

Use of fecal calprotectin as marker of disease activity in patients under maintenance treatment with infliximab for ulcerative colitis [on behalf of BIRD¹⁴]

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Background: To evaluate the evolution of fecal calprotectin levels in patients with ulcerative colitis (UC) under maintenance treatment with infliximab.

Methods: 113 UC patients, 83 from Belgium and 30 from Norway, in clinical remission under a stable 5 mg/kg Q8W infliximab therapy were followed-up over 1 year. Faecal calprotectin was measured monthly. Clinical and biochemical examination was performed at each infusion. Sigmoidoscopies were performed at inclusion and after 1 year, or earlier if patients dropped out of the study due to flare. "Active disease" was defined by the clinical Mayo score during the study or by an endoscopic score of ≥ 2 at week 52. "Deep remission" was defined by a normal endoscopy at the start of the study and at week 52 associated with clinical Mayo scores at all times < 3 .

Results: After 1 year, 83 (73.5%) of 113 patients remained in clinical remission and continued the study till week 52. Discontinuation was observed in 28 patients: 7 (5.8%) due to flare, 5 (4.4%) due to safety issues (2 hypersensitivity reaction, 1 joint pain, 1 adrenal tumor, 1 polyneuropathy) and 16 due to withdrawal of consent. "Active disease" was observed in 13/113 (11%) patients and "deep remission" in 30/113 (26.5%) patients. In patients in deep remission median calprotectin levels were less than 50 mg/kg at all measured time points. Patients who flared had significantly higher calprotectin levels at the moment of flare (median calprotectin levels of 477 mg/kg). Significant increase was already observed 3 months before flare. Further ROC analysis (flare vs deep remission at last evaluation) suggested that a calprotectin level > 300 mg/kg showed a reasonable sensitivity (58.3%) and high specificity (93.3%) to model flare and a calprotectin level < 50 mg/kg to model deep remission (sensitivity 83.3% and specificity 83.3%). Two consecutive calprotectin measurements of > 300 mg/kg predicted a flare with a sensitivity of 61.5% and specificity of 100% (remission vs flare).

Conclusions: In UC patients under infliximab maintenance therapy calprotectin levels highly correlate with disease activity. Deep remission is associated with very low levels. A flare is associated with high levels (median >300 mg/kg). Two consecutive calprotectin levels of >300 mg/kg predict a flare.