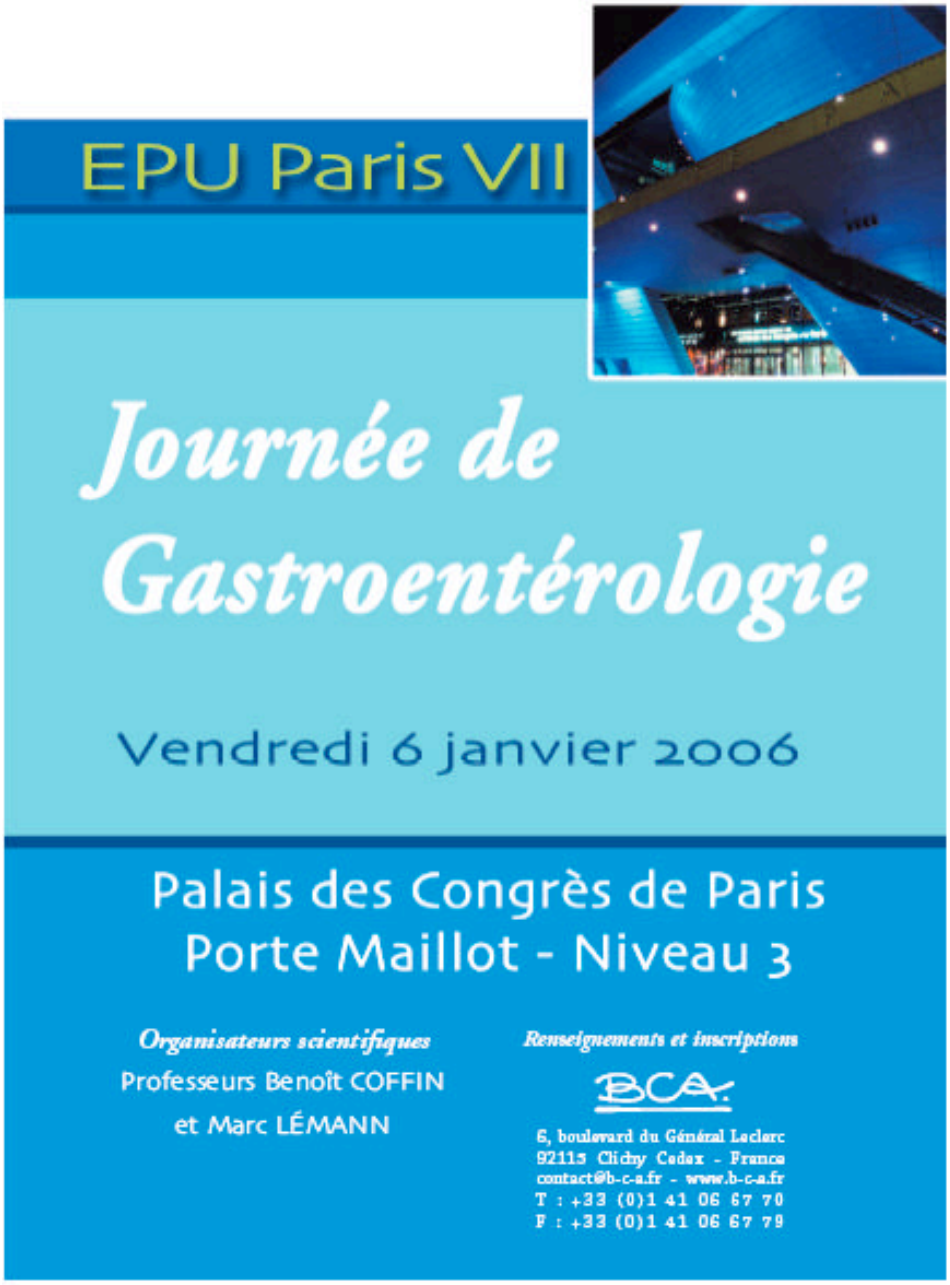

L'ARTICLE 2005 AYANT CHANGE LA PRATIQUE

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N Engl J Med. 2005 8;353:2462-76.

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BACKGROUND

Infliximab, a chimeric monoclonal antibody directed against tumor necrosis factor alpha, is an established treatment for Crohn's disease but not ulcerative colitis.

METHODS

Two randomized, double-blind, placebo-controlled studies--the Active Ulcerative Colitis Trials 1 and 2 (ACT 1 and ACT 2, respectively)--evaluated the efficacy of infliximab for induction and maintenance therapy in adults with ulcerative colitis. In each study, 364 patients with moderate-to-severe active ulcerative colitis despite treatment with concurrent medications received placebo or infliximab (5 mg or 10 mg per kilogram of body weight) intravenously at weeks 0, 2, and 6 and then every eight weeks through week 46 (in ACT 1) or week 22 (in ACT 2). Patients were followed for 54 weeks in ACT 1 and 30 weeks in ACT 2.

RESULTS

In ACT 1, 69 percent of patients who received 5 mg of infliximab and 61 percent of those who received 10 mg had a clinical response at week 8, as compared with 37 percent of those who received placebo (P<0.001 for both comparisons with placebo). A response was defined as a decrease in the Mayo score of at least 3 points and at least 30 percent, with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or an absolute rectal-bleeding subscore of 0 or 1. In ACT 2, 64 percent of patients who received 5 mg of infliximab and 69 percent of those who received 10 mg had a clinical response at week 8, as compared with 29 percent of those who received placebo (P<0.001 for both comparisons with placebo). In both studies, patients who received infliximab were more likely to have a clinical response

at week 30 (P< or =0.002 for all comparisons). In ACT 1, more patients who received 5 mg or 10 mg of infliximab had a clinical response at week 54 (45 percent and 44 percent, respectively) than did those who received placebo (20 percent, P<0.001 for both comparisons).

CONCLUSIONS

Patients with moderate-to-severe active ulcerative colitis treated with infliximab at weeks 0, 2, and 6 and every eight weeks thereafter were more likely to have a clinical response at weeks 8, 30, and 54 than were those receiving placebo. (ClinicalTrials.gov numbers, NCT00036439 and NCT00096655.)