การพ่นยาแบบปกติ

2. อุปกรณ์การพ่นยาแบบดัดแปลง

เป็นอุปกรณ์สำหรับพ่นยาแบบฝอยละอองที่ผู้วิจัยดัดแปลงขึ้นจากแนวคิดการเพิ่มพื้นที่เพื่อเก็บกักฝอยละออง (reservoir) ชุดอุปกรณ์เครื่องกำเนิดฝอยละออง เพื่อเพิ่มประสิทธิภาพในการพ่นฝอยละอองสำหรับเด็ก ประกอบด้วย สายนำก๊าซยาว 210 เซนติเมตร ชุดอุปกรณ์กำเนิดฝอยละอองขนาดเล็ก ท่อคอร์รูเกต (corrugated tube) ความยาว 6 นิ้ว เส้นผ่านศูนย์กลาง 22 มิลลิเมตร และหน้ากากพ่นยาเด็ก (ดังภาพ)

ภาพ 2 รูปภาพอุปกรณ์การพ่นยาแบบดัดแปลง

3. แบบแผนการพ่นยาด้วยเครื่องกำเนิดฝอยละอองขนาดเล็ก

เป็นแบบแผนที่ผู้วิจัยเรียบเรียงใหม่โดยอ้างอิงจากการทบทวนวรรณกรรม งานวิจัยที่เกี่ยวข้องกับการพ่นยาแบบฝอยละอองมีวิธีปฏิบัติตามลำดับต่อไปนี้

ตารางที่ 1 แบบแผนการพ่นยาด้วยเครื่องกำเนิดฝอยละอองขนาดเล็ก

วิธีปฏิบัติ	เหตุผล
1.สอบถามความพร้อมของเด็กและผู้ปกครองในการพ่นยา นำเด็กและผู้ปกครองเข้าห้องปฏิบัติการพยาบาล และให้นำของเล่นที่เด็กชอบเข้ามาได้ จัดให้ผู้ปกครองและเด็กนั่ง	เตรียมความพร้อมและทวนสอบความเข้าใจ
2.อธิบายผู้ปกครองและเด็กเล็กด้วยภาษาที่เข้าใจได้ง่าย ให้ทราบว่าจะทำการพ่นฝอยละอองยาโดยครอบหน้ากากไว้ที่บริเวณใบหน้าของเด็กเล็กและให้จับหน้ากากให้แนบสนิทกับใบหน้าเด็ก เมื่อมีควันออกมาทางหน้ากาก ให้สูดหายใจเข้าออกตามปกติ ใช้เวลาในการพ่น 10-15 นาที หรือจนกว่าจะมีมีควันออกมาให้เห็น	เพื่อให้ผู้ปกครองและเด็กเล็กรับรู้ เข้าใจขั้นตอนและเตรียมตัวเผชิญเหตุการณ์ข้างหน้าได้ การครอบหน้ากากให้สนิทกับใบหน้าจะลดการสูญเสียของยา (Hui-Ling Lin et al, 2007)
3. ล้างมือ เตรียมอุปกรณ์การพ่นยา ผสมยาซัลบูตามอลตามแผนการรักษา เข้ากับน้ำเกลือ 0.9% ให้ได้จำนวน 4 ซีซี ใส่ในกระเปาะยาในกลุ่มทดลองใช้อุปกรณ์พ่นยาแบบประยุกต์ ส่วนกลุ่มควบคุมใช้อุปกรณ์การพ่นยาแบบปกติ (ในการวิจัยจะใช้อุปกรณ์ใหม่ทุกราย)	เพื่อประกันความเท่าเทียมกันของเครื่องมือที่ใช้ในการทดลองและปริมาณของสารละลายตั้งต้น (ยา+ น้ำเกลือ 0.9%) ปริมาตร 4 ซีซี มีความเหมาะสมในการพ่นยา (อรุณวรรณพฤทธิพันธุ์, 2546; Fink, 2003)
4. นำอุปกรณ์พ่นยาแบบประยุกต์, อุปกรณ์พ่นยาแบบปกติ มาชั่งน้ำหนักด้วยเครื่องชั่งไฟฟ้า จากนั้นนำยาซัลบูตามอลผสมกับน้ำเกลือ 0.9% ให้ได้ปริมาณ 4 ซีซี ใส่ในกระเปาะยา ในกลุ่มทดลองใช้อุปกรณ์พ่นยาแบบประยุกต์ ส่วนในกลุ่มควบคุมจะใช้อุปกรณ์พ่นยาแบบปกติ	เป็นการวัดปริมาณของสารละลายตั้งต้นที่ใช้ในการพ่นยา เพื่อนำไปคำนวณหาปริมาณของสารละลายที่เหลือในกระเปาะพ่นยาหลังจากพ่นยาเสร็จ

5. จัดท่าเด็กเล็กนั่งบนตักผู้ปกครอง และหันหน้าไปด้านข้าง ให้ผู้ปกครองโอบกอดบุตรไว้หรืออุ้มพาดบ่าผู้ปกครอง	เป็นท่านั่งที่เด็กได้รับความรู้สึกอบอุ่นปลอดภัยและสามารถกอดตรึงเด็กไว้ได้
6. ต่อสายยางนำก๊าซเข้ากับแหล่งท่อกาซออกซิเจน แรงดัน 50 ปอนด์ต่อตารางนิ้ว และต่ออีกด้านเข้ากับก้นกระเปาะยา	เพื่อให้ก๊าซไหลเข้าสู่ระบบของอุปกรณ์พ่นยา
7. เปิดก๊าซออกซิเจนให้มีอัตราการไหล 8 ลิตร/ นาที เมื่อเห็นหมอกควัน จะเริ่มครอบหน้ากากพ่นยาให้เด็ก ผู้ช่วยวิจัยเริ่มจับเวลาเมื่อเปิดออกซิเจนโดยแนะนำให้เด็กสูดลมหายใจเข้า ออกตามปกติ ถ้าเด็กให้ความร่วมมือดีให้หายใจเข้าช้าๆลึกๆ เป็นระยะๆ พร้อมสังเกตอาการข้างเคียงที่อาจเกิดขึ้น	เป็นแรงดันก๊าซที่ทำให้เกิดฝอยละอองยาขนาด 2-5 ไมครอนมากที่สุด (วิภา รีชัยพิชิตกุล, 2542; Hess, 2000)
8. ในขณะพ่นฝอยละอองยา ถ้าเด็กเล็กดิ้นรน หรือร้องให้ผู้ปกครองปลอบโยน ให้เล่นของเล่นได้ และถ้าเด็กมีอาการหายใจหอบมากขึ้น หายใจลำบาก หรือมีอาการปกติ เช่นปลายมือ ปลายเท้าเขียว ไอบ่อยมาก หยุดการพ่นไว้และให้เด็กพัก ให้ออกซิเจนทางจมูก 2-3 ลิตร/นาที และรายงานแพทย์ทันที	เพราะเมื่อเด็กต่อต้านการรักษามาก ไม่มีผลดีทางด้านการรักษา ควรปลอบโยนให้เด็กสงบก่อนและให้ผู้ปกครองรู้สึกผ่อนคลาย (ธิติดา ชัยศุภมงคลลาภ, 2550)
9. เมื่อพ่นยาไปจนยาใกล้จะหมดหมอกควันละอองยาจางลงจะเกิดเสียงดังไม่สม่ำเสมอ (sputtering) เกิดขึ้นที่กระเปาะยา ทำการเคาะกระเปาะพ่นยาเบาๆเป็นระยะๆ	เพื่อให้น้ำยาที่เกาะตามผนังกระเปาะหล่นแล้ววนกลับไปผลิตเป็นฝอยละอองใหม่ ผู้ป่วยจะได้รับฝอยละอองเพิ่มขึ้น (McCallion et all., 1996)
10. เมื่อเสียงดังไม่สม่ำเสมอหยุด หมอกควันของละอองยาหมดลง แสดงว่ายาพ่นหมดแล้ว ปิดการไหลของออกซิเจน ผู้ช่วยวิจัยหยุดการจับเวลา แล้วจึงถอดหน้ากากออกจากเด็ก	สิ้นสุดการพ่นฝอยละออง (Gavin, Dunne, Kallstrom, Timothy & Gregory, 2009)

11. นำอุปกรณ์พ่นยาแบบประยุกต์ที่ประกอบด้วยกระเปาะยาต่อกับท่อคอร์รุเกต และหน้ากากพ่นยา ส่วนอุปกรณ์พ่นยาแบบปกติเอาเฉพาะส่วนกระเปาะยาและหน้ากากพ่นยา ใส่ในถุงซิบล็อค ไปชั่งน้ำหนักด้วยเครื่องด้วยเครื่องชั่งไฟฟ้า	เนื่องจากถุงซิบล็อกมีแผ่นฟิล์มที่มีคุณสมบัติสกัดกั้นการระเหยของฝอยละอองยาออกซึ่งจะช่วยเก็บฝอยละอองไว้ได้ เพื่อนำไปคำนวณหาปริมาณของสารละลายที่เหลือในกระเปาะพ่นยาหลังจากพ่นยาเสร็จ

เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูล

คำชี้แจง

เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูล มี 3 แบบ คือ 1) แบบบันทึกการพ่นยาแบบฝอยละออง 2) เครื่องชั่งน้ำหนักไฟฟ้า (Electronic balance) 3) นาฬิกาจับเวลา

1. แบบบันทึกการพ่นยาแบบฝอยละออง

เป็นแบบบันทึกที่ผู้วิจัยเรียบเรียงใหม่จากการทบทวนวรรณกรรม มี 3 ส่วนคือ ข้อมูลพื้นฐาน น้ำหนักของอุปกรณ์การพ่นยา และระยะเวลาในการพ่นยา

ส่วนที่ 1 ข้อมูลพื้นฐาน

Code (สำหรับผู้วิจัย)

กลุ่มตัวอย่างลำดับที่/ HN...../…….. ☐

อายุ…….ปี……เดือน ☐

เพศ……. ☐

การวินิจฉัยโรค…… ☐

ระดับความรุนแรงของโรค (โดยใช้แบบวัดดัชนีปอดฉบับปรับปรุง)

ระดับความรุนแรงของโรค……. ☐

แบบวัดดัชนีปอดฉบับปรับปรุง

	0	1	2	3
Oxygen saturation, %	>95	93-95	90-92	<90
Accessory muscle use	ไม่มี	ใช้กล้ามเนื้อช่วยหายใจ 1จุด	ใช้กล้ามเนื้อช่วยหายใจมากกว่า 1 จุด	ใช้กล้ามเนื้อ paradoxical thoracoabdominal
อัตราส่วนหายใจเข้าต่อหายใจออก	2:1	1:1	1:2	1:3

Heart rate, /min <3 ปี ≥3 ปี	<120 <100	120-140 100-140	141-160 121-140	>160 >140
Respiratory rate,/min <6 ปี	<30	31-45	46-60	>60
Wheezing	ไม่มี	ฟังเสียงวี้ดได้ในช่วงสุดท้ายของการหายใจออก	ฟังเสียงวี้ดได้ในขณะหายใจเข้าและหายใจออกได้ชัดเจน	ฟังเสียงวี้ดได้ในขณะหายใจเข้าและหายใจออกหรือเสียงลมหายใจเข้าและออกเบา

ส่วนที่ 2 น้ำหนักของอุปกรณ์พ่นยา

อุปกรณ์ที่ใช้พ่นยาในการทดลองครั้งนี้ ☐ แบบดัดแปลง

☐ แบบปกติ

น้ำหนักของอุปกรณ์พ่นยา ก่อนทำการพ่นยา……กรัม

น้ำหนักของอุปกรณ์พ่นยา หลังจากพ่นยาเสร็จ…….กรัม

ส่วนที่ 3 ระยะเวลาในการพ่นยา

ระยะเวลาที่ใช้ในการพ่นยา……นาที

2. เครื่องชั่งน้ำหนักไฟฟ้า (Electronic balance)

เป็นเครื่องชั่งน้ำหนักไฟฟ้า (electronic balance) แบบความละเอียดสูง สามารถวัดได้จุดทศนิยม 3 ตำแหน่ง

3. นาฬิกาจับเวลา

เป็นนาฬิกาจับเวลา สามารถจับเวลาได้เป็นวินาที

APPENDIX D
LIST OF EXPERTS

The protocol of aerosol nebulization were validated by three experts in stroke:

1. Lecturer M.D. Harutai Kamalaporn
   Division of Pulmonology, Department of Pediatric, Faculty of Medicine Ramathibodi Hospital, Mahidol University.
2. Mrs. Thitida Chaisupmongkollarp
   Division of Pulmonology, Department of Pediatric, Faculty of Medicine Ramathibodi Hospital, Mahidol University.
3. Ms. Jongrak Utrarachkij
   Division of Pulmonology, Department of Pediatric, Faculty of Medicine Ramathibodi Hospital, Mahidol University.

APPENDIX E

The certification of the Institutional Review Board of the Faculty of Medicine Ramathibodi Hospital, Mahidol University

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
๒๗๐ ถนนพระราม ๖ แขวงทุ่งพญาไท เขตราชเทวี กทม. ๑๐๔๐๐
โทร. (๐๒) ๒๐๑-๑๐๐๐

Faculty of Medicine Ramathibodi Hospital, Mahidol University.
270 Rama VI Road, Ratchathewi, Bangkok 10400, Thailand
Tel. (662) 201-1000

Documentary Proof of Ethical Clearance
Committee on Human Rights Related to Research Involving Human Subjects
Faculty of Medicine Ramathibodi Hospital, Mahidol University

No MURA2014/325

Title of Project	Effects of Adapted Small Volume Jet Nebulizer On Dead Volume and Duration of Aerosol Therapy in 1-5 Years Old Asthmatic Children
Protocol Number	ID 06 – 57 – 30
Principal Investigator	Miss Uraiwan Sroiudom
Official Address	Ramathibodi School of Nursing Faculty of Medicine Ramathibodi Hospital Mahidol University

The aforementioned project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki.

Signature of Secretary Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Duangrurdee Wattanasirichaigoon, M.D.
Signature of Chairman Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Pratak O-Prasertsawat, M.D.
Date of Approval	July 7, 2014
Duration of Study	3 Months

APPENDIX F

The certification of Srisaket Hospital Institutional Review Board on Human Research

เอกสารรับรองจริยธรรมการวิจัยในมนุษย์

เอกสารฉบับนี้ เพื่อแสดงว่าโครงการวิจัย

เรื่อง ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยาและระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ ๑ -๕ ปีที่เป็นโรคหอบหืด

ผู้วิจัยหลัก / เจ้าของผลงาน คือ นางสาวอุไรวรรณ สร้อยอุดม

สถาบัน / หน่วยงาน นักศึกษาพยาบาลศาสตรมหาบัณฑิต สาขาการพยาบาลเด็ก โรงพยาบาลรามาธิบดี คณะแพทยศาสตร์ มหาวิทยาลัยมหิดล

ได้ผ่านการพิจารณาจากคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์โรงพยาบาลศรีสะเกษแล้ว **เห็นชอบ** ให้ผ่านการพิจารณารับรองด้านจริยธรรมการวิจัยในมนุษย์ สามารถดำเนินการวิจัยได้ และเห็นว่าผู้วิจัยต้องดำเนินการตามโครงการวิจัยที่กำหนดไว้ หากจะมีการปรับเปลี่ยนหรือแก้ไขใดๆ ควรผ่านความเห็นชอบจากคณะกรรมการพิจารณาจริยธรรมการวิจัยอีกครั้ง

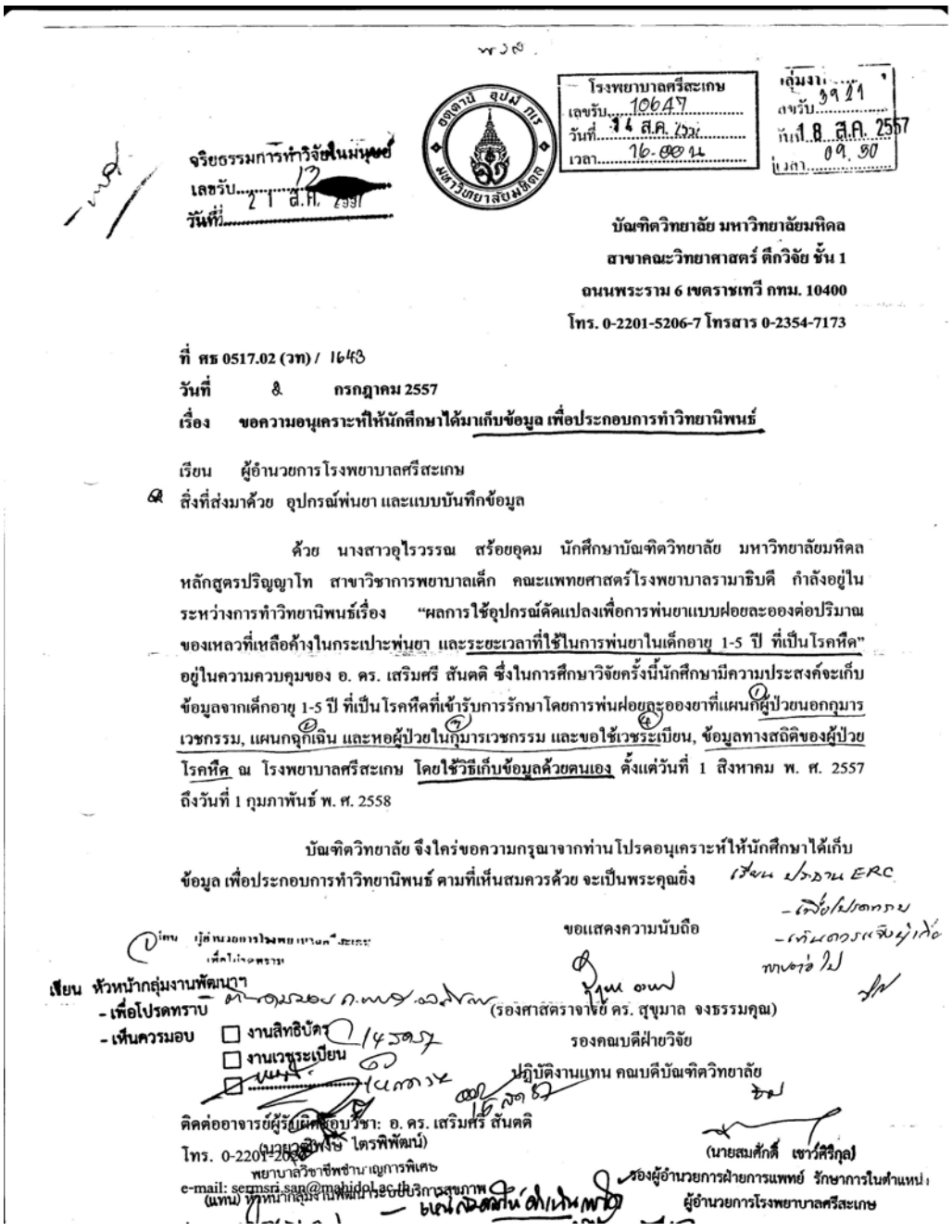
ออกให้ ณ วันที่ ๒๐ เดือน สิงหาคม พ.ศ. ๒๕๕๗

ลงชื่อ .....
(นายสุที วงค์ละคร)
ประธานกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์
โรงพยาบาลศรีสะเกษ

ลงชื่อ .....
(นายอุดม เพชรภูวดี)
ผู้อำนวยการโรงพยาบาลศรีสะเกษ

APPENDIX G

The letter of introduction issued to request for permission to collect data to Srisaket Hospital



จริยธรรมการทำวิจัยในมนุษย์
เลขรับ 21 ส.ค. 2557
วันที่

โรงพยาบาลศรีสะเกษ
เลขรับ 10647
วันที่ 14 ส.ค. 2557
เวลา 16.00 น.

กลุ่มงาน
เลขรับ 3921
วันที่ 18 ส.ค. 2557
เวลา 09.30

บัณฑิตวิทยาลัย มหาวิทยาลัยมหิดล
สาขาคณะวิทยาศาสตร์ ตึกวิจัย ชั้น 1
ถนนพระราม 6 เขตราชเทวี กทม. 10400
โทร. 0-2201-5206-7 โทรสาร 0-2354-7173

ที่ ศธ 0517.02 (วท) / 1643
วันที่ 8 กรกฎาคม 2557
เรื่อง ขอความอนุเคราะห์ให้นักศึกษาได้มาเก็บข้อมูล เพื่อประกอบการทำวิทยานิพนธ์

เรียน ผู้อำนวยการโรงพยาบาลศรีสะเกษ
สิ่งที่ส่งมาด้วย อุปกรณ์พ่นยา และแบบบันทึกข้อมูล

ด้วย นางสาวอุไรวรรณ สร้อยอุคม นักศึกษาบัณฑิตวิทยาลัย มหาวิทยาลัยมหิดล หลักสูตรปริญญาโท สาขาวิชาการพยาบาลเด็ก คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี กำลังอยู่ในระหว่างการทำวิทยานิพนธ์เรื่อง "ผลการใช้อุปกรณ์ดัดแปลงเพื่อการพ่นยาแบบฝอยละอองต่อปริมาณของเหลวที่เหลือค้างในกระเปาะพ่นยา และระยะเวลาที่ใช้ในการพ่นยาในเด็กอายุ 1-5 ปี ที่เป็นโรคหืด" อยู่ในความควบคุมของ อ. ดร. เสริมศรี สันตติ ซึ่งในการศึกษาวิจัยครั้งนี้นักศึกษามีความประสงค์จะเก็บข้อมูลจากเด็กอายุ 1-5 ปี ที่เป็นโรคหืดที่เข้ารับการรักษาโดยการพ่นฝอยละอองยาที่แผนกผู้ป่วยนอกกุมารเวชกรรม, แผนกฉุกเฉิน และหอผู้ป่วยในกุมารเวชกรรม และขอใช้เวชระเบียน, ข้อมูลทางสถิติของผู้ป่วยโรคหืด ณ โรงพยาบาลศรีสะเกษ โดยใช้วิธีเก็บข้อมูลด้วยตนเอง ตั้งแต่วันที่ 1 สิงหาคม พ. ศ. 2557 ถึงวันที่ 1 กุมภาพันธ์ พ. ศ. 2558

บัณฑิตวิทยาลัย จึงใคร่ขอความกรุณาจากท่านโปรดอนุเคราะห์ให้นักศึกษาได้เก็บข้อมูล เพื่อประกอบการทำวิทยานิพนธ์ ตามที่เห็นสมควรด้วย จะเป็นพระคุณยิ่ง

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APPENDIX H

The table of the amount of dead volume and duration of control group

บุคคล (ที่)	ปริมาณของเหลวที่เหลือค้างในกระเปาะ (ซีซี)	ระยะเวลาที่ใช้ (นาที)
1	1.36	12.48
2	1.299	17.32
3	1.218	16.45
4	1.053	16.36
5	0.716	15.1
6	1.811	11.55
7	1.454	15.08
8	1.443	14.23
9	1.359	11.51
10	0.96	12.13
11	1.487	10.18
12	1.006	15.3
13	0.627	12.41
14	0.81	14.04
15	0.822	11.09
16	0.952	12.46
17	0.972	14.11
18	1.137	10.42
19	2.568	9.07
20	0.804	11.11
21	1.544	19.22
22	1.286	15.57
23	1.925	12.38
24	1.176	11
25	1.268	9.27
26	1.293	12.39
27	0.654	13.25
28	0.776	13.4
29	1.065	11.3
30	1.237	11.16
31	0.775	12
32	1.224	11.26

APPENDIX I

The table of the amount of dead volume and duration of Experimental group

บุคคล (ที่)	ปริมาณของเหลวที่เหลือค้างในกระเปาะ (ซีซี)	ระยะเวลาที่ใช้ (นาที)
1	1.48	16.05
2	1.097	11.01
3	0.824	13.05
4	0.948	11.21
5	0.745	13.42
6	0.818	14.04
7	1.319	11.47
8	1.198	15.15
9	1.042	12.12
10	0.8	12.48
11	1.739	11.45
12	1.613	11.35
13	1.523	11.12
14	1.572	12.05
15	0.742	12.57
16	0.852	16.29
17	0.583	10.42
18	0.868	12.06
19	0.98	11.58
20	1.615	17.19
21	0.348	14.54
22	1.172	16.05
23	1.329	15.31
24	0.923	10.33
25	0.533	11.16
26	0.699	13.17
27	0.613	13.52
28	0.808	13.3
29	0.737	10.3
30	0.983	10.21
31	0.567	11.19
32	0.592	13.27

BIOGRAPHY

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