Long-Term Efficacy of Fistula Healing and Response with ADA Through 2 Years

Population	Endpoint	Month since baseline*	All ADA (EOW+EW combined)
% of pts with fistulas at BL of CHARM, (n/N)	Fistula healing	6	30 (21/70)
		12	33 (23/70)
		18	54 (38/70)
		24	51 (36/70)
% of pts with fistulas at BL of CHARM, (n/N)	≥50% Fistula response	6	46 (32/70)
		12	49 (34/70)
		18	70 (49/70)
		24	61 (43/70)

*18 and 24 months represent 6 and 12 months of OLE after 12 months of blinded therapy in the CHARM study.

the blinded study and at 6 and 12 months of the OLE follow-up study (for a total of 24 months of therapy).
Results: Results are in the table below.
Conclusion: Sustainable efficacy of ADA in fistula healing and response is evident after 2 years. ADA has shown sustained response in almost two-thirds of the patients in the OLE who had fistulas at baseline of CHARM and sustained closure in more than half of the ADA-treated patients.

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Adalimumab Therapy for Patients with Ulcerative Colitis Who Have Lost Response or Are Intolerant of Infliximab

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Purpose: Adalimumab (ADA), a human antibody to tumor necrosis factor (TNF), is an effective treatment for patients with Crohn's disease who have lost response or are intolerant of infliximab (INF). We assessed the clinical response and adverse effects of adalimumab in patients with ulcerative colitis (UC) who have failed INF due to intolerance or loss of clinical response.
Methods: We queried the Inflammatory Bowel Disease Database at UCSF to identify all patients with a history of UC who were treated with ADA. The following data were retrospectively collected: patient demographics, clinical history, adverse events on IFX and ADA, and clinical response to therapy. Response to therapy was measured using the Simple Clinical Colitis Activity Index, where response was defined as a score of <5.
Results: Five patients (3 M/2 F) were identified with UC and treatment with ADA. The mean age was 29.6 [range 23–36] years, and 80% had pancolitis. All patients had duration of colitis of at least 5 years, and all were previously treated with INF. Three patients had an initial response to INF but eventually lost response despite 10 mg/kg every 4 week dosing, one patient never achieved a durable response to INF, and one patient had a severe infusion reaction in part due to episodic dosing of INF. One patient eventually responded to ADA after 11–12 weeks but required increased dosing to 40 mg weekly. One patient stopped ADA due to significant myalgias and fatigue. The remaining three patients failed to achieve a response to ADA and have been referred for colectomy.
Conclusion: ADA is well tolerated in patients with UC. Prospective studies in INF-naive patients and past responders to INF are needed to determine its efficacy in this group.

FUNCTIONAL BOWEL DISORDERS

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Predictors of Small Intestinal Bacterial Overgrowth in Patients with Irritable Bowel Syndrome

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Purpose: Patients with irritable bowel syndrome (IBS) have been associated with a higher prevalence of small intestinal bacterial overgrowth (SIBO) when compared to healthy controls. The aim of this study was to identify risk factors for SIBO in patients with IBS.
Methods: A total of 45 consecutive patients diagnosed with IBS who underwent hydrogen and methane breath testing for SIBO were identified retrospectively after excluding patients with other coexistent gastrointestinal and systemic disorders. Based on the referring physician substrate preference, 13 patients underwent glucose breath testing (GBT); 17 underwent lactulose breath testing (LBT); and 15 were given a combined glucose and lactulose solution. Among the 45 patients evaluated, 11 had positive breath tests (cases) and 34 had negative tests (controls). The cases and controls were compared with respect to age, duration of IBS symptoms, gender, predominant symptom, and Body Mass Index (BMI).
Results: Among the 45 patients with IBS who underwent breath testing, 11 (24.4%) had a positive test (5 with positive LBT, 5 with positive combined lactulose and glucose solution, and 1 had a positive GBT). A significant difference was seen in mean age and mean duration of symptoms in IBS patients with positive breath tests when compared to IBS patients with negative breath tests. In the multivariate analysis using ANCOVA, only duration of IBS symptoms remained statistically significant.
Conclusion: To our knowledge, this analysis is the first to evaluate age and duration of symptoms as a risk factor for a positive breath test in an IBS population. Our report suggests duration of IBS symptoms is independently associated with a significant risk for SIBO. Our results suggest it may be

Table 1. Patient data

Patient	Previous INF dose	Reason for stopping INF	ADA dose	Clinical response	Time to response	ADA adverse effects
1	10 mg/kg q4 weeks	Lost response	80 mg weekly	No		None
2	10 mg/kg q4 weeks	Lost response	40 mg weekly	Yes	11–12 weeks	None
3	10 mg/kg q4 weeks	Lost response	40 mg weekly	No		None
4	10 mg/kg q4 weeks	Lost response	40 mg every other week	No		None
5	5 mg/kg (episodic)	Severe infusion reaction	40 mg every other week	No		Myalgias, fatigue