

Randomised trial spacer v nebuliser for acute asthma

P C Parkin, N R Saunders, S A Diamond, P M Winders, C Macarthur

Abstract

Sixty hospitalised children with asthma aged 1-5 years were randomised to spacer or nebuliser. A clinical score was measured at baseline and every 12 hours. There were no differences between groups in the score over time, or secondary outcome measures. The spacer is an effective delivery method for young hospitalised asthmatic children.

(Arch Dis Child 1995; 72: 239-240)

Keywords: asthma, spacers, nebulisers, metered dose inhalers.

It has now been shown that metered dose inhalers (MDIs) with spacers are as effective as nebulisers in adults and older children. Until recently, preschool aged asthmatic children requiring inhalation treatment used nebulisers because of poor coordination.

Few studies have evaluated the effectiveness of the MDI and spacer in the preschool population. The objective of this study was to compare the effectiveness of bronchodilator delivery by MDI and Aerochamber with mask (MDIAM, Trudell Medical) with a nebuliser, in young hospitalised asthmatic children.

Subjects and methods

Hospitalised children with moderate acute asthma between 1 and 5 years of age were randomly allocated to MDIAM (a 140 ml volume cylindrical spacer with a one way valve) or nebuliser after stabilisation in the emergency department. The research nurse only was blinded. The study was approved by the Hospital for Sick Children research ethics board and informed parental consent was obtained.

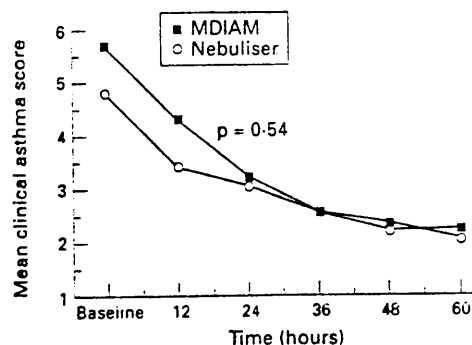
To determine equivalent doses of bronchodilators, it was assumed that the ratio of the amount of drug inhaled by nebuliser compared with MDI and spacer was 1:4. Children randomised to the nebuliser received salbutamol 0.15 mg/kg and ipratropium bromide 125 µg, suspended in 3 ml of 0.9% saline solution over 15 minutes by facemask and nebuliser driven by compressed air. Children randomised to the MDIAM received salbutamol four puffs (400 µg) if they weighed less than 12 kg, five puffs (500 µg) if they weighed 12 to 16 kg, and six puffs (600 µg) if 16 kg or heavier, with ipratropium bromide two puffs (40 µg) by MDIAM. All children also received intravenous or oral steroids.

The primary outcome measure was a 10 point clinical asthma score measuring five parameters (respiratory rate, wheezing, indrawing, observed dyspnoea, and inspiratory to expiratory ratio) measured at baseline and every 12 hours for the first 60 hours of hospitalisation. Secondary outcome measures included time to discharge, time to four hourly dosing interval, and total number of inhaled doses required. Nurses assessed ease of administration and patient tolerance on a five point Likert scale. Parents reported symptoms at seven and 14 days after discharge.

The Student's *t* test was used for continuous variables, and the χ^2 test for categorical variables. Repeated measures analysis of variance was used to test the change in clinical asthma score over time with repeated measures analysis of covariance to adjust on covariates. The sample size of 30 patients in each group provided approximately 90% power to detect a (clinically important) difference in the clinical asthma score of 2, given a SD of 1.5, and an α level of 0.05. Patients who crossed over to the other delivery setup were analysed according to their original group assignment (intention to treat analysis).

Results

Sixty patients (mean (SE) age 35 (1.9) months) were enrolled. There were no differences on baseline characteristics, other than the preintervention clinical asthma score (MDIAM v nebuliser: 5.7 v 4.8, $p=0.02$). Nine patients allocated to the MDIAM group crossed over to the nebuliser. The intention to treat analysis (adjusted on the baseline clinical asthma score difference) showed no significant difference between the groups ($p=0.54$). At 60 hours, the adjusted mean (SE) clinical asthma score in the MDIAM group was 2.0 (0.3), compared with 2.2 (0.3) in the nebuliser group.



Mean clinical asthma score in the two groups over time.

Division of General Pediatrics and Pediatric Outcomes Research Team (PORT), Hospital for Sick Children and Department of Pediatrics, University of Toronto, Toronto, Ontario, Canada
P C Parkin
N R Saunders
C Macarthur

Department of Pharmacy, Hospital for Sick Children, Toronto
S A Diamond

Department of Nursing, Hospital for Sick Children, Toronto
P M Winders

Correspondence to: Dr Patricia C Parkin, Division of General Pediatrics, Hospital for Sick Children, 555 University Avenue, Toronto, Ontario, Canada M5G 1X8.

Accepted 8 November 1994

(figure). There were no differences on the secondary outcome variables (MDIAM *v* nebuliser): hours to discharge, 53 (4.3) *v* 46 (4.3), $p=0.27$; hours to four hourly dosing interval, 24 (3.3) *v* 19 (3.3), $p=0.31$; and total number of inhaled doses received, 21 (2.0) *v* 17 (2.0), $p=0.10$. Nurses rated the nebuliser easier to administer ($p<0.01$) and better tolerated by patients ($p<0.01$). At seven days, 37% of MDIAM patients reported no symptoms, compared with 43% of nebuliser patients ($p=0.60$), while at 14 days, 63% of MDIAM patients reported no symptoms, compared with 67% of nebuliser patients ($p=0.79$). No study patient was readmitted to hospital in the two weeks after discharge.

Discussion

The results of this randomised trial suggest that delivery of bronchodilators by MDIAM is as effective as by nebuliser in hospitalised young asthmatics. Nine children in the MDIAM group crossed over to the nebuliser; however, of these only four met the *a priori* stopping rules and, therefore, could be considered failures.

In older children, the MDI with spacer has been found to be as effective as the nebuliser.¹ A randomised trial in preschool aged asthmatics found the MDI with spacer as effective as the nebuliser in the outpatient setting.² Other single arm studies also suggest that the MDI and spacer is effective in this population.³⁻⁵ We are unaware of any other studies

comparing MDI and spacer with nebuliser in preschool aged asthmatics in the inpatient setting.

There are several reasons to consider the use of the MDIAM in young hospitalised asthmatics, including reduction in hospital costs, and the opportunity for continued at-home management, and/or long term prophylaxis. Bowton *et al* found a 25% reduction in monthly costs after the substitution of MDIs for nebulisers in a large, adult, tertiary care centre.⁶

We believe that the MDIAM can be used in the effective management of young hospitalised asthmatics, after stabilisation in the emergency department.

This study was supported by a grant from Physicians Services Incorporated (PSI #91-27), and Paediatric Consultants, the Hospital for Sick Children. Trudell Medical, Canada supplied the Aerochamber with mask, and Novopharm, Canada supplied salbutamol metered dose inhalers.

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