How to use a rotahaler

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SUMMARY The bronchodilator response after five different modes of salbutamol inhalation by rotahaler was assessed in 15 asthmatic children in a double blind cross over study. Inspiratory flow rates lower than 50 litres/minute were associated with a significant reduction in response compared with flow rates higher than 60 litres/minute, but tilting the head back during inhalation and holding the breath for 10 seconds had no significant effect on bronchodilation. Peak inspiratory flow rates measured in 150 normal children and 13 asthmatic children with acute wheeze showed that many young children and many children with severe bronchoconstriction were unable to generate a sufficiently high inspiratory flow rate to obtain maximum benefit from rotahaler treatment. Children using a rotahaler should be taught to inhale as quickly as possible and not with a quiet deep breath as recommended in the instruction leaflets.

The rotahaler was designed to make inhaled medication more convenient and effective for asthmatic patients. Improving the success of this treatment, however, is not only a matter of inhaler design but also of optimising and simplifying instructions and the mode of inhalation. There is, at present, considerable doubt about the best technique for using the rotahaler in asthmatic children. The instruction leaflets provide some guidance on the correct manner of use, but the basis of these instructions has not been confirmed in controlled clinical trials.

We conducted a series of studies in asthmatic children to elucidate the optimum rate of inhalation, the importance of tilting the head back during inhalation, and the importance of holding the breath afterwards. Furthermore, we have studied the maximum inspiratory flow rates that can normally be generated through the rotahaler in both normal and asthmatic children.

Patients and methods

Study 1—modes of inhalation. Eleven boys and four girls aged 7 to 14 years (mean 11 years) participated in the study. All suffered from chronic or episodic wheeze associated with an increase in forced expiratory volume in one second (FEV_1) of at least 15% after one puff of terbutaline. They received regular inhaled treatment with corticosteroids and β_2 stimulants. The study was approved by the ethical committee of Northern Jutland, and informed con-

sent was obtained from all children and their parents.

The children were studied on six separate occasions at the same time of day. Before each visit, treatment with inhaled corticosteroids and β_2 agonists was stopped for 48 and 12 hours respectively. A study on each child was only performed if the baseline FEV_1 was within 15% of its value on the first study day, and if this was not the case the child was asked to make a further visit on another day.

The patients inhaled through a rotahaler in series with a pneumotachygraph. One capsule of placebo or 0.2 mg salbutamol was given on each study day and the children wore a nose clip during inhalation. The differential pressure signal from the pneumotachygraph (proportional to the flow rate of inspired air) was fed to a pressure transducer, from which the analogue signal was integrated to give the inhaled volume. Throughout the inhalation the children could see the variation with time of both inspiratory flow rate and inhaled volume on the screen of an oscilloscope. This was used as a teaching aid so that all children, after some practising in the morning, were able to make reproducible, standardised inhalations at a fixed inspiratory flow rate. Inspiratory flow rates and volume were recorded for analysis.

During treatment the children inhaled as deeply as possible from residual volume. They repeated the inhalation until the capsule was emptied. The capsule was always inserted into the rotahaler and split by an adult.

The design was that of a controlled double blind, double dummy cross over study. During the first four study days the children were treated with placebo (A), salbutamol inhaled at 30 to 50 l/minute (slow=B), salbutamol inhaled at 60 to 80 l/minute (medium=C), and salbutamol inhaled at 90 to 120 l/minute (fast=D) in a randomised cross over fashion. During these days the head was tilted back during inhalation which was followed by breath holding for 10 seconds. When the results from the first four days had been analysed the children participated for another two days of fast inhalation, one day without a breath holding pause (E) and one day without tilting the head back during the inhalations (F) (randomised sequence).

Pulmonary function was measured before, and at 30 and 90 minutes after each treatment. The measurements were performed in a body box and the bronchodilator response was assessed by measuring changes in FEV₁, forced vital capacity, residual volume, and specific airways conductance. Both absolute values and the percentage of the predicted value were evaluated. The best of three measurements was studied.

Study 2—peak inspiratory flow rates in normal children. To evaluate the maximum inspiratory flow rates that various age groups of children can generate through the rotahaler, 159 children aged between 3½ and 15 years were taught to inhale as quickly as possible through a loaded rotahaler in series with the pneumotachygraph. The flow and volume *v* time curves were recorded and the best of three measurements was analysed. In addition, peak expiratory flow rate was measured on a Mini Wright peak flow meter, and FEV₁ and forced vital capacity on a dry wedge spirometer (Vitalograph) (best out of three). These measurements were done in all children in a kindergarten and a small public school who were able to cooperate (nine were unable to).

Study 3—acute asthma. Thirteen asthmatic children aged between 6 and 12 years (mean=8.9 years) were studied as described in study 2 during an episode of acute wheeze and again after their pulmonary function had improved.

Statistics. Friedman's test was used to evaluate any overall difference between treatments. If significant effects for treatment or time were found the results were analysed by parametric and non-parametric methods (paired *t* tests and Wilcoxon's rank sum test). As these results were similar, however, only the results of the *t* tests are given. Values given in the text are mean (SEM).

Results

Modes of inhalation. The FEV₁ as a percentage of the predicted value before and after use of the rotahaler on the six days of treatment is shown in Fig. 1. There was no statistically significant difference between the initial FEV₁ on the six days of treatment. The FEV₁ before treatment varied from 47% to 72% (mean 59.7%) of the predicted value.

All active treatments resulted in a significant increase in FEV₁ compared with placebo. The improvement after medium and fast inhalations was significantly greater than that after slow inhalations (*P*<0.01). There was no difference between the response to medium and fast inhalations with the head tilted back and a breath holding pause of 10 seconds. At fast inhalation rates neither tilting the head back nor holding the breath influenced the bronchodilator effect.

On the whole the results were similar for forced vital capacity and specific airways conductance. For residual volume the difference between slow inhalations and the various other active treatments failed to reach statistical significance.

Mean peak inspiratory flow rate was 43 (range 36 to 50) litres/minute on the slow day, 69 (range 60 to 80) litres/minute on the medium day and 108 (range 71 to 130) litres/minute on the fast day (the two youngest children were unable to generate flows above 90 litres/minute). There was no significant difference in the flow rates between the three fast days (D, E, and F), nor was there any difference between the mean inhaled volume on the six days (this varied from 2.32 to 2.40 litres).

Fig. 1 Mean forced expiratory volume in one second as a percentage of the predicted value after various modes of inhaling 0.2 mg salbutamol or placebo from a rotahaler (see text).

Peak inspiratory flow rates of normal children. Peak inspiratory flow rate varied significantly with age ($r=0.83$; $P<0.01$) and with peak expiratory flow ($r=0.90$; $P<0.01$) (Figs. 2 and 3). In addition, inhaled volume was found to correlate significantly with forced vital capacity ($r=0.79$; $P<0.01$).

Acute asthma. The mean peak inspiratory flow rate measured during acute attacks of bronchoconstriction, when mean peak expiratory flow was 102 litres/minute, was significantly lower than the mean peak inspiratory flow rate measured after recovery, when mean peak expiratory flow had increased to 247 litres/minute ($P<0.01$) (Fig. 4). During acute wheeze, nine children had inspiratory flow rates below 50 litres/minute.

Fig. 2 Peak inspiratory flow rate through a rotahaler in various age groups of children (A=a child who was found to suffer from asthma during the study).

Fig. 3 Variation in peak inspiratory flow rate through a rotahaler and peak expiratory flow rate in 150 children.

Fig. 4 Peak inspiratory flow rate through a rotahaler in 13 asthmatic children during an episode of acute wheeze and after recovery.

Discussion

The instruction leaflets accompanying the rotahaler recommend a quiet deep inhalation. This may be best for adults and older children but the peak inspiratory flow rates that the children in the various age groups in the present study were able to generate through the rotahaler and the finding of a reduced effect at low inspiratory flows, indicate that such advice will result in reduced bronchodilation in many children. Furthermore, the study showed that tilting the head back during inhalation, and breath holding afterwards can be safely omitted from the instructions. This would facilitate teaching and perhaps improve compliance.

The lack of benefit from holding the breath after inhalation has also been shown in some studies in adults using pressurised aerosols,¹ but this finding does not agree with those of Newman.² Newman, however, only found a beneficial effect of breath holding at very low inspiratory flow rates (25 litres/minute). To our knowledge the importance of tilting the head back during inhalation so that the particles may follow a straighter path to the trachea has not previously been investigated under controlled conditions, nor has the importance of breath holding been studied in patients using a rotahaler.

The correlation between inspiratory and expiratory pulmonary function measurements agrees with the clinical observation that many asthmatics complain not only of expiratory but also of inspiratory difficulties during episodes of wheeze. This has some important clinical implications, since it means that younger children who can normally use a

rotahaler efficiently, may not be able to gain full benefit during attacks of acute bronchoconstriction or in periods of bad control of symptoms. In these cases it may be necessary to increase the inhaled dose or to use other ways of drug delivery. These suggestions are supported by the results of a recent clinical trial.³

Our finding that the bronchodilator response was reduced at slow inspiratory flow rates is quite opposite to that in adults using pressurised aerosols,^{2,4} and emphasises doubts about the validity of extrapolating results from one inhaler to another. We do not know the exact cause of the reduced effect. It has been shown in vitro, however, that the drug/lactose powder mix in the capsules requires a certain amount of inspiration energy to break up the agglomerates into sufficiently small particles (personal communication from Glaxo), and it is possible that the reduced effect after slow inhalations was due to insufficient breaking up of the large drug/lactose particles.

Studies with pressurised aerosols and teflon particles have shown that high inspiratory flow rates may increase the likelihood of a more central deposition of drug in the lungs.^{2,5,6} There has been no direct study of the rotahaler comparing pulmonary deposition at different rates of inhalation. We think that the theoretical advantage of medium rate inspiration is easily outweighed by the difficulties of administering this regimen in children because of the variation in inspiratory flow rate with age and day to day differences in pulmonary function. We therefore suggest that fast inhalations should be recommended for children using a rotahaler until controlled clinical studies of the day to day manage-

ment of ambulatory asthmatics have proved otherwise.

Conclusion

Children should be taught to inhale as quickly as possible through their rotahaler. They need not tilt their head back during the inhalation or hold their breath afterwards. During episodes of wheeze young children may gain less benefit from rotahaler treatment because they cannot generate sufficiently high inspiratory flow rates.

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An article by Reiser and Warner on inhalation treatment for asthma appears in the Personal practice section of this issue.