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Title: Asthma exacerbation with fluticasone propionate/formoterol fumarate combination therapy versus its individual components

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Body: Background: Asthma control remains suboptimal in many patients as indicated by exacerbations and deteriorating symptoms. This pooled analysis of up to 5 randomized double-blind studies assessed the effects of fluticasone propionate (FLUT) and formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM) on asthma exacerbations. Methods: Adults and adolescents with asthma (all severities) were randomized to FLUT/FORM (100/10, 250/10 or 500/20 μg bid), or equivalent nominal doses of FLUT (100, 250 or 500 μg bid; 5 studies) or FORM (10 μg bid; 3 studies) for 8 or 12 weeks. The proportion of patients with an exacerbation was assessed. Mild-to-moderate exacerbation was defined as peak expiratory flow rate >30% below baseline, awakening at night due to asthma or rescue medication use >3–4 times/day (each on ≥2 consecutive days); severe exacerbation was need for additional therapy, or emergency visit/hospitalization due to asthma. Results: Significantly fewer patients reported exacerbations with FLUT/FORM than FLUT (27% [172/641] vs 33% [211/643]; odds ratio [OR] 0.75; 95% CI 0.59, 0.96) or FORM (18% [62/341] vs 31% [108/345]; OR 0.49; 95% CI 0.34, 0.70). The annualised exacerbation rate was significantly lower with FLUT/FORM than FLUT (ratio 0.69; 95% CI 0.61, 0.79; p<0.001) or FORM (0.55; 95% CI 0.44, 0.68; p<0.001). The risk of severe exacerbation was similar for FLUT/FORM and FLUT (2% [12/641] vs 3% [18/643]; OR 0.66; 95% CI 0.32, 1.39), but lower with FLUT/FORM than FORM (2% [8/341] vs 10% [33/345]; OR 0.23; 0.10, 0.50). Conclusion: FLUT/FORM significantly reduces the risk of reported asthma exacerbations (any severity) compared with its individual components.