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Title: A double-blind, double-dummy, randomized study of beclomethasone/formoterol versus fluticasone/salmeterol in treatment of moderate to severe asthma in Taiwan

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Body: Background Inadequate asthma control by ICS alone asks for the combination with LABA, and the extrafine formulation of BDP/F allows 2.5-fold lower dose of BDP to achieve the same efficacy. This study compared the efficacy, safety and tolerability of BDP/F with those of FP/S in patients with moderate to severe asthma. Objective To show that the onset action of BDP/F was superior to that of FP/S in patients with moderate to severe asthma. Methods: This was a double-blind, double-dummy, randomized, multicenter study. A total of 253 patients whose asthma was not adequately controlled after 2-week run-in period were randomized to receive BDP/F or FP/S treatment for 12 weeks. Results The superiority of BDP/F over FP/S in the change from baseline pre-dose FEV_1 to week 12 post-dose 5-min FEV_1 was not demonstrated in this study (BDP/F: 0.20L, FP/S: 0.14L; $p>0.05$). FEV_1 and FVC increased significantly immediately after inhalation of BDP/F (from 5 min). Similar results were found in the FP/S group in terms of FEV_1, but FVC did not improve significantly until 30 min after inhalation of FP/S. Patients who received BDP/F showed significantly higher improvements in FEV_1 and FVC at post-dose 5 min as compared with those who received FP/S. Both groups showed comparable results in PEF, asthma control rate and use of rescue medication. Conclusions BDP/F was as efficacious as FP/S in improving pulmonary function, PEF, and asthma control. Furthermore, a trend of more rapid onset of action was found in the BDP/F group. The safety profile showed that both BDP/F and FP/S were well-tolerate in Taiwanese patients with moderate to severe asthma.