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Title: Comparison of bronchodilator effect of salbutamol delivered via MDI + spacer and DPI in children with asthma

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Body: Background: Inhaled short acting beta2-agonists are widely used in asthma treatment. Studies comparing the efficacy of salbutamol containing pressurized metered dose inhalers (pMDI) and dry powder inhalers (DPI) in the paediatric asthma population are limited. Aim: This study aimed to compare the bronchodilator response to a salbutamol pMDI plus spacer and to a salbutamol DPI by children and adolescents with asthma related bronchoconstriction. Methods: 80 patients aged 5 to 18 years with physician diagnosed asthma with a forced expiratory volume in one second (FEV1) < 85% were enrolled in a single centre, randomized, open label study. Patients were randomized to salbutamol 200 ug via pMDI (Ventolin HFA Inhalation Aerosol, GlaxoSmithKline, UK) plus large volume spacer (Volumatic, GlaxoSmithKline, UK), or salbumatol 200 ug via DPI (Buventol Easyhaler, Orion Pharma, Finland). The primary variable was FEV1 change from baseline, the co-primary endpoint was forced expiratory flow 25–75% (FEF25-75%) change from baseline 20 minutes after administration of salbutamol. Results: FEV1 change from baseline was 19.77% (SD: 15.519) and 13.93% (SD: 12.828) in the PMDI + spacer group and in DPI group respectively. The difference was not significant (p=0.069, 95% CI: -12.149, 0.472). FEF25-75% change from baseline 37.11% (SD: 35.293) and 30.20% (SD: 31.241) in the PMDI + spacer group and in DPI group respectively. The difference was not significant (p = 0.3564, 95% CI: -21.75, 7.923). Conclusion: The present study shows that salbutamol DPI is a valid alternative for relieving bronchoconstriction in children (5 to 18 years of age) with asthma.