SPACER DEVICE SELECTION MAY NOT IMPACT BRONCHODILATOR RESPONSIVENESS IN ASTHMATIC CHILDREN

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Background

Assessment of spirometry before and after bronchodilators is used in the diagnosis and management of asthma.

Spacers are used to deliver greater quantities of salbutamol to the patient.

The impact of spacer device selection on clinical bronchodilator responsiveness (BDR) is poorly understood.

Previous bench studies have shown a difference in drug delivery between large and small volume spacers.

Aims

The aim of this study was to investigate

- if spacer selection has an effect on BDR in asthmatic children
- and at what salbutamol dose BDR reached significance.

We hypothesised that the *in vitro* differences seen in bench testing would not impact on clinical efficacy defined by change in spirometry after salbutamol inhalation and ATS response criteria.

Methods

This study compared spirometry and BDR with a disposable spacer (Lite Aire; Thayer Medical) and a multi-patient use spacer (Space Pod; Medical Developments International).

Subject eligible
- aged 6 – 18 years with Dr diagnosed asthma
- parentally reported symptoms in the past year
- able to perform acceptable spirometry
- all β2 agonist medication withheld for 12 hrs prior to the visits

Two visits to Respiratory laboratory (5-10 days apart)
Spacer allocation randomised.

Spirometry was performed at baseline and after 200, 400, 800 and 1200µg cumulative doses of salbutamol.

Compared differences in percent increase in FEV_1 and absolute mean FEV1 between the two spacers.

Recorded number of children who reached a clinical BDR (200ml and 12% increase in FEV_1 from baseline) after each cumulative dose of salbutamol.

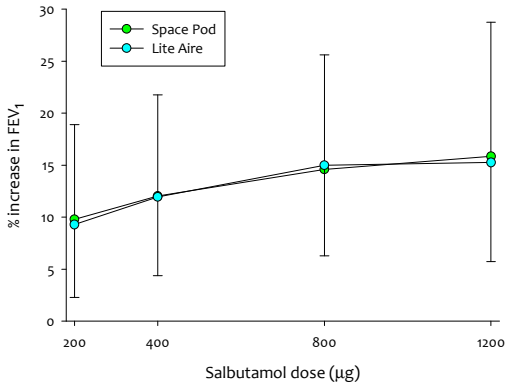
Results

26 children (15 male) have attended the laboratory. The average age at first visit was 12.6years. 20 children have completed both visits.

Mean (range) baseline lung function

- FVC 2.92 (1.83-5.67)
- FEV_1 2.20 (1.25-3.73)
- FEV_1/FVC 75 (58-93)

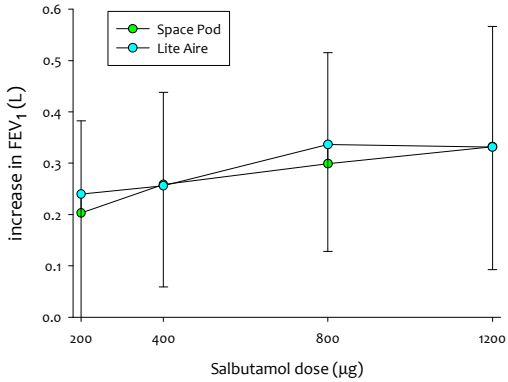
Fig 1.1 - % Increase in FEV_1 with increasing doses of salbutamol using different spacers



No significant differences in percent increase in FEV_1 from baseline to any dose were found between the two spacers.

The largest percent difference in mean FEV_1 between the spacers at any dose was 1%.

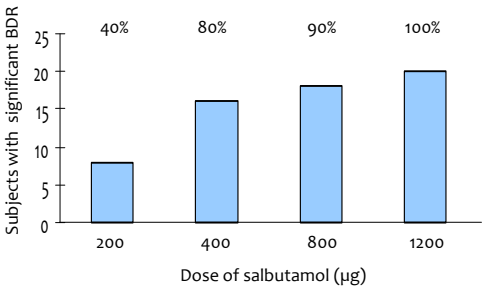
Fig 1.2 - Absolute mean FEV_1 with increasing doses of salbutamol using different spacers



No significant differences in absolute mean FEV_1 at any dose.

The largest mean difference between spacers at any dose was 20ml.

Fig 2.1 - Number of subjects with a significant BDR with increasing doses of salbutamol



20 of the 26 children had a clinical BDR on first visit.

80% of these children had a significant BDR by 400µg of salbutamol. 90% by 800µg and 100% by 1200µg.

Discussion

These data suggest that the differences in *in vitro* spacer drug delivery performance may not translate to significant clinical differences in the BDR of asthmatic children.

These results suggest disposable spacers may be used in clinical BDR testing of children in respiratory laboratories.

20% of children who had a clinical BDR did not have significant response by 400µg of salbutamol.

The current ATS guidelines for BDR testing may lead to the underestimation of the presence of a clinically relevant BDR in asthmatic children.

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