

Colonoscopy and confocal laser endomicroscopy to assess barrier dysfunction.

Primary endpoint:

To comparatively assess the predictive values of barrier healing, endoscopic remission & histologic remission for predicting occurrence of major adverse outcome (MAO) (disease flare, IBD hospitalization or surgery, dose escalation of steroids, immunosuppressants, small molecules or biologics) in IBD patients in clinical remission.

Results:

The probability of MAO-free survival was significantly higher in IBD patients with endoscopic remission compared to endoscopically active disease.

Histologic remission predicted MAO-free survival in patients with UC but not in CD.

Barrier healing on endomicroscopy was superior to endoscopic and histologic remission for predicting MAO-free survival in both, UC and CD.

Conclusion:

Barrier healing is associated with decreased risk of disease progression in clinically remittent IBD patients with superior predictive performance compared to endoscopic and histologic remission. Analysis of barrier function might be considered as a future treatment target in clinical trials.

Intestinal barrier healing is superior to endoscopic and histologic remission for predicting major adverse outcomes in IBD: the prospective ERICA trial

Table 2. Diagnostic performances of endoscopic remission, histologic remission and barrier healing for predicting major adverse outcomes in UC and CD patients.

Parameter	Accuracy (95% CI-Interval)	Sensitivity (95% CI-Interval)	Specificity (95% CI-Interval)	PPV (95% CI-Interval)	NPV (95% CI-Interval)
Ulcerative Colitis					
Endoscopic Remission (MES<1)	70.4% (59.2 – 80%)	88% (68.8 – 97.5%)	62.5% (48.6 – 75.1%)	51.2% (42 – 60.2%)	92.1% (79.8 – 97.2%)
Endoscopic healing (MES=0)	75.3% (64.5 – 84.2%)	44% (24.4 – 65.1%)	89.3% (78.1 – 96%)	64.7% (43.3 – 81.5%)	78.1% (71.4 – 83.7%)
Robarts Histologic Remission*	66.7% (55.3 – 76.8%)	84% (63.9 – 95.5%)	58.9% (45 – 71.9%)	47.7% (39 – 56.6%)	89.2% (76.6 – 95.4%)
Nancy Histologic Remission [†]	69.1% (57.9 – 78.9%)	84% (63.9 – 95.5%)	62.5% (48.6 – 75.1%)	50% (40.6 – 59.4%)	89.7% (77.7 – 95.7%)
Barrier Healing Colon	85% (75.3 – 92%)	68% (46.5 – 85.1%)	92.7% (82.4 – 98%)	81% (61.4 – 91.9%)	86.4% (78.2 – 91.9%)
Crohn's disease					
Endoscopic Remission [‡]	54% (43.7 – 64.2%)	76.3% (59.8 – 88.6%)	40.3% (28.1 – 53.6%)	43.9% (37.4 – 50.7%)	73.5% (59.3 – 84.1%)
SES-CD [§]	62% (51.8 – 71.5%)	65.8% (48.7 – 80.4%)	59.7% (46.5 – 72%)	50% (40.6 – 59.4%)	74% (63.6 – 82.2%)
Histologic Remission [¶]	56% (45.7% – 65.9%)	68.4% (51.4 – 82.5%)	48.4% (35.5 – 61.4%)	44.8% (37 – 52.9%)	71.4% (59.4 – 81%)
Barrier Healing Ileum	72.7% (62.9 – 81.2%)	50.4% (33.4 – 66.6%)	86.5% (75.8 – 94.2%)	70.4% (53.7 – 83%)	73.6% (66.7 – 79.6%)
Barrier Healing Ileum	88.7% (80.6 – 94.3%)	69.4% (51.9 – 83.7%)	100% (94.1 – 100%)	100%	84.7% (77.2 – 90.1%)

PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval; *, Histologic remission according to the Robarts' Histology index; †, Histologic remission according to the Nancy Histology index; ‡, Endoscopic remission was defined as absence of erosions and ulcerations; §, SES-CD-3-Endoscopic remission; ¶, Histologic remission was defined according to a modified Riley Score.

