Title: Formoterol/Budesonide Turbuhaler Versus pMDI Salbutamol for Acute Asthma in Outpatient Emergency Setting: A Prospective, Randomised, Open-Label Study

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| **Introduction**  The Global Initiative for Asthma (GINA) has suggested the need for studies on inhaled corticosteroid (ICS)-formoterol in the Emergency Department (ED). Symbicort® Turbuhaler contains budesonide, an ICS, and formoterol, a rapid and long-acting beta2-agonist (LABA) that causes rapid bronchodilation within 1–3 minutes of inhalation, comparable with salbutamol.  **Objectives**  This study aimed to compare the discharge rates of budesonide/formoterol (Symbicort®, 160/4.5 mcg/inhalation) versus pressurised metered-dose inhaler (pMDI) salbutamol (100mcg/puff) in acute asthma in outpatient ED.  **Method**  This single-centre, prospective, randomised, and open-label study collected data on adult asthma patients who attended the outpatient ED for mild to moderate asthma exacerbation. The intervention arm’s subjects received budesonide/formoterol turbuhaler, and the control arm’s subjects received pMDI salbutamol with a valved holding chamber. Both arms followed the same Asthma Bay treatment protocol regarding intravenous hydrocortisone and other medications in case of incomplete response to the initial treatment. Stratified randomisation with variable baseline ICS use was used in this study. Direct discharge rate from Asthma Bay was the primary outcome. Discharge criteria include resolution of symptoms, negative rhonchi, not tachypneic, oxygen saturation (SpO2) >95% on room air, peak expiratory flow rate (PEFR) >60-80% of personal best, stable blood pressure and heart rate. Vital signs at pre and post-treatment were also compared.  **Results**  Seventy-four (n=37 for each arm) asthma patients were recruited. Baseline clinical characteristics were comparable between the two arms. Direct discharge rates from ED were comparable between the two arms (p=1.000). Post-treatment vital signs (respiratory rate, SpO2, PEFR) were similar between the two arms, except for the higher increment of heart rate (p<0.001) and lesser reduction of blood pressure in the control arm (p=0.013). Hydrocortisone use was significantly higher in the control arm (n=19, 51.4%) than in the budesonide/formoterol arm (n=6, 16.2%) (p=0.001).  **Conclusion**  Budesonide/formoterol turbuhaler is as effective as pMDI salbutamol in treating asthma exacerbation in the outpatient ED with less effect on heart rate and lower usage of intravenous corticosteroids. The demonstrated efficacy of budesonide/formoterol turbuhaler makes it an additional option for acute asthma in the outpatient ED setting and during any infectious respiratory disease outbreak such as COVID-19.  **Keywords:**  budesonide-formoterol; acute asthma; emergency department  Word count: 349 |