2012. Basiliximab

RCT/ Basiliximab/UC /Recurrence

Basiliximab Does Not Increase Efficacy of Corticosteroids in Patients With Steroid-Refractory Ulcerative Colitis

Randomized controlled trial
Patients with mod-severe ulcerative colitis with corticosteroid-refractory response despite 14 days of oral prednisone (40-50mg/d) were randomly assigned to 20mg, 40mg basiliximab (BASILX) or placebo at weeks 0,2 and 4.

Primary endpoint: Clinical remission at w8.

Results: N=149
- Clinical remission at w8: 28% placebo vs 29% BASILX40mg vs 26% BASILX20mg, p=ns for both comparisons.
- BASILX was generally well tolerated although 6.1% had serious adverse events compared to 3.9% in placebo.

Conclusion:
Basiliximab does not increase the effect of corticosteroids in the induction of remission in outpatients with corticosteroid-resistant moderate to severe UC.

*Basiliximab is a chimeric monoclonal antibody that binds CD25 inhibiting IL-2 mediated proliferation lymphocytes.

Table 2. Clinical Response, Clinical Remission, and Mucosal Healing at Weeks 4 and 8

	BSX 20 mg (n = 46)	BSX 40 mg (n = 52)	BSX combined (n = 98)	PBO (n = 51)
Clinical remission				
Wk 4				
n (%)	8 (17.4)	7 (13.4)	15 (15.3)	8 (15.7)
P value[a]	1.00	.79	1.00	
Wk 8				
n (%)	12 (26.1)	15 (28.8)	27 (27.6)	14 (27.5)
P value[a]	1.00	1.00	1.00	
Clinical response				
Wk 4				
n (%)	28 (60.9)	28 (53.8)	56 (57.1)	33 (64.7)
P value[a]	.67	.23	.29	
Wk 8				
n (%)	33 (71.2)	37 (71.1)	70 (71.4)	38 (74.5)
P value[a]	.49	.50	.43	
Mucosal healing				
Wk 4				
n (%)	24 (52.5)	31 (59.4)	55 (56.1)	28 (54.9)
P value[a]	.84	.69	1.00	
Wk 8				
n (%)	29 (63.0)	35 (67.3)	63 (64.3)	33 (64.7)
P value[a]	1.00	.68	1.00	

[a]Fisher exact test comparing each treatment group with PBO.

Sands BE et al. Gastroenterology. 2012; 143:356-364