

Complete mucosal healing of distal lesions induced by twice-daily budesonide 2-mg foam promoted clinical remission of mild-to moderate ulcerative colitis with distal active inflammation: double-blind, randomized study

Phase 3 randomized, double-blind multicenter trial. Ulcerative colitis including left and extensive colitis patients were randomized to: twice-daily budesonide 2mg/25ml foam or placebo foam. Oral 5ASA, oral salazosulfapyridine or probiotics were allowed, rest of therapies prohibited.

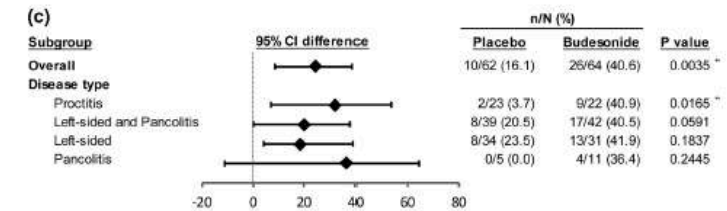
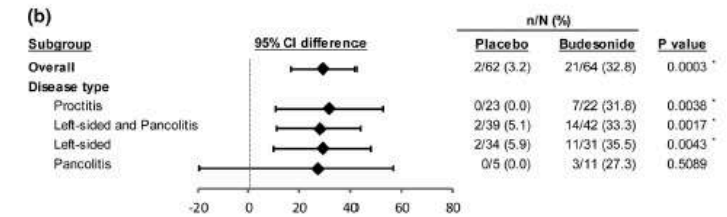
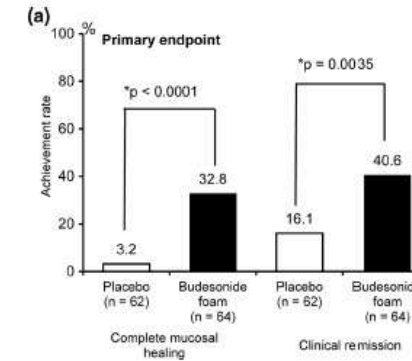
Primary endpoints: Percentage of complete mucosal healing of distal lesions at week 6 and clinical remission

Results:

- Complete mucosa healing week 6: 32.8% budefoam vs 3.2% pbo, $p < 0.0001$
- Clinical remission week 6: 40.6% budefoam vs pbo, $p = 0.0035$
- Efficacy was consistent across different disease extension.

Conclusion:

This study confirmed for the first time complete mucosal healing with twice-daily budesonide 2-mg foam in mild-to-moderate ulcerative colitis with distal active inflammation. The results also indicated that complete mucosal healing of distal lesions by budesonide foam promotes clinical remission of ulcerative colitis



		Clinical remission, n/N (%)				
		Overall	Proctitis	Left-sided/Pancolitis	Left-sided Pancolitis	
Complete mucosal healing	Achieved	16/21 (78.2)	5/7 (71.4)	11/14 (78.6)	9/11 (81.8)	2/3 (66.7)
	Not achieved	1/43 (25.6)	5/15 (33.3)	8/28 (21.4)	4/20 (20.0)	6/28 (21.4)

