Oral Prolonged Release Beclomethasone Dipropionate and Prednisone in the Treatment of Active Ulcerative Colitis: Results From a Double-Blind, Randomized, Parallel Group Study
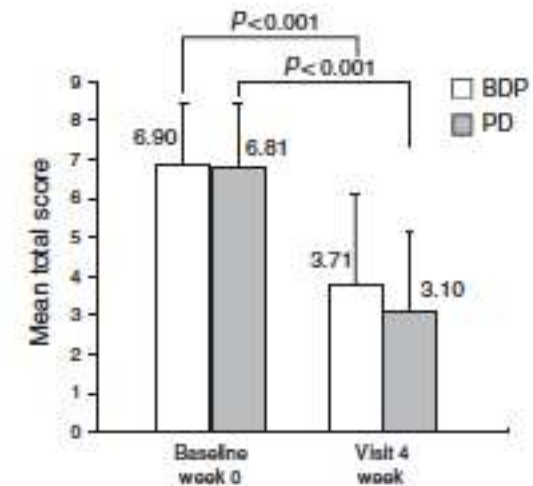
Double-blind randomized trial.
Patients with mild-moderately active ulcerative colitis were randomly assigned to: beclomethasone dipropionate (BDP) 5mg once daily for 4 weeks and then every other day for another 4 weeks vs oral prednisone (PD) 40mg once daily for 2 weeks tapered of 10 mg every 2 weeks during the 8-week study period.
5ASA allowed to be continued. Thiopurines, steroids or TNFinhibitors whithin previous 3 months (6 months for TNF) were not permitted.

Primary endpoints: Non-inferiority of BDP vs PD in terms of DAI score reduction by at least 3 points at week 4.

Results: N=282
- DAI response rates at week 4: 64.6% DBP vs 66.2% PD, demonstrating non-inferiority p=0.78.
- Steroid related adverse events and cortisol <150nmol/L at week 4 were comparable between groups.

Conclusion:
BDP was non-inferior to PD in the treatment of mild-moderate active ulcerative colitis with good safety profile in both groups.

Table 2. Primary and secondary efficacy end points (DAI and CAI)

	BDP	PD	Difference	95% CI	P-value
Primary efficacy end point					
DAI responders at week 4 (ITT population)	84 (64.6%)	90 (66.2%)	−1.56	−13.00 to 9.88	0.78
DAI responders at week 4 (PP population)	84 (65.1%)	86 (65.2%)	−0.04	−11.60 to 11.53	0.97
Secondary efficacy end points (ITT population)					
Patients with DAI <1 at week 4	25 (19.2%)	31 (22.8%)	−3.56	−13.34 to 6.21	0.38
Change in DAI total score at week 4*	−3.17	−3.75	0.58	0.09 to 1.07	0.02
Change in CAI total score at week 4*	−3.05	−3.60	0.54	0.04 to 1.04	0.04
Change in CAI total score at week 8*	−3.58	−4.32	0.74	0.12 to 1.36	0.02

BDP, beclomethasone dipropionate; CAI, Clinical Activity Index; CI, confidence interval; DAI, Disease Activity Index; ITT, intention-to-treat; PD, prednisone; PP, per-protocol.
Clinical response was defined as a DAI score <3 or a reduction in the DAI score by at least 3 points for patients with a baseline DAI ≥7.
*Results from ANCOVA model (difference is BDP—PD).

Figure 2. The total mean Disease Activity Index (DAI) score at baseline and week 4. Bars represent s.d.

Van Assche G et al. Am J Gastroenterol 2015; 110:708–715