

## SHORT REPORT

## A randomised crossover trial of facemask efficacy

J T Hayden, N Smith, D A Woolf, P W Barry, C O'Callaghan

Arch Dis Child 2004;89:72-73

The efficacy of different facemasks that can be used in the delivery of aerosol medication to children with recurrent wheeze or asthma was investigated. The results showed a statistically significant difference between some of the masks used, which has important implications for current clinical practice

Inhalational therapy is the mainstay of treatment for asthma. For young children a spacer device with a facemask attachment is the delivery method of choice.<sup>1</sup> Facemasks are also used for older children unable to inhale effectively from a spacer mouthpiece. The type of spacer chosen may significantly alter the amount of drug delivered.<sup>2</sup> Little is known of the effect the facemask has on drug delivery. Knowledge of the inhaled dose is particularly important for the delivery of drugs such as inhaled steroids, where inadequate delivery may be responsible for treatment failure, and excessive dosing may increase the risk of side effects.<sup>3</sup>

The objective of this study was to investigate the effect different facemasks have on aerosol drug delivery, through a spacer device, in children with recurrent wheeze or asthma.

## METHODS

Ethical approval for this study was granted from the Peterborough and Fenland Research Ethics Committee. Twenty four children, 7 years old or younger (range 6-81 months, mean age 38 months), with asthma or recurrent wheezing who currently use a spacer device to administer their treatment were enrolled from the Peterborough Hospital Paediatric Outpatient Department from April to June 2000. Those who were acutely unwell, who had concurrent infectious diseases, or whose parents thought that they would become excessively distressed were excluded.

Each child used a spacer device with each of three different facemasks (fig 1): Laerdal mask, normally used with the Volumatic (Allen & Hanburys, Uxbridge, UK) and the Aerochamber (Trudell Medical, London, Canada) devices; McCarthy mask, formerly used with the Nebuhaler (Astra Pharmaceuticals, Kings Langley, UK); and King Systems mask (King Systems Corporation, Noblesville, USA), not



Figure 1 Facemasks: King Systems; Laerdal; McCarthy. (Note that the McCarthy mask does not have any side holes; these have been sealed.)

currently distributed with a spacer device. The facemasks were used in a predetermined randomly assigned order selected by the concealed envelope technique. Assignment was unknown to the investigator at the time of recruitment.

Children inhaled budesonide (AstraZeneca, Lund, Sweden), with the facemask being tested through a stainless steel non-electrostatic spacer (AstraZeneca, Lund, Sweden). A single actuation of budesonide (200 µg per actuation) was fired into the spacer and the child breathed for 20 seconds from the device. Filters (3M Filtrete based filter papers) interposed between the spacer and facemasks trapped any drug likely to be inhaled. The amount of budesonide deposited on the filter was assayed by high performance liquid chromatography. A data logger device attached to the spacer (Profile Therapeutics, Heath Place, Bognor Regis, West Sussex, UK) recorded actuation of the pMDI and the volume of air inhaled from the spacer.<sup>4</sup>

## RESULTS

All participants completed the tests and there were no adverse events encountered, including participant distress. Data from the 72 filters collected were analysed (fig 2). Data collected from one of the participants was excluded from analysis because a dose actuation did not register on the data logger, making an interpretation of the filter dose collected unreliable.

The mean dose collected using the McCarthy mask was 11.62 µg (SD 29.0, 95% CI 0.57 to 23.81), the Laerdal 60.69 µg (SD 29.6, 95% CI 47.9 to 73.5), and King Systems 60.83 µg (SD 25.5, 95% CI 49.8 to 71.9). When compared using the paired *t* test, there was a statistically significant difference ( $p < 0.0001$ ) in the mean dose collected between the McCarthy and both Laerdal and King Systems mask, but not between the latter two masks ( $p = 0.98$ ).

Further analysis of the crossover data, to test whether the order of facemask use affected the dose collected, revealed no evidence of period effect or interaction ( $p > 0.05$  in all groups). There was a high correlation between average

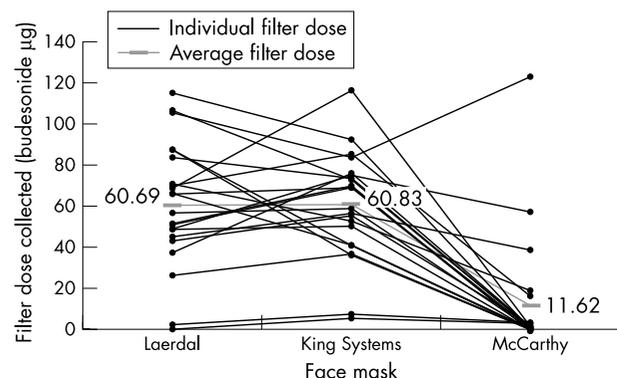


Figure 2 Scatter graph comparing the dose collected with the facemask used for each participant.

inhaled dose and average inhaled volume of air recorded by the data logger ( $r = 0.98$ ).

## DISCUSSION

We have shown that the choice of facemask attached to a spacer device may greatly affect the inhaled volume and consequently the dose of drug available to be delivered to young children.

We acknowledge the importance of within patient variability on aerosol delivery<sup>5</sup> (such that the filter dose collected from a given patient is likely to vary on different occasions), but this effect has been minimised by the crossover design and involving a number of participants.

The drug dose prescribed frequently correlates poorly with the dose delivered. For some children this may make the use of prophylactic medications ineffective, increasing the risk of acute attacks and long term morbidity. For others, high concentrations may be inhaled resulting in a rise in steroid induced side effects.

In vitro data highlight the importance of facemask seal.<sup>6</sup> We hypothesise that the poor results from the McCarthy mask were due to a poor seal with the face, and recommend that the importance of an effective seal be further investigated.

The choice of facemask is therefore clearly an important component of inhalation systems and this should be evaluated further.

## ACKNOWLEDGEMENTS

We thank D Hammal for her assistance in data analysis.

### Authors' affiliations

**P W Barry, C O'Callaghan**, Institute of Lung Health, University of Leicester, and Children's Hospital, Leicester Royal Infirmary, UK  
**J T Hayden, D A Woolf**, Department of Paediatrics, Peterborough District Hospital, UK  
**N Smith**, Profile Therapeutics, Heath Place, Bognor Regis, UK

Correspondence to: Dr P W Barry, Clinical Sciences Building, Leicester Royal Infirmary, Leicester LE2 7LX, UK; pwb1@btinternet.com

Accepted 14 March 2003

## REFERENCES

- 1 **O'Callaghan C**, Barry PW. Asthma drug delivery devices for children. *BMJ* 2000;**320**:664.
- 2 **Barry PW**, O'Callaghan C. Inhalational drug delivery from seven different spacer devices. *Thorax* 1996;**51**:835-40.
- 3 **Committee on Safety of Medicines**. Focus on corticosteroids. *Current problems in pharmacovigilance* 1998;**24**:5-10.
- 4 **O'Callaghan C**, Hill S, Barry PW, *et al*. In-vivo validation of an MDI spacer data logger. *J Aerosol Med* 2000;**13**:66.
- 5 **Janssens HM**, Devadason SG, Hop WC, *et al*. Variability of aerosol delivery via spacer devices in young asthmatic children in daily life. *Eur Respir J* 1999;**13**:787-91.
- 6 **Everard ML**, Clark AR, Milner AD. Drug delivery from holding chambers with attached facemasks. *Arch Dis Child* 1992;**67**:580-5.

