

Table. Multivariable Model Predicting Continuous Clinical Response.

Predictor	Odds Ratio	95% Confidence Interval	P-value
Calprotectin wk 6 (log)	0.55	0.394–0.775	.0006
Calprotectin change from wk 0–6 (log)	1.34	0.989–1.810	.0587
Treatment (golimumab maintenance vs withdrawal)	1.91	1.234–2.957	.0037

Mayo every 4 wk (loss of response was confirmed by endoscopy); patients who maintained response through wk 54 were considered to be in CCR.^[1] Our current analysis sought to identify early predictors of CCR.

Methods: This post hoc analysis included 456 patients from PURSUIT who were responders at wk 6 after golimumab induction and entered maintenance treatment.^[2] Potential predictors evaluated were age; gender; disease duration (≤ 5 y vs > 5 y); disease extent (extensive vs limited); Mayo score at induction wk 0 (< 9 vs ≥ 9); Mayo score at induction wk 6; stool frequency and rectal bleeding (Mayo) at induction wk 6; CRP, calprotectin, and lactoferrin at induction wk 6 and change from induction wk 0–6; Mayo change from induction wk 0–6; CRP normalization at induction wk 6; mucosal healing (Mayo endoscopy score 0 or 1) at induction wk 6; and golimumab maintenance vs withdrawal. Potential interactions between factors were evaluated. Final stepwise selection of terms was used with significance levels for entry and retention of 0.50 and 0.15, respectively.

Results: In univariate analysis, factors significantly associated with CCR were treatment group, wk-6 fecal calprotectin, and wk-6 lactoferrin. Wk-6 calprotectin and lactoferrin were correlated ($r=0.78$; $P<0.0001$). results of the final multivariable model are shown in Table.

Conclusions: In this post hoc analysis of PURSUIT, maintenance treatment with golimumab and wk-6 calprotectin levels were significant predictors of CCR in moderate to severe UC patients who responded to golimumab induction at wk 6.

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References:

- [1] Sandborn WJ et al, (2014), Subcutaneous golimumab maintains clinical response in patients with moderate-to-severe ulcerative colitis, *Gastroenterology*, 146(1):96-109.
- [2] Sandborn WJ et al, (2014), Subcutaneous golimumab induces clinical response and remission in patients with moderate-to-severe ulcerative colitis, *Gastroenterology*, 146(1):85-95.

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Azathioprine and 6-Mercaptopurine use in the Swiss IBD cohort: adverse effects, causes of discontinuation and risk of "flares" according to 6-TG levels

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Background: To characterize and analyze in the Swiss IBD Cohort : a) reported Azathioprine (AZA) and 6-Mercaptopurine (6-MP) adverse effects (AE), b) causes of discontinuation and c) response to therapy according to gastroenterologists' clinical judgment, d) whether level of 6-TGN < 235 pmol/8 x 10⁸ red blood cells (RBC) is associated with a higher risk of "flare" occurrence.

Methods: Retrospective statistical description, Cox model and Kaplan-Meier survival estimation.

Results: 1499 patients with Crohn's Disease (CD) and 1066 with Ulcerative colitis (UC).

a) Of 1670 patients ever treated with AZA/6-MP, there were 611 reported AE: 149 intolerances are observed (24.4%), 81 pancreatitis (13.2%), 61 hepatitis (10.0%), 33 hematologic side effects (5.4%), 20 hypersensitivities (3.2%), 17 infections (2.8%), 13 cases of fatigue (2.1%), 7 malignancies (1.2%) and 207 not further specified AE (33.9%).

b) Of 566 reported causes of discontinuation according to gastroenterologists' clinical judgment, 209 "treatment no long needed" (36.9%), 196 "breakthrough/loss of response" (34.6%), 92 "patient wish" (16.3%), 45 "primary non-response" (7.9%) and 21 "Conception/Pregnancy or wish of it" (3.7%) were described.

c) Of 1187 gastroenterologists' clinical judgment of AZA/6-MP responses, 417 (35%) were judged as "successful", 639 (54%) as "failure", 131 (11%) "unknown".

d) Of 364 CD patients under AZA/6-MP, 199 (54.7%) developed a "flare" during the observation period (median 13.3 mo, IQR 11.9-23.4, range 5.8-59.0). Of 204 patients with UC under AZA/6-MP, 106 (52.0%) developed a "flare" during the observation period (median 14.0 mo, IQR 12.2-24.9, range 7.3-48.2). 6-TGN levels ≥ 235 pmol/8 x 10⁸ RBC showed a not statistically significant tendency to improve "flare"-free survival time in CD and UC (HR=1.157, 95CI: 0.680-1.971, p=0.590).

Conclusions: In the SIBDC, AZA/6-MP are frequently used, AE and failure are frequently reported, 6-TGN levels ≥ 235 showed a tendency to improve "flare"-free survival.

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Durability of the anti-HBs titers after vaccination against Hepatitis B virus (HBV) in patients with Inflammatory Bowel Disease (IBD)

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