

Evaluation Of The Bronchodilator Effect And Side Effect Profile Of A Salbutamol Dry Powder Inhaler Device: A Prospective Observational Study

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Citation

G Du Toit, G Brown, B Joshua, C Motala, H Nell, E Weinberg. *Evaluation Of The Bronchodilator Effect And Side Effect Profile Of A Salbutamol Dry Powder Inhaler Device: A Prospective Observational Study*. The Internet Journal of Pediatrics and Neonatology. 2003 Volume 4 Number 1.

Abstract

Dry Powder Inhalation devices are currently used for the administration of inhaled Corticosteroids (ICS) and short acting B₂ agonists (SABA). Most generic asthma medications are only available as Metered Dose Inhalers (MDI), with the consequence that Dry Powder Inhaler (DPI) devices are infrequently a therapeutic option in regions where medication costs are the overriding concern. Potential advantages of the DPI inhalation device as compared to MDI and nebulisation include; affordability, ease of use, reduced administration time and lack of CFC propellants.

INTRODUCTION

The aims of the study were to assess the bronchodilator efficacy and side effect profile of a low cost salbutamol DPI device when used in a busy Allergy Clinic. In addition, we sought to assess the attitudes of nursing staff, parents and patients, after having used the DPI device.

METHODS

For inclusion into the study, patients must have been able to activate the DPI through generating sufficient inspiratory flow. All consenting patients with clinical signs of asthma or if the FEV₁ was <80% of predicted for height, received salbutamol 200ug administered using the DPI device. If symptoms persisted or FEV₁ remained <80% of predicted, the DPI was repeated (+10 minutes). Patients with no improvement in FEV₁ after 2 administrations of DPI, were considered treatment failures, and would have received wet nebulisation to access for "reserve bronchodilator capacity". This treatment regimen is standard RCCH Allergy Clinic practice. Primary efficacy variable was mean change in FEV₁ 15 minutes post 1st administration DPI, if required FEV₁ +10 minutes post second DPI administration and after wet nebulisation. Secondary variables were symptom outcome and perceptions of the device. Descriptive statistics were calculated and expressed as mean, SD and 95% confidence interval (CI) of the mean. The response in FEV₁ was analysed using ANOVA, with a significance level of

0.05.

RESULTS

Fifty-one symptomatic asthmatic children (28 male/23 female) were enrolled. Mean age was 11 years (range 7 -16). Eighty four percent of patients were on ICS medications and in addition, 24% received long acting B₂ agonists. Recent cough and wheeze were reported in 80 % and 55% of patients respectively. The mean FEV₁ pre bronchodilator was 1.27L (0.5L). This was significantly lower than the mean previous best FEV₁ of 1.53L (0.4L), p<0.001. The mean change in FEV₁ 15 minutes post DPI, compared to baseline, was 370 mL (CI 296 to 446mL) p<0.001. Four percent of patients required a second administration of the DPI with a mean additional change at 25 minutes of 100 mL (CI -57 to 255), p>0.05. No patients required wet nebulisation. Adverse events reported were tremor in 4% and nausea in 8% of patients. Ninety eight percent of patients perceived the device easy to use and 94% of patients preferred the DPI to the MDI-Spacer combination. Ninety five percent of caregivers expressed confidence in the DPI device, were it to be required for the relief of acute asthma.

DISCUSSION

The findings of this independent study, confirm the favourable RCCH Allergy and Asthma Clinic experience when using the low cost salbutamol DPI (Cipla Medpro®) device for the acute relief of symptomatic asthma. In spite of

the possible bias introduced by the open label study design we conclude that the device was both effective and safe in children with symptomatic asthma. In addition, the Salbutamol DPI device was considered to be effective and

easy to use, by patients and staff alike. These findings are particularly helpful when cost constraints restrict the use of dry powdered inhalers.

References

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