enquiry. Firstly, could it be some property of the physical suspension that makes it less effective (all other anti-asthma nebuliser preparations are in the form of a solution); secondly, could the physical characteristics of the suspension have affected nebuliser function, reducing its efficiency; and, thirdly, could the recommended dose simply be too low (most other nebuliser dosages are considerably higher than inhaler dosages, though the proportion of either that reaches the lungs is said to be similar at about 9–12%\(^6\) )? It is impractical to expect toddlers and young children to be able to tolerate a higher dose at each sitting as even the nebuliser time for 3 ml of suspension (50 mcg/ml) represented an appreciable burden to many of our parents and children.

Although no side effects were noted in our study, there is a theoretical risk of secondary steroid effects upon the facial skin if beclomethasone is delivered by face mask, and the manufacturers do recommend that a mouth piece be used. In our experience, however, young children tolerate face masks much more readily than mouthpieces, and this might therefore constitute a greater risk in long term treatment.

Clearly, if beclomethasone dipropionate suspension is to continue to be recommended on the basis of the undoubted efficacy of the drug itself then further clinical trials of its usefulness in the currently available dosage and in the appropriate age group are urgently required.

We thank the children and their parents. We also thank Professor D Hull, Dr P Barbor, Dr D Johnston, and Dr N Rutter for allowing us to study patients under their care. Financial support was gratefully received from the Asthma Research Council.

References


Correspondence to Professor A D Milner, Department of Child Health, Queen’s Medical Centre, Nottingham NG7 2UH.

Received 23 May 1986

Commentary

S W CLARKE

Department of Thoracic Medicine, Royal Free Hospital, London

The discrepancy between the similar studies of Storr et al\(^1\) who obtained a positive result and Webb et al\(^2\) a negative one with the same drug, inhaled beclomethasone dipropionate, is puzzling and raises several questions.

The studies were similar but not identical insofar as Storr et al’s was a double blind parallel study and Webb et al’s a double blind crossover one, though this should not necessarily matter. Even so, there was a (non-significant) trend in favour of beclomethasone in that of Webb et al and the discrepancy may be in the study designs.

The most obvious difference is the dose inhaled, 2 ml (100 μg) versus 3 ml (150 μg), respectively. But the lower dose worked and the higher dose failed to do so, ruling out a dose related effect.

Nebulisation details were incomplete for both studies and in neither was the optimal liquid volume (usually drug + saline) of 4 ml used — this to reduce the proportion of dead volume left in the nebuliser after conclusion and to optimise the output.\(^2\) It seems likely, however, that both systems produce similar respirable (about 2–5 μm) particles.\(^3\) Nevertheless, the inescapable conclusion must be that the drug does not work but that in the study of Webb et al it somehow failed to reach the lungs—such doses of beclomethasone have virtually no systemic effect.

In both studies the children inhaled the nebulised drug through a face mask, close fitting in the study of Storr et al and loose fitting in the study of Webb et al. With loose fitting masks much of the drug may impact on the face and lips, leaving little to be inhaled.\(^4\)

Although it is difficult to pinpoint the error precisely, nevertheless, when using nebulised drugs, strict attention should be paid to the details of nebulisation and inhalation, otherwise anomalous results may arise.

References

4 Clarke SW, Newman SP. Therapeutic aerosols. 2 Drugs available by the inhaled route: Thorax 1984;39:1–7.