

**Comparison of Vibrating Mesh Nebulizer versus Jet Nebulizer in the
Pediatric Asthma Patient a Randomized Controlled Trial**

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**The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board**

Title:

Comparison of Vibrating Mesh Nebulizer versus Jet Nebulizer in the Pediatric Asthma Patient a Randomized Controlled Trial

Principal Investigator:

Gerald Moody RRT-NPS, Clinical Research Coordinator – Respiratory Care Department, Children's Medical Center - Dallas

1. Introduction and Purpose:

The purpose of this study is to compare clinical outcomes related to our current practice of using a jet nebulizer (JN) with aerosol mask (AM) or mouthpiece (MP) versus a vibrating mesh nebulizer (VMN) with a valved-mask (VM) or MP in the treatment of acute moderate to severe asthma in Children's Medical Center Dallas Emergency Department (CMCED). We hypothesize that using the combination of a VMN and VM or MP will result in fewer hospital admissions, treatments and length of stay in CMCED when compared to our current practice of using a JN and AM or MP.

2. Background:

Inhaled β -agonists are the treatment of choice for patients presenting in the emergency department for acute asthma exacerbation[1-4]. There are different types of aerosol delivery devices and patient interfaces available to administer therapy. JN's and metered dose inhalers (MDI) are commonly used as the main aerosol delivery device in treatment of acute asthma in pediatric patients. A mouthpiece or mask may be used as a patient interface for either device. Interface selection is usually based on patient size, age, compliance, or availability of stocked product.

Current recommendations for the initial treatment of moderate to severe asthma in the emergency department are to administer three β -agonist treatments over 1 hour in 20 minute increments or one treatment continuously over an hour [1, 4]. MDI's or nebulizers can be used to administer intermittent therapy but nebulizers must be used to deliver continuous treatment. Current data suggest continuous nebulized albuterol (CNA) reduces hospital admissions and offers time savings in the delivery of asthma therapy when compared to intermittent treatments.[5, 6] Mouthpieces deliver more aerosolized medication than aerosol masks but it is difficult for children to hold and seal the mouthpiece between their lips for 1 hour during continuous therapy.[7]

VMN's are more efficient and deliver higher concentrations of medication in simulated lung models when compared to JN's.[7-10] In a recent simulated lung model study the combination of a VMN and VM delivered significantly more medication than a JN with AM, and when VMN was used with a mouthpiece there was almost an 8 fold increase in drug delivery.[7] Further studies are needed to assess the clinical efficacy of delivering higher dosages.

3. Concise Summary of Project:

This study will compare clinical outcomes of using a JN with AM or MP versus VMN with VM or MP in the treatment of acute moderate to severe asthma in CMCED. Patients will be treated according to CMCED's current Acute Asthma Clinical Pathway Algorithm for ED (AACPA) and randomized to receive aerosol therapy via JN with AM or MP (control group) or VMN with VM or MP (study group). Study personnel will screen CMCED census through the EMR for patients diagnosed with acute asthma exacerbation with an initial assessment of moderate to severe asthma (AS 5-12), according to the AACPA. Study personnel will approach the parents for study consent as soon as possible after CMCED admission and before any bronchodilator treatment begins. We are evaluating nebulizer devices in this study. Investigators and treating physicians will be blinded to which nebulizer was assigned to each patient. Primary study outcomes will be hospital admission rates. Secondary study outcomes will be number of treatments and length of stay in CMCED.

4. Study Procedures:

Upon admission to CMCED patients diagnosed with acute asthma exacerbation will receive an initial assessment and asthma score (AS), per the AACPA. Patients assessed with moderate to severe asthma exacerbation (Moderate; AS 5-8, Severe; 9-12) will be eligible for enrollment in the study. Patients with impending respiratory failure will not be approached for enrollment. Once enrolled, patients will be randomized to receive aerosol therapy via JN with AM or MP (control group) or VMN with VM or MP (study group). Randomization process will consist of numbering 220 envelopes from 1-220 (110 for each arm). Using a simple randomization method each numbered envelope will be assigned to study or control group with a corresponding card placed inside indicating JN or VMN. Envelopes will then be sealed and held by PI. Envelopes will be assigned to study subjects in numerical order. Mask or mouthpiece selection will be made based on patient's age and/or ability to comply with using a mouthpiece. Patients will be treated according to CMCED's AACPA with the following modifications to allow for blinding and data collection:

Phase 1a (1st hour)

- According to AACPA initial treatment consists of three β-agonist treatments (albuterol & Ipratropium), which can be delivered in 20-minute increments or combined and given continuously over one hour. For blinding and assessment purposes 3 intermittent treatments will be given instead of continuously for this study.
- Two study personnel will be used to provide treatment:
 - One will administer all treatments with assigned nebulizer, perform pre-study assessments and note the start time of the treatment. Once aerosol treatments are completed the assigned nebulizer will be placed in a non-transparent bag for blinding.
 - The second "blinded" study personnel will perform post assessment and assign an AS.
- Since JN and VMN aerosolization rates differ, post assessment by blinded study personnel will not occur until 20 minutes has elapsed from initiation of treatments.
- Patients will receive an AS after each treatment and will be treated accordingly.
- If after the 1st treatment a patient receives an AS of 1-4 (mild) they will be treated according to the "mild" pathway.
- If patients receive an AS of 5-12 (moderate to severe) they will receive their 2nd treatment and/or 3rd treatments.
- Patients will continue to be assessed and scored every 20 minutes regardless of AS.
- This procedure will be repeated until all 3 three treatments and/or assessments are completed in Phase 1a of AACPA.

- Once patients have finished treatments in Phase 1a they will either move to Phase 1b, be discharged or be admitted per AACPA guidelines.
- For consistency in CMCED length of stay and discharge criteria patients will be monitored for 40 minutes after their last treatment before discharge orders.
- If at any time or any Phase, the patient is deemed to be in impending respiratory failure by treating physician, they will be removed from the study and be treated according to physician orders.

Phase 1b (2nd hour)

- Treatments will be administered in the same fashion as Phase 1a with their assigned nebulizer.
- If an additional hour long treatment is ordered per AACPA, 3 intermittent treatments given in 20 minute increments will be administered in the same manner as Phase 1a.
- Once patients have finished treatments in Phase 1b they will either move to Phase 1c, be discharged or admitted per AACPA guidelines.

Phase 1c (3rd hour)

- If patients advance to Phase 1c, they will receive subsequent aerosol treatments and assessments in the same manner until they are either (1) admitted to hospital, or (2) discharged from CMCED per AACPA guidelines/pathway.
- If continuous bronchodilator treatment is ordered per AACPA in Phase 1c then study procedure will stop and patient will be treated per standard practice using large volume jet nebulizer.

5. Sub-Study Procedures:

N/A

6. Criteria for Inclusion of Subjects:

2 to 18 year old (up to 19th birthday) otherwise healthy children with primary diagnosis of acute moderate to severe exacerbation of asthma presenting to Children's Medical Center Emergency Department, Dallas.

7. Criteria for Exclusion of Subjects:

- Children < 2 years old
- Children with comorbid/complex medical conditions such as: congenital or acquired cardiovascular disease, cystic fibrosis, chronic lung disease (other than asthma), bronchopulmonary dysplasia, airway anomalies (e.g., tracheomalacia) or immunodeficiency syndromes.
- Patients with coexisting medical condition such as pneumonia
- Patients in impending respiratory failure as determined by treating physician
- Patients that have had oral corticosteroids within 24hrs of CMCED admission
- Patients that have had bronchodilator treatment within one hour of CMCED admission

8. Sources of Research Material:

Electronic medical record (EMR) will be used to collect data regarding vital signs (HR, RR, SpO₂), breath sounds, work of breathing, and asthma scores. Additional data collected from EMR and used for analysis will be demographics, diagnosis, previous medical history, medication dosages, number of treatments administered, and time in CMCED. Other data not collected in EMR will be recorded on case report forms (CRFs) and entered into a secure password protected EXCEL spreadsheet. Data collected on CRFs will include nebulizer used for treatment based on randomization, type of interface used for treatment (AM, VM, MP), bronchodilator use prior to CMCED admission, oral corticosteroid administration pre/post CMCED admission, patient tolerance/compliance with aerosol treatment, as well as any adverse side effects.

9. Recruitment Methods and Consenting Process:

Study personnel will screen CMCED census through the EMR for patients diagnosed with acute asthma exacerbation and an initial assessment of moderate to severe asthma (AS 5-12), per the AACPA. Patients that have an existing treatment relationship with Co-Investigator Physician might also be approached for enrollment. Study personnel will approach the parents for study consent as soon as possible after CMCED admission and before any bronchodilator treatment begins. Enrollment will be available only to Spanish and English speaking families due to availability of translation services; a translator will be utilized for consent and documentation purposes for Spanish speaking families only. The expected duration of this study is 3-4 months.

10. Potential Risks:

- 1) Loss of Confidentiality**
- 2) Delivery of inhaled Short-Acting Beta₂-Agonists, in general, cause few systemic adverse effects[4]:
 - Tachycardia
 - Skeletal muscle tremor
 - Hypokalemia
 - Increased lactic acid
 - Headache
 - Hyperglycemia

11. Subject Safety and Data Monitoring:

Patient's well-being and medical status will be monitored by CMCED staff throughout their emergency department stay in line with current standards of care and according to the AACPA. Vital signs will be monitored pre and post each aerosol treatment. If a vital sign is noted to be abnormal or an adverse event occurs, the RT or nurse for that patient will notify treating physician and PI. There will be a written report created of any adverse events that occur during treatments and a report will be made to the PI and the PI's faculty sponsor within 24 hours. Any reported adverse events will be reviewed at the time they are reported to determine if the adverse event was in any way caused by the study procedure. Any events deemed due to the study procedure will cause the study to be halted and further reviewed. Changes to the study procedure will be made as needed and reported to the IRB. The study will resume upon approval. Data will also be reviewed weekly by PI and co-investigator for any trends in safety concerns.

12. Procedures to Maintain Confidentiality:

To protect subject confidentiality, all data will be kept in a password-protected Excel database and all hard copies of data case report forms will be stored in a locked filing cabinet within PI's badge access restricted office. Only PI will have key to locked cabinet. Subjects will be given a study identification number, and patient identifiers will not be included in the database or hard copies of files. No patient name or identifying information will be included in any dissemination of study findings. The master list that links patient identifiers to the study subject will be kept recorded in a secure password protected EXCEL spreadsheet and paper copy under lock at the Pls office. It will be made very clear during the consent procedure that the patient/legal guardian will be free to withdraw from the study at absolutely any time, for any reason. Upon completion of data collection, all PHI will be de-identified. Only the study team will have access to study records and data. If a patient revokes authorization for participation in the study, all data will be discarded and will not be used. Data will be collected during the study days, specifically for purpose of the study

13. Potential Benefits:

Potential benefits derived from use of VMN for research subjects are:

- Decreased treatment times
- Fewer overall treatments
- Decreased time in Emergency Department
- Decreased admissions
- Decreased medication dosages

Potential benefits derived from use of VMN to others with similar problems are:

- Decreased treatment times
- Fewer overall treatments
- Decreased Emergency Department and/or primary care physician visits
- Decreased hospital admissions
- Decreased medication dosages
- Better control of symptoms and/or exacerbations

Potential benefits to society derived from use of VMN are:

- Decreased healthcare costs
- Decreased Emergency Department utilization

14. Biostatistics:

Original Power/Sample Size Calculation

Based on a comparable study[11], the hospital admission rate is estimated to be 60% in the jet nebulizer group and 33% in the vibrating mesh nebulizer group, respectively. A sample size of 60 patients per group (120 patients in total) will achieve 80% power to detect statistically significant difference in hospital admission rates between the two groups (significance level=0.05, 2-sided).

Blinded Interim Power Analysis

At 108 patients a blinded interim power analysis revealed the rate of hospitalization is 20/108 or 18.5%. This is considerably lower than the rates anticipated in the original design. This is an indication that either the study population is much different than the population in the referenced work or the implementation of the intervention is different in this study. The overall rate of admission was around 45% in the referenced work. As an estimate of the effect of the intervention, maintaining something similar to a 2 to 1 admission rate between arms, this would indicate the comparison will be between one arm with a 12.5% admission rate and a second arm with a 27.5% admission rate. The same power calculation as before is repeated here for the lower rates which are more in line with what is being observed. This indicates that the shift in rates does have an impact on the power of the study. The study would require 220 subjects to still have 80% power to detect the difference. At the current sample size of 120, the study only has 53.8% power.

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The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: Comparison of Vibrating Mesh Nebulizer versus Jet Nebulizer in the Pediatric Asthma Patient a Randomized Controlled Trial

Funding Agency/Sponsor: CHILDREN'S MEDICAL CENTER FOUNDATION

Principal Investigator: Gerald Moody RRT-NPS

You may call the study doctors or research personnel during regular office hours at 214-456-1367. At other times, you may call them at 469-236-5105

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:

Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?

This study is being done to find out whether a vibrating mesh nebulizer with valved mask or mouthpiece can treat your asthma better than a jet nebulizer with aerosol mask or mouthpiece. Both devices are FDA approved. The jet nebulizer is our standard of care in Children's Medical Center Emergency Department.

Why is this considered research?

This is a research study because:

- Vibrating mesh nebulizer is being compared to the standard jet nebulizer. Both devices are approved by the FDA for delivering aerosolized medication. The

researchers are interested in learning which nebulizer is more effective and/or safer in treating your condition/disorder.

The following definitions may help you understand this study:

- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups
- Single-blind means that you will know which nebulizer you are receiving but the researchers will not know.
- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you have asthma.

Do I have to take part in this research study?"

No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?

About 220 people will take part in this study at Children's Medical Center, Dallas.

What is involved in the study?

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

Group Assignment

If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive aerosol treatment with either a jet nebulizer or vibrating mesh nebulizer. You have a 50/50 chance of receiving treatment with jet nebulizer or vibration mesh nebulizer.

The group you will be in is decided by simple randomization. Neither you nor the researchers will be allowed to choose which group you are assigned to.

This is Single-blinded study, you will know which nebulizer has been assigned to you but the researcher performing post assessments will not know which nebulizer was used to administer your treatments.

Procedures and Evaluations during the Research

During the course of this study you will be treated according to Children's Medical Center Emergency Department (CMCED) Acute Asthma Clinical Pathway Algorithm (AACPA) which is standard of care. Aerosolized bronchodilator (Albuterol and Ipratropium) treatments will not change based on which nebulizer you have been randomly assigned. You will receive nebulizer treatment with either a mask or mouthpiece depending on your age and ability to use a mouthpiece.

Two study personnel will be used to provide nebulizer treatment. One will provide initial assessment and treatment and a second study personnel, who does not know which nebulizer was used, will perform an assessment after each treatment.

After each treatment you will be assessed for additional treatments per the AACPA. Subsequent aerosol treatments and assessments will continue in the same manner until you are either (1) admitted to hospital, or (2) discharged from the emergency department.

If continuous bronchodilator treatment is ordered per AACPA then study procedure will stop and you will be treated per standard practice using large volume jet nebulizer.

How long can I expect to be in this study?

You will be in this study until you are either discharged from the emergency department or admitted to the hospital for asthma exacerbation.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers.

What are the risks of the study?

Study Procedure/Intervention

Vibrating mesh nebulizers may deliver more medication than standard jet nebulizers and possibly increasing common side effects associated with bronchodilators which are:

- Tachycardia (faster than normal heart rate)
- Skeletal muscle tremor (twitching or shakiness)
- Hypokalemia (low potassium in blood)
- Increased lactic acid (lactic acid is the product of cell metabolism)
- Headache (pain in head or neck)

- Hyperglycemia (excess glucose (sugar) in blood)

You will be treated according to Children's Medical Center Emergency Department Acute Asthma Clinical Pathway Algorithm.

These are the same risks that you would experience whether you were in the study or not.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

How will risks be minimized or prevented?

Your well-being and medical status will be monitored by CMCED staff throughout your emergency department stay in line with current standards of care and according to the AACPA. Vital signs will be monitored before and after each aerosol treatment. If a vital sign is noted to be abnormal or an adverse event occurs, the Respiratory Therapist (RT) or nurse for that patient will notify treating physician and Principal Investigator (PI). If at any time the patient is deemed to be in impending respiratory failure by treating physician, they will be removed from the study and be treated according to physician orders.

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Follow the researchers' instructions.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?

If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away.

What are the possible benefits of this study?

If you agree to take part in this study, there may or may not be direct benefits to you.

The researchers cannot guarantee that you will benefit from participation in this research.

Potential benefits derived from use of VMN for research subjects are:

- Decreased treatment times
- Fewer overall treatments
- Decreased time in Emergency Department
- Decreased admissions
- Decreased medication dosages

Potential benefits derived from use of VMN to others with similar problems are:

- Decreased treatment times
- Fewer overall treatments
- Decreased Emergency Department and/or primary care physician visits
- Decreased hospital admissions
- Decreased medication dosages
- Better control of symptoms and/or exacerbations

Potential benefits to society derived from use of VMN are:

- Decreased healthcare costs
- Decreased Emergency Department utilization

We hope the information learned from this study will benefit others with acute asthma exacerbation in the future. Information gained from this research could lead to better asthma treatment.

What options are available if I decide not to take part in this research study?

You do not have to participate in this research to receive care for your medical problem. You can be treated with standard of care nebulizer and per treating physician orders.

Will I be paid if I take part in this research study?

No. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?

Yes, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

If randomized to receive treatment via VMN, you will not be charged for study device.

What will happen if I am harmed as a result of taking part in this study?

It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Children's Medical Center.

You retain your legal rights during your participation in this research

Can I stop taking part in this research study?

Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Your doctor may be a research investigator in this study. She is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?

Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The

information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Aerogen, Ltd
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Whom do I call if I have questions or problems?

For questions about the study, contact Gerald Moody RRT-NPS at 214-456-1367 during regular business hours and at 469-236-5105 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

Name of Participant (Printed)

Signature of Participant Date Time AM / PM

Legally Authorized Representative's Name (Printed)

Legally Authorized Representative's Signature Date Time AM / PM

Name of Person Obtaining Consent (Printed)

Signature of Person Obtaining Consent Date Time AM / PM

ASSENT OF A MINOR:

I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

Participant's Signature (age 10 through 17) _____ AM / PM

Date _____ Time _____

Interpreter Statement:

I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature on the associated short form.

Name of Interpreter (Printed) _____ AM / PM

Signature of Interpreter _____ Date _____ Time _____