Bronchodilator therapy and hyperactivity in preschool children

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METHODS

Sample
Athletic children aged 2–6 years were recruited from the paediatric respiratory clinic at Guy's and St Thomas' Hospital. The exclusion criteria included: global learning difficulties, history of being ventilated in the neonatal period, history of epilepsy and taking anticonvulsants, use of psychotropic medication, use of inhaled salbutamol within four hours prior to the testing session, and use of systemic steroids within two weeks of the testing session. From a possible sample of 33 children, four were excluded and the parents of 10 children refused to participate, mainly because of problems of arranging the testing session, and use of systemic steroids within two weeks of the testing session. From a possible sample of 33 children, four were excluded and the parents of 10 children refused to participate, mainly because of problems of arranging the testing session. A sample of 19 children (eight boys and 11 girls) were therefore included in the study.

The sample children aged between 25 and 64 months (mean 48.3), all with asthma as defined by variable airways obstruction and response to bronchodilator therapy. The study was approved by the St Thomas' Hospital ethics committee.

Procedure and instruments

At the time of recruitment, the following baseline information was obtained for each subject: asthma history, family social class, and hyperactive behaviour using the Conners’ Parent Rating Scale—Revised Short Form, which provides an index of hyperactivity. These data were also collected for children whose parents decided not to take part. All parents were asked about the effect of salbutamol on their child.

The testing sessions took place on two occasions within the children’s respiratory unit. On each visit the children were examined to ensure that there was no evidence of active asthma. The children were randomly assigned to either salbutamol or placebo (normal saline), with the alternate solution being administered at the second visit. The parent and the observers were blind to which solution was being used. At each visit, observer ratings on the child’s behaviour were made by the principal researchers (a paediatrician and a child psychiatric nurse), using the Pre-School Behavioural Observation Schedule (PS-BOS). This instrument allows for the systematic rating of the child’s level of activity while he/she plays with a standardised set of toys. Play sessions were held, and rated, before and after the inhalation of 5 ml nebulised solution (normal saline or salbutamol 5 mg), administered via a 5 litre oxygen driven nebuliser.

While the child was engaged in the assessment, the parent again completed the Conners’ Parent Rating Scale, basing their responses on the child’s behaviour in the play session after the administration of the nebulised solution.

At the second visit, one week later, the assessment was repeated in the same format, but with the child crossed over blindly to the alternate solution.

Statistical analysis

To assess whether the participants in the study differed from those who refused to participate, a two sample t test for continuous variables, and a χ2 test for comparison of proportions for discrete variables were used.

The reliability of the PS-BOS ratings between the two observers was assessed using the Wilcoxon signed rank test.

The Wilcoxon signed rank test was also used to compare the PS-BOS scores for activity derived from the play sessions before and after nebulisation with salbutamol and normal saline.

Correlation coefficients and linear regression analysis were used to examine the association between the scores on the baseline Conners’, the Conners’ post-saline nebulisation, and the Conners’ post-salbutamol.

RESULTS

The children who entered the study did not differ significantly from the 10 children who refused to participate in terms of: social class, daily inhaled steroid intake measured in micrograms, age in months, proportion of males to females, and Conners’ index of hyperactivity. Parents universally reported the belief that salbutamol made their children overtly active.

There was a high level of inter-rater reliability between the two observers on the PS-BOS, enabling the average score to be used in the data analysis. This measure revealed no evidence of an increase in the child’s activity after administration of salbutamol.

Parental ratings of activity on the Conners’ questionnaire revealed no significant difference between baseline and post-salbutamol scores.

DISCUSSION

Studies have found effects of β2 agonists on the central nervous system, such as appetite suppression, headache, nausea, sleep disturbances, and increase in postural tremor. In the
Bronchodilator therapy and hyperactivity in preschool children

clinical situation, parental report has suggested that nebulised salbutamol leads to an increase in the child's level of activity; all the parents of the children in this study believed that salbutamol made their children overactive.

This study has formally addressed this issue and has failed to show (from both observer ratings and parental report) any statistically significant difference in activity following the administration of nebulised salbutamol. This could be because there is no such effect to be found or that our small sample size has not enabled us to detect it, reflecting a type II error. However, this would be surprising given the order of behavioural change described by parents.

Our findings thus leave the question as to why parents report notable hyperactivity following salbutamol. One explanation for our negative findings is that the hyperactivity could be a Freon/propellant effect from the use of inhalers rather than a consequence of salbutamol per se. Alternatively, the effect on activity could be dose related and only appears after repeated administration of salbutamol. It also has to be recognised that the child's circumstances and context could be important factors in his/her response to salbutamol. The parents are describing their child's behaviour at home and when salbutamol is required to treat an asthma attack. Our work took place in a controlled setting within the hospital environment, and when the children were well. These very different situations might be associated with different responses to salbutamol on the part of the child, and/or affect the observations of their parents.

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FROM BMJ JOURNALS .................................................................

Parental guidance ... may be unsuitable for younger children

Education and self management fail to control asthma in preschool children, a new randomised control trial targeting parents has found. Current thinking that patients should be given information on self management to help reduce illness from asthma seems warranted according to trials of children over a wide age range (2–16 years). Stevens et al, however, report contradictory results from their prospective randomised, controlled trial in two UK centres of the effect of educating parents of preschool children about managing their child's asthma and providing a self management plan.

Over 13 months they recruited 200 children aged 18 months–5 years on admission to the children's ward or emergency department of either hospital with a primary diagnosis of asthma or wheeze. The intervention group received a booklet about asthma in preschool children, a written guided self management plan, and two educational sessions with a specialist respiratory nurse; the control group had usual clinical care. Outcomes—including GP consultations, prescriptions for asthma or wheeze, readmissions, or emergency department visits—were measured up to 12 months.

Both groups (intervention 87 children; control 90 children) had comparable baseline characteristics and did not differ significantly for any outcome measure.

The authors point to the major difference in children's age between their trial and previous trials. They suggest that repeat consultations and readmissions in their study may have been for episodic viral asthma, common in young children and present in 56% of the recruits. Current advice may therefore be unsuitable for preschool children.

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