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 more studies on inhaled corticosteroid (ICS)-formoterol in the Emergency Department (ED) setting. Symbicort® Turbuhaler contains budesonide, an inhaled corticosteroid (ICS), and formoterol, a long-acting beta2-agonist (LABA). Formoterol is a rapid-onset LABA that causes rapid bronchodilation within 1–3 minutes of inhalation, comparable with salbutamol. As needed (PRN) ICS-formoterol is superior over SABA alone in reducing moderate to severe exacerbations, but its efficacy and safety in ED setting is unclear. **Objectives**This study aimed to compare the outcomes of budesonide/formoterol (Symbicort®, 160/4.5 mcg/inhalation) versus pressurised metered-dose inhaler (pMDI) salbutamol (100mcg/puff) in acute (mild-moderate) asthma in outpatient ED. **Method**This single-centre, prospective, randomized, and open-label study collected data on adult asthma patients who were presented to the outpatient ED for mild to moderate asthma exacerbation. The intervention arm’s subjects received budesonide/formoterol (Symbicort® 160/4.5mcg) turbuhaler, and the control arm’s subjects received pMDI salbutamol with a valved holding chamber. Stratified randomization with variable baseline ICS use was used in this study. Direct discharge rate from Asthma Bay was the primary outcome. Vital signs pre- and post-treatment between the two arms 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 outcomes (respiratory rate, oxygen saturation, peak expiratory flow rate) 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). Intravenous 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 mild to moderate acute asthma exacerbation 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: 340 |