Pressure flow characteristics of the valve in spacer devices

F H SENNHAUSER AND P D SLY

Professorial Department of Thoracic Medicine, Royal Children's Hospital, Melbourne, Australia

SUMMARY   The valve system in the mouth piece of two spacer devices was analysed. Pressures required to open and close the non-rebreathing valve were very low (<0·1 kPa). Inspiratory flow requirements were within physiological limits for infants' normal tidal breathing. Expiratory flow requirements varied significantly, and the flow required to prevent rebreathing from the chamber may exceed the physiological flow limits for normal tidal breathing.

Recurrent wheezing attacks in children aged less than 18 months are common but difficult to treat.[1] The use of conventionally nebulised medication is not commonly recommended in this age group because of inefficacy of bronchodilators. Oral bronchodilators have more side effects than inhaled β_2 agonists and are frequently not helpful. Clinical experience, however, shows that, even in early infancy, improvement of broncho-obstructive symptoms can be achieved in some infants by treating them with inhaled bronchodilators. Wet nebulisers can be used to deliver bronchodilators but are time consuming and expensive. A simpler and cheaper device would allow inhaled broncho-dilators to be used more widely, particularly at home.

Aerosol holding chambers (spacer devices) have recently been introduced to assist aerosol delivery in children too young to use metered dose aerosol successfully. These devices have been shown to decrease oropharyngeal deposition and increase deposition in the lungs, so long as they have an appropriate design.[2] Two commercially available spacers appear to fulfil the design requirements. These are the Volumatic and the Nebuhaler.

The use of spacer devices has been advocated in infants by attaching a face mask to the mouth piece.[3] However, no information is available on the pressure and flow that are required to operate the non-rebreathing valves. The present study was performed to define pressure and flow character-istics of the valve system and their inter-relationship with the orientation of the airspacer. This know-ledge is necessary before we try to define the place

of spacer devices in the treatment of small and sick infants who might be unable to generate the necessary flow and pressure to operate the valve system. Failure to open the valve during inspiration would result in failure to deliver the bronchodilator, while failure to close the valve during expiration would leave the infant vulnerable to rebreathing from the spacer.

Methods

The valve system in the mouth piece of the commercially available spacer devices Nebuhaler (Astra) and Volumatic (Glaxo) were analysed. Five examples of each model were tested. Simulated 'inspiration' and 'expiration' through the mouth piece was performed by slowly increasing air flow until the valve opened or closed, respectively. Pressure inside the spacer was measured to deter-mine precisely when the valve closed or opened. The time of valve closure or opening was obtained when the spacer pressure changed abruptly. The pressure on the mouth side of the valve and flow across the valve (Fleisch No 1 pneumotachograph) were recorded at that time. The position of the spacer recommended for use in adults is horizontal. It seemed more likely that the spacers would be given to infants lying supine (spacer vertical) or propped up in their parent's arms (spacer at an angle of about 45°).

We therefore recorded mouth pressure and flow with the spacer held in three different orientations: horizontal, at an angle of 45°, and vertical. The mouth piece end of the device was raised (45°, vertical) during inspiration and declined (45°, vertical) during expiration in order to measure the opening and closing pressure respectively. For each of the 10 spacers the measurements were repeated five times in a random order in each position. The intradevice and interdevice coefficients of variation for the obtained values were calculated for both spacers. In addition, the effect of activating a metered dose inhaler on the spacer valve was tested by repeating the measurements in one position (inspiration, 45° vertical) after 10, 20, and 100 activations, respectively. Student's independent t test was used to compare sample means.

Table 1   *Mean (SD) inspiratory and expiratory flow rates in ml/second*

	Inspiration			Expiration		
	Vertical	*45°*	*Horizontal*	*Vertical*	*45°*	*Horizontal*
Nebuhaler (n=5)	12·0 (1·3)	11·9 (1·7)	9·9 (1·3)	73·9 (2·5)	71·3 (5·2)	38·1 (6·3)
Volumatic (n=5)	10·3 (0·6)	9·7 (1·0)	7·0 (1·0)	24·3 (4·0)	20·7 (3·5)	16·0 (5·0)

*All differences between space devices were significant (p<0·0001).

Table 2   *Coefficients of variation for inspiratory and expiratory flow rates (%)*

	Inspiration			Expiration		
	Vertical	*45°*	*Horizontal*	*Vertical*	*45°*	*Horizontal*
Nebuhaler (n=5)						
Intradevice						
Median	9	13	8	3	4	11
Range	5–17	6–18	8–13	1–5	3–9	6–19
Interdevice	11	14	13	3	7	16
Volumatic (n=5)						
Intradevice						
Median	4	10	7	6	6	24
Range	1–6	5–12	4–22	4–22	3–29	15–49
Interdevice	6	11	14	17	17	31

Results

In each position the expiratory flows required to close the valve were higher than the inspiratory flows required to open the valve (*t* test, p<0·0001) and were greater with the Nebuhaler in all positions than with the Volumatic (*t* test, p<0·0001) (table 1). The pressures required to open and close the spacer valves were always less than 0·1 kPa (negative or positive) in all positions.

The intradevice coefficients of variation for the two airspacers did not differ significantly (*t* test, p>0·05) (table 2). The interdevice coefficients of variation were similar for Volumatic and Nebuhaler except during expiration when the coefficients for Volumatic were more variable.

The use of a metered dose inhaler did not effect the valve function of either spacer. The flows and pressures required to open the valves following 10, 20, or 100 activations of the inhaler were not significantly greater than those required to open the valve under control conditions.

Discussion

Spacer devices potentially represent a significant advance in the treatment of asthma as they allow inhaled β_2 agonists to be given to younger children who are unable to use a metered dose aerosol successfully. However, before these devices are widely adopted, their physical characteristics need to be evaluated. The results of the present study have shown that the pressures needed to open and close the valve in both airspacers are minimal (<0·1 kPa). These pressures should easily be generated even by small or sick infants.

The inspiratory flows required to open the spacer valves were very low (range 7–12 ml/second) regardless of the position of the spacer even with the spacer vertical (valve uppermost). These values of inspiratory flow can easily be achieved by infants. Reported values for peak inspiratory flow during tidal breathing in infancy range between 80–150 ml/second.[4–6] In addition, inspection of flow-volume loops in both healthy infants and those with bronchial obstruction show that during most of normal tidal inspiration the flow is sufficient to open the valve. Before the use of spacers becomes widespread in infants with bronchial obstruction, some assessment of whether such infants can generate sufficient pressure and flow to operate the valve is needed.

During expiration the flows required to close the Volumatic valve were slightly higher than those required to open the valve, but lie still in a range easily achievable by infants. The flows required to close the Nebuhaler valve were significantly higher than those required to close the Volumatic valve. In the vertical position the expiratory flows averaged 73·9 ml/second (range 69·8–81·5 ml/second) for the Nebuhaler and 24·3 ml/second (range 11·7–31·2 ml/second) for the Volumatic. These flows required for valve closure in Nebuhaler may not be achievable by infants. The reported values for peak tidal expiratory flow in normal infants (5 to 11 months of age) are 70 ml/second.[5] During most of expiration the flow is likely to be considerably less, especially in infants with obstructive airway diseases. Infants with expiratory flow limitation during tidal breathing can not increase expiratory flows without increasing lung volume. Failure to close the spacer valve exposes the infant to the risk of rebreathing.

The intradevice and interdevice coefficients of variation for both types of spacer devices are acceptable. The higher coefficients of variation found during expiration in the Volumatic spacer device than found for Nebuhaler are interesting but of no clinical importance. Thus the intradevice or interdevice variability is not an additional factor to be considered when using airspacers in infancy.

Although up to 100 activations of a metered dose inhaler did not result in an increase in the pressure or flow required to open the spacer valve, prolonged use without adequate cleaning could result in the valve becoming 'sticky', thus requiring greater pressures and flows to operate the valve. Furthermore, the simulated inspiration and expiration in the present study were performed using room air. It is possible that humid expired air could cause the valve to become 'sticky'.

In conclusion, our results show that the flows required to open the valves in the Volumatic and Nebuhaler spacer devices are within the range of reported values that can be achieved even by flow obstructed infants. Flows required to close the valve, however, may not lie within reported physiological limits for normal tidal breathing of even healthy infants. Further studies, with particular reference to the flows generated during tidal breathing, and the orientation of the device, are needed to evaluate the possible role of aerosol holding chambers in the treatment of wheezy infants.

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Polycystic ovary syndrome in a virilised, premenarcheal girl

C F CLARKE,* A T PIESOWICZ,* K EDMONDS,† AND D GRANT‡

Queen Mary's Hospital for Children, Carshalton, †Queen Charlotte's and Chelsea Hospital, and ‡Hospital for Sick Children, London

SUMMARY A premenarcheal girl aged 12 years presented with an abdominopelvic mass and virilisation. A large ovarian cyst was removed at laparotomy. A histological diagnosis of polycystic ovarian syndrome was made, with no evidence of an associated masculinising tumour.

Polycystic ovary disease was initially described by Stein and Leventhal in 1935 as comprising the triad of obesity, hirsutism, and amenorrhoea in women with bilaterally enlarged polycystic ovaries.[1] In more recent years the term 'polycystic ovary syndrome' has come to be applied to a broad range of clinical features including hirsutism, secondary amenorrhoea or other menstrual irregularities,