Metered-Dose Inhaler versus nebulizer for the treatment of acute asthma exacerbation in preschool children

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Pro/con MDI vs Nebulizer for acute asthma exacerbation in preschool children





Objectives

- 1. Learn about aerosols drug delivery.
- 2. Understand the benefits of MDI devices and the disadvantages of nebulizers.
- 3. Discuss the arguments for MDI use compared to nebulizer use.
- 4. Review studies that support MDI use- regarding efficacy, cost effectiveness and patient and parents' satisfaction.
- 5. Review GINA, CTS and AHS recommendations for the treatment of acute asthma exacerbation in preschool children.

Background-Inhaled Aerosol drug delivery

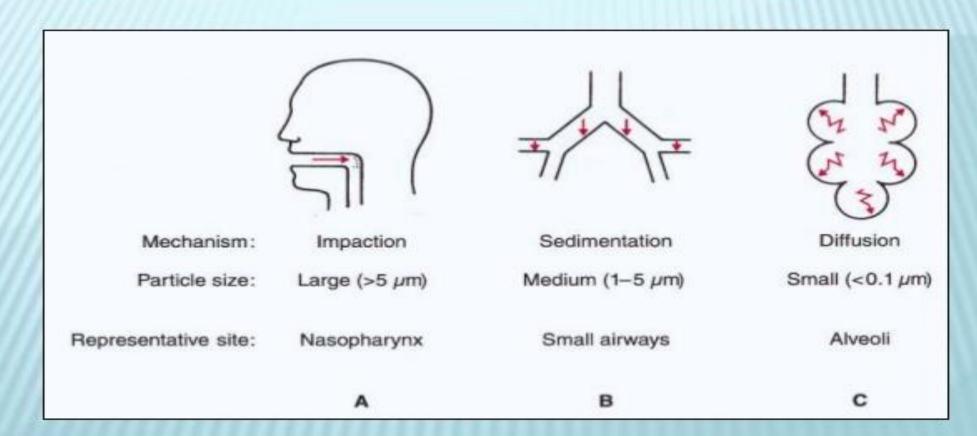
Aerosol is a suspension of solid/liquid particles in gas.

Inhaled Aerosol drug delivery improves **efficacy and decreases side effects** compared to other routes of administration.

Variables determine aerosol deposition: particle size, breathing pattern, anatomic and functional status of the lungs and mode of inhalation.



Mechanisms of deposition of aerosol

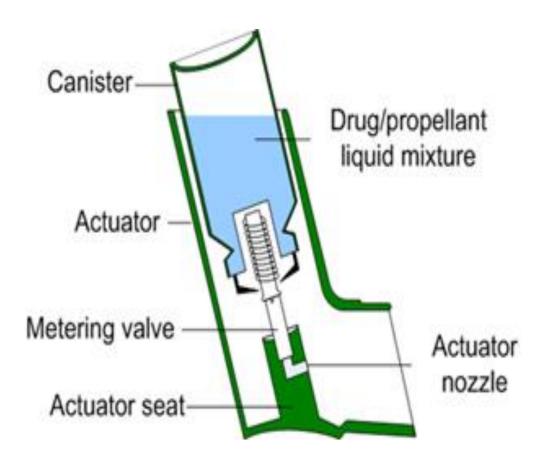


Background-Inhaled Aerosol drug delivery

Aerosols Use for the treatment of many respiratory disorders in children (including asthma).

Inhaled selective B2 agonist is the **drug of choice for acute asthma** in children, and can be delivered by **nebulizer or MDI**.

Background-MDI Metered Dose Inhaler



MDI –a pressurized inhaler that delivers medication by using a propellant spray.

First introduced in 1956 by Riker Laboratories.

MDI consists of 3 major components:

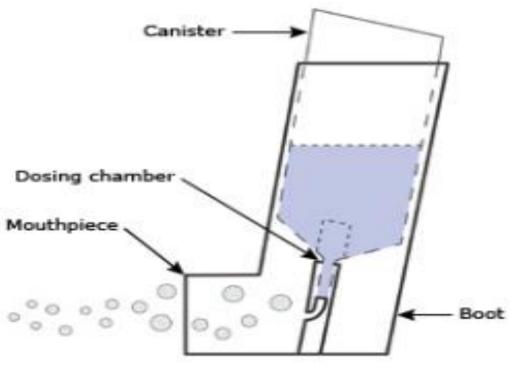
Pressurized Canister -Contains the drug suspended in a mixture of propellants.

Metering valve, metered quantity of the formulation.

Actuator and mouthpiece

Pressure MDI





Benefits of MDI compared to nebulizer

- 1. MDI is more convenient (easy and rapid administration) and is portable.
- 2. MDI is more efficient.
- 3. MDI has less side effects
- 4. MDI is more cost effective.
- MDI increases child and parents' satisfaction from the treatment.
- 6. MDI reduces the risk of bacterial contamination.
- 7. MDI produces accurate and reproducible dosing.

MDI Disadvantages

- 1. MDI required <u>correct coordination</u> of actuation and inspiration due to the **high** velocity of discharge of particles.
- 2. This activity is **difficult for children**, for patients with severe muscle weakness or patients with hand deformities.
- 3. Improper technique increases oropharyngeal drug deposition and side effects.
- 4. It is hard to determine when the MDI is empty.

MDI/AD (accessory devices) –spacer

The development of MDI/AD accessory devices (spacer) in the early 1980, improved the administration of aerosol bronchodilators through MDI and resolved the need for coordination.



Spacer devices

A spacer is an **open-ended tube** or bag.

Spacer allows the aerosol to settle in the chamber and the propellant to evaporate.

Spacers are **100-700ml in volume** and have a distance of **10-30 cm** between the MDI edge and the mouth.

<u>Spacer should be with one way valved-VHC-valve</u> holding chamber



A number of spacer devices are commercially available









Benefits of spacer

- 1. Provides a reservoir of trapped aerosol that can be inhaled for 3-5 sec ,decreases the velocity of the particles and eliminates the need for coordination.
- 2. Decreases the oropharyngeal drug deposition and improves distal delivery of the drug.



Nebulizer- background

Widely used to deliver aerosol therapy in children.

Nebulizers are commonly used in patients who are very ill and in situations where large drug doses are needed.

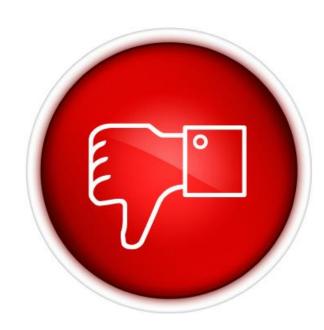
Nebulizer benefits

- 1. Allows provision of **oxygen** in case of hypoxia.
- 2. Large doses of the drug can be delivered (antibiotics-such as Tobramycin).
- 3. Some medications are available only in liquid form (DNAase, hypertonic saline).



Nebulizer Disadvantages

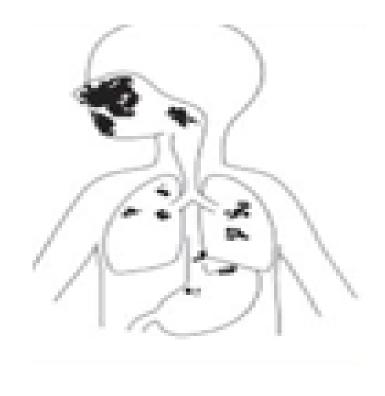
- 1. Requires a **power source** /compressed air or oxygen.
- 2. Needs more delivery time that decreases compliance.
- 3. Requires regular maintenance (clean after every use).
- Large particles impact in the upper airway ,systemically absorbed, more side effects.
- More expensive (equipment, staff time and drug cost).
- 6. Risk of **infections** (Gram negative).
- 7. Risk of **drug exposure** to staff and caregiver.
- Highly variable rate of aerosol delivery. Inefficient/waste medication.
- 9. Noisy and intimidate.

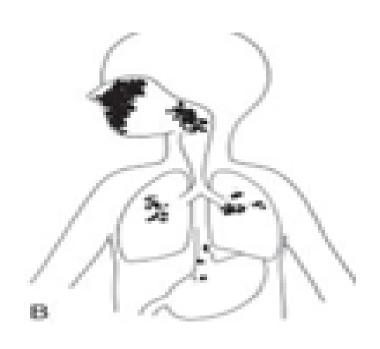


Radiolabeled Ventolin deposition MDI vs NEB

MDI USE WITH NON TIGHTLY FITTED MASK

NEB USE WITH NON TIGHTLY FITTED MASK

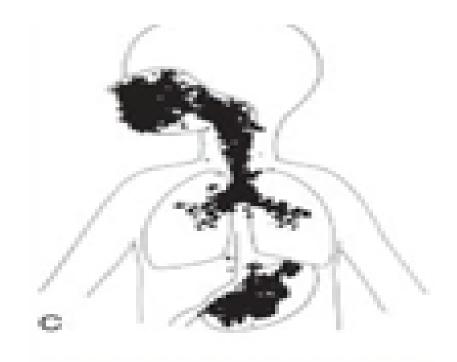


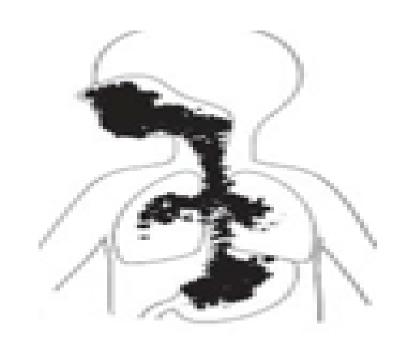


Radiolabeled Ventolin deposition MDI vs NEB

MDI USE NON COOPERATIVE CHILD



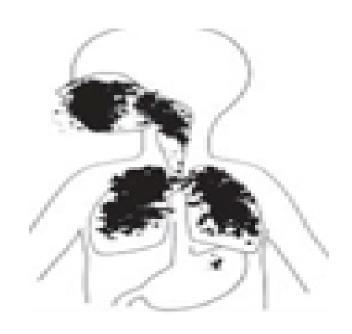


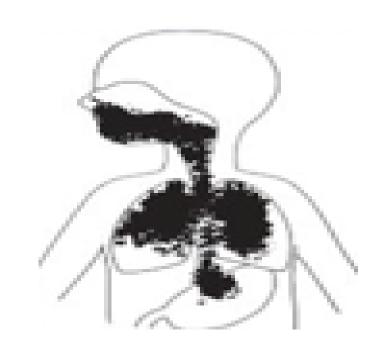


Radiolabeled Ventolin deposition MDI vs NEB

MDI USE IN COOPERATIVE CHILD WITH FITTED MASK

NEB USE IN COOPERATIVE CHILD WITH FITTED MASK





Pro- MDI use

Efficacy

Cost effectiveness

Patient and parents satisfactions

Efficacy

Metered-Dose Inhaler Accessory Devices in Acute Asthma

Efficacy and Comparison With Nebulizers: A Literature Review

Israel Amirav, MD; Michael T. Newhouse, MD, FRCPC

Efficacy

10 RCT-randomized controlled trials,

301 children (0-18y) treated with B agonists via MDI+AD and **274 children** via nebulizers.

Major outcomes: PFT, SaO2 and clinical assessment.

Results: 2 studies showed that MDI+AD was more effective than nebulizer, 8 studies MDI+AD is as effective as nebulizer.

There was a **tendency to prefer the use of MDI+AD** (convenience, fast, patient preferences and cost effective).

Conclusion: MDI+AD should be the first line treatment in acute asthma in children.

Summary of Study Design and Results in Studies Comparing Treatments for Acute Childhood Asthma*

Source, y	Setting	Mean Age (Range), y	No. (Total) Subjects, MDI/SVN	Dose Ratio, MDI:SVN	Variables Measured			
					Clinical Outcome	Saoz	PFT	Results of MDI vs SVN
Freelander and Van Asperen, ¹⁴ 1984	ED	7.6 (3-13)	14/14 (28)	1:2	Yes	No	Yes	ŧ
Fuglsang and Pedersen,16 1986	ED	10.0 (7-14)	21/21 (21)†	1:1	Yes	No	Yes	Better
Pendergast et al,16 1989	ED	4.5 (3-7)	18/9 (27)	1:2, 1:4	Yes	No	No	į.
Ba et al, 17 1989	Hospital	11.9 (7-18)	14/13 (27)	1:4	Yes	No	Yes	
Lee et al,18 1991	Office	3.2 (0.5-6)	16/17 (33)	1:3	Yes	Yes	No	
Kerem et al, 19 1993	ED	10.3 (6-14)	17/16 (33)	1:5	Yes	Yes	Yes	.
Lin et al,20 1995	ED/clinic	8.3 (5-16)	56/55 (111)	1:6	Yes	Yes	Yes	Better
Parkin et al,21 1995	Hospital	3.0 (1-5)	30/30 (60)	1:4	Yes	No	No	
Chou et al, ²² 1995	ED	7.7 (NA)	71/81 (152)	NA	Yes	Yes	Yes	= or Better
Williams et al,23 1996	ED	10.4 (6-18)	42/18 (60)	1:6.9	Yes	Yes	Yes	

Efficacy

β-AGONISTS THROUGH METERED-DOSE INHALER WITH VALVED HOLDING CHAMBER VERSUS NEBULIZER FOR ACUTE EXACERBATION OF WHEEZING OR ASTHMA IN CHILDREN UNDER 5 YEARS OF AGE: A SYSTEMATIC REVIEW WITH META-ANALYSIS

JOSÉ A. CASTRO-RODRIGUEZ, MD, AND GUSTAVO J. RODRIGO, MD

The Journal of Pediatrics • August 2004

Results

6 RCT that were published between 1998-2003.

491 children (<5y) were randomly received B agonist via MDI+VHC or nebulizer.

Primary outcome- hospital admission.

Secondary outcomes -clinical score (severity assessment), duration of treatment in the ED, RR, SO2 and HR.

Results primary outcome-hospital admission

Primary outcome- hospital admission

Children with MDI+VHC showed a significant **lower admission rate** (>50%) compared to nebulizer (OR 0.42, 95% CI 0.24-0.72, P=0.02).

More significant among children with moderate to severe wheezing exacerbations (OR 0.27, 95% CI 0.13-0.54, P=0.0003).

Primary outcome- hospital admission

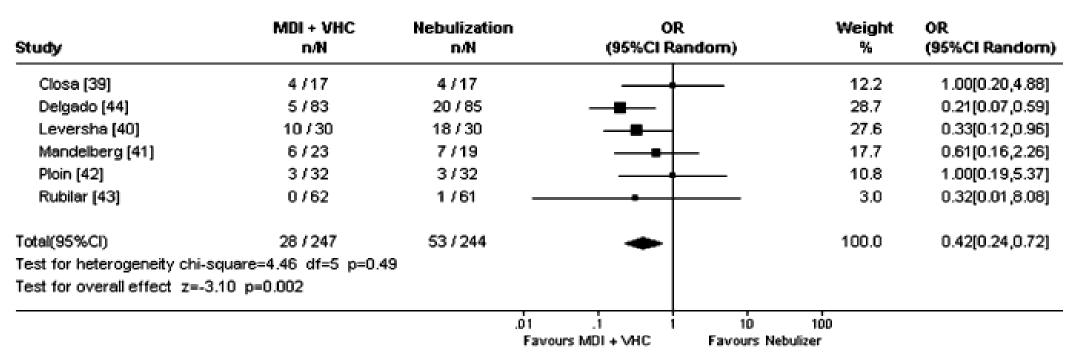


Fig 1. Pooled odds ratios of hospital admissions comparing treatment with β-agonists by MDI+VHC or nebulizer. Logarithmic scale was used for plotting odds ratios. Width of horizontal line represents 95% CI around point estimate (black square). Size of point estimate represents relative weight (percentage of weight) of each trial in the pooled summary estimate (diamond). Vertical line is line of no effect (OR, 1.0).

Results-secondary outcomes

- 1. Five studies with clinical scores were analyzed. The analysis showed a significant decrease of severity in the clinical score with MDI+VHC use (95%CI -0.68 to -0.20, p=.0003).
- 2. Two out of three studies that **reported HR** showed **significant increase of HR** with **nebulizer use**.
- One study showed a significant increase in RR with nebulizer use.
- 4. No differences in **oxygen saturation**.

Secondary outcome- clinical score

Study	MDI + VHC n	mean(sd)	Nebulizer n	mean(sd)	SMD (95%CI Rar		SMD (95%Cl Random)
Closa (39)	17	2.70(2.00)	17	4.10(2.20)		10.1	-0.65[-1.34,0.04]
Delgado [44]	83	3.70(1.70)	85	4.30(2.60)	-	33.7	-0.27[-0.58,0.03]
Leversha [40]	30	4.60(1.80)	30	5.10(1.80)		16.8	-0.27[-0.78,0.23]
Mandelberg [41]	23	4.90(1.20)	19	5.20(1.20)		12.5	-0.25[-0.86,0.36]
Rubilar [43]	62	3.50(0.80)	61	4.20(1.00)	-	26.9	-0.77[-1.14,-0.40]
Total(95%CI)	215		212		•	100.0	-0.44[-0.68,-0.20]
Test for heterogeneity of	:hi-square=5.43	df=4 p=0.25			-		
Test for overall effect 2	-	-					
lest for overall effect 2	z=3.66 p=0.0003						
					Favours MDI + VHC	2 4 Favours Nebulizer	

Fig 2. Pooled SMD in clinical score after treatment with β-agonists by MDI+VHC or nebulizer. SMD represents difference in means between groups displayed on SD units. Width of horizontal line represents 95% CI around point estimate (black square). Size of point estimate represents relative weight (percentage of weight) of each trial in the pooled summary estimate (diamond).

Study conclusion

B agonists by MDI+VHC was more effective.

Side effects were lower suggesting less systemic absorption.

Conclusion: MDI+VHC should be used as a first choice to administer beta-agonists in children<5y of age for the treatment of acute exacerbation of wheezing/asthma in the PED.

Efficacy



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J Asthma, 2016; 53(10): 1059–1062 © 2016 Taylor & Francis. DOI: 10.1080/02770903.2016.1185114



PHARMACOTHERAPY

Spacers versus nebulizers in treatment of acute asthma – a prospective randomized study in preschool children

Niki Mitselou, MD1, Gunilla Hedlin, MD, PhD2, and Carl-Axel Hederos, MD, PhD3

Spacer versus nebulizer for the treatment of acute Asthma in preschool children

Aim: to compare the use of spacer device to nebulizer device to administer bronchodilators in acute asthma attack in the PED in preschool children (0-6y).

RCT that included 98 children (0-6y).

45 pt were treated with MDI, 53 pt with nebulizer.

Primary outcome: admission rates and LOS (length of stay) PED.

Secondary outcomes: SO2, RR, HR.

Spacer versus nebulizer for the treatment of acute Asthma in preschool children

Results:

Primary outcome- LOS-PED and admission rates were similar.

Secondary outcomes- HR, RR, SO2- showed no significant differences.

Conclusion: MDI with spacers <u>are at least as effective</u> as nebulizers in the delivery of B- agonists to treat preschool children with acute asthma/wheezing.

Cochrane systematic review-2013-Holding chambers (spacers) versus nebulizers for beta-agonist treatment of acute asthma (Review)

Aim: To assess the effects of spacers compared to nebulizers for the delivery of beta agonists for acute asthma.

Selection criteria: RCT in adults and children (>2y) with asthma.

39 trials that included 1897 children and 729 adults.

33 trials were conducted in the ER and equivalent community settings, 6 trials in inpatients with acute asthma.



Cochrane systematic review-2013-Holding chambers (spacers) versus nebulizers for beta-agonist treatment of acute asthma (Review)

Results and conclusions: (Regarding children).

- 1. No significant difference in hospital admission rates.
- 2. LOS-PED was significantly shorter with spacer use. The mean time difference was 33 minutes less.
- 3. HR was lower with spacer use, mean difference -5% difference.
- 4. Tremor was lower with spacer use (RR 0.64; 95% CI 0.44 to 0.95).

The latest and largest systematic review - 2016





Allergy

REVIEW ARTICLE

Inhaled short-acting bronchodilators for managing emergency childhood asthma: an overview of reviews

M. Pollock¹, I. P. Sinha², L. Hartling¹, B. H. Rowe³, S. Schreiber¹ & R. M. Fernandes^{4,5}

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13 systematic reviews including 56 trials (RCT+/CCT).

5526 children (0-18y) who were treated in the PED or equivalent care setting for acute exacerbation of asthma or recurrent wheeze.

Exclusion criteria: single first episodes of wheezing or bronchiolitis.

Allergy EUROPEAN JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY



Interventions: inhaled SABA ,SAAC (short acting anticholinergics) and inhaled magnesium sulfate that were administered via MDI +/- spacer or nebulizers.

Primary outcomes: hospital admission, LOS in the PED, ICU +/-ventilation.

Secondary outcomes: clinical assessment, adverse effects (N/V, tremor), **PFT**-PEF, FEV1.





1. Results regarding B-agonist via MDI vs Nebulizer:

Primary outcome:

- 1. For children < 3y : 6 trials, (490 children)- treatment with MDI+spacer led to 44% decrease in admission. Limited to younger children with moderate to severe asthma only.
- 2. For children age 3-18y: 10 trials (784 children) showed no difference in admission. 3 trials (396 children) showed that MDI with spacers led to decrease in PED LOS of about 30min regardless of asthma severity.





- 1. Results: for secondary outcomes:
 - For children <3y :inconsistent.
 - For children 3-10y: SABA via MDI showed decreased incidence of tremor by 37% compared to nebulizer.

<u>Conclusion</u>: SABA should be given as the first line bronchodilator with the use of MDI + spacer in children with mild to moderate attacks, particularly in young children.



Economic impact of Salbutamol inhalation procedure in ED.

Most studies showed that MDI is associated with significant economic gains and decreased costs.

ORIGINAL RESEARCH • RECHERCHE ORIGINALE

A Cost Analysis of Salbutamol Administration by Metered-Dose Inhalers with Spacers versus Nebulization for Patients with Wheeze in the Pediatric Emergency Department: Evidence from Observational Data in Nova Scotia

Paul Spin, MA, PhD ABD*; Ingrid Sketris, PharmD, MPA(HSA)[†]; Barbara Hill-Taylor, BSP, MLIS[†]; Courtney Ward, MA, PhD*; Katrina F. Hurley, MD, MHI[‡]

CJEM 2017;19(1):1-8

<u>Aim</u>: to evaluate the **relative costs of MDI versus nebulizer** for Salbutamol inhalation.

<u>Methods</u>: Retrospective cohort study that collected data from patients' charts to estimate the associations between MDI/nebulizer and costs, LOS-PED and LOS-hospital and the probability of hospital admission.

<u>Population:</u> a random sample of **822 children** presenting with wheeze to the PED in IWK Health Centre in Maritime Canada.

664 were treated via MDI and 158 with NEB.

Cost of MDI versus nebulizers

	Resource Use	CDN\$*/Unit	CDN\$/Patient, 1 treatment
MDI-s			
MDI†	1 unit /patient	2.95/Unit	2.95‡
Spacer§	1 unit/5 patients	33.07/Unit	6.61
Nursing Time¶	140.4 seconds/treatment	31.88/hour	1.24
			Total = 10.80
NEB			
Mask	1 unit/patient	0.97/Unit	0.97
Tubing	1 unit/patient	0.27/Unit	0.27
Nebule	1/treatment	0.43/Unit	0.43
Nursing Time¶	1,256.6 seconds/treatment	31.88/hour	11.13
Salbutamoll	5 mg/treatment	0.06/mg	0.30
			Total = 13.10
MDI-s and NEB			
Inpatient Cost	-	1,077/day	-

Results:

- 1. **PED-LOS** was **similar** in both groups.
- 2. Treatment with MDI showed lower costs and improved clinical outcomes.
 - 1. Reduction in admission rate of 4.4% (p<0.05) and reduction of 25h on average in inpatient stay (for those who were admitted).
 - 2. Saving of 24CND\$/pt in PED costs.
 - 3. Saving of 180CND\$/pt in total cost per visit (p<0.001) mostly due to lower inpatient costs.

Conclusion: MDI for salbutamol inhalation was associated with significant economic gains.

Cost-effectiveness of Metered-Dose Inhalers for Asthma Exacerbations in the Pediatric Emergency Department

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KEY WORDS

asthma, metered-dose inhalers, nebulizers, β agonist, cost-effectiveness

ABBREVIATIONS



WHAT'S KNOWN ON THIS SUBJECT: Treatment of mild and moderate asthma exacerbations in emergency departments can be efficaciously delivered by using either metered-dose inhalers or wet nebulization. Cost is a frequently cited reason for not using metered-dose inhalers over nebulization in emergency departments.



WHAT THIS STUDY ADDS: Metered-dose inhalers are a costefficient mode of delivery for bronchodilators, and transitioning from nebulization to metered-dose inhaler in pediatric emergency departments may result in significant cost savings associated with each admission averted.

TABLE 2 Baseline Model of Cost-effectiveness of an MDI Versus Nebulization in the Treatment of ED Pediatric Asthma Exacerbations

Treatment Protocol	Cost, Can\$	Effect (Admission Averted)	Incremental Cost-effectiveness (Can\$ per Admission Averted)
Overall MDI and space chamber with hospital admission costs	262.73	0.906	
Averaged drug and delivery-device costs	14.94		
Averaged nursing time for the LOS in ED costs	27.42		
Probability of admission multiplied by hospital admission costs	220.37		
Wet nebulization with hospital admission costs	417.68	0.844	
Averaged drug and delivery-device costs	4.75	_	
Averaged nursing time for the LOS in ED costs	46.60		
Probability of admission multiplied by hospital admission costs	366.33		
Incremental	-154.95	0.062	-2499.16

Child and parents satisfaction with MDI

J. Paediatr. Child Health (2002) 38, 604–607

Child and parent satisfaction with the use of spacer devices in acute asthma

EM COTTERELL,1,2 M GAZARIAN,2 RL HENRY,2 MW O'MEARA1,2 and SR WALES1

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Child and parents satisfaction with MDI

<u>Aim</u>: to evaluate both child and parents' satisfaction with the use of MDI + spacer.

<u>Methods</u>: Parents and children >8y, presented to the PED with mild to moderately severe acute asthma attack and were treated with bronchodilators by MDI. They were asked to complete separate questionnaires independently.

Child and parents satisfaction with MDI

Results: 111 parents, 17 children responded.

84% of the parents found it easy/very easy to use the spacer.

84% of the parents preferred the spacer over the nebulizer.

82% of the children preferred spacer because it was quicker and easier to use.

Conclusion: the use of spacer devices in mild-moderately severe acute asthma is highly acceptable for children and parents.

Alberta Health Services pharmacy Services



Issue 16: February 2017

Drugs and Therapeutics Backgrounder

Nebule to Metered Dose Inhaler (MDI) with spacer Therapeutic Interchange

BOTTOM LINE: Whenever possible, any order for <u>nebulized</u> ipratropium, salbutamol, combination ipratropium/salbutamol, or budesonide should be interchanged to a MDI with spacer.

<u>Background</u>: Conversion of nebulized ipratropium, salbutamol, combination ipratropium/salbutamol, or budesonide to a MDI with spacer reduces the risk of medical air/oxygen misconnects, spread of infection, drug exposure to staff, and adverse effects to patients.

<u>Efficacy:</u> MDI with spacer produces outcomes that are at least equivalent to administration by nebulizer in both adults and pediatrics in the emergency department and inpatient settings.^{1,2} Dose equivalence between drugs given by nebulization or MDI with spacer is not well–defined in the literature.^{1,2} The proposed dose conversions have been used successfully within AHS and Covenant Health.

Alberta Health Services pharmacy Services



Issue 16: February 2017

Drugs and Therapeutics Backgrounder

Treatment by wet nebulization is restricted to:

- Severe, life-threatening respiratory disease (e.g. those with severe or impending respiratory arrest, those with hypoventilation or ventilation compromise, continuous nebulization, end-stage COPD, CF);
 OR
- Patients who are uncooperative or are unable to follow the directions required for MDI with spacer use;
 OR
- Patients with a history of poor response to MDI with spacer

As with any medication change, it is important for a provider (e.g. clinical pharmacist, physician, nurse, or respiratory therapist) to do a patient assessment of dose response and side effects.

CHOICE OF INHALER DEVICE

Inhaled therapy constitutes the comerstone of asthma treatment in children 5 years and younger. A pressurized metered dose inhaler (pMDI) with a valved spacer (with or without a face mask, depending on the child's age) is the preferred delivery system⁴⁷⁰ (Box 6-7) (Evidence A). This recommendation is based on studies with beta₂-agonists. The spacer device should have documented efficacy in young children. The dose delivered may vary considerably between spacers, so consider this if changing from one spacer to another.

The only possible inhalation technique in young children is tidal breathing. The optimal number of breaths required to empty the spacer depends on the child's tidal volume, and the dead space and volume of the spacer. Generally 5–10 breaths will be sufficient per actuation. The way a spacer is used can markedly affect the amount of drug delivered:

- Spacer size may affect the amount of drug available for inhalation in a complex way depending on the drug
 prescribed and the pMDI used. Young children can use spacers of all sizes, but theoretically a lower volume
 spacer (<350 mL) is advantageous in very young children.
- A single pMDI actuation should be delivered at a time, with the inhaler shaken in between. Multiple actuations into
 the spacer before inhalation may markedly reduce the amount of drug inhaled.
- Delay between actuating the pMDI into the spacer and inhalation may reduce the amount of drug available. This
 varies between spacers, but to maximize drug delivery, inhalation should start as soon as possible after actuation.



Diagnosis and management of asthma in preschoolers: A Canadian Thoracic Society and Canadian Paediatric Society position paper

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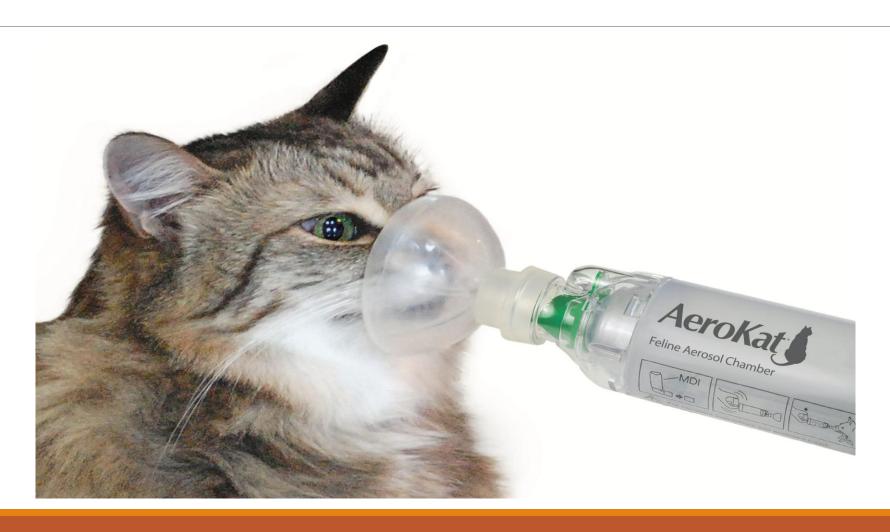
Can Respir J Vol 22 No 3 May/June 2015

Take home message

- 1. MDI with spacer should be used as a first choice to administer beta-agonists in children<5y for the treatment of acute asthma exacerbation.
- 2. MDI is more convenient (rapid and easy administration).
- 3. MDI is more efficient with less side effects and less risk of drug and bacterial exposure.
- 4. MDI is cost effective and increases child and parents satisfaction.



Questions?

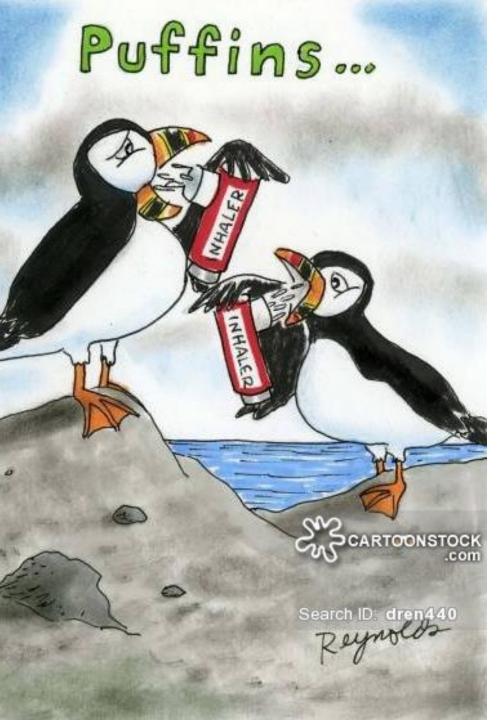


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