

## **FECAL LEUKOCYTE ESTERASE: AN ALTERNATIVE BIOMARKER TO FECAL CALPROTECTIN IN INFLAMMATORY BOWEL DISEASE.**

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**Background:** Fecal calprotectin (FC) is a non-invasive biomarker used in inflammatory bowel disease (IBD) management and risk stratification of non-specific gastrointestinal symptoms. Leukocyte esterase is an inexpensive and widely available point-of-care inflammatory marker present on urinalysis test strips.

**Aims:** We aim to assess the diagnostic accuracy of fecal leukocyte esterase (FLE) relative to FC and endoscopy and demonstrate its use as an alternative biomarker for IBD.

**Methods:** In this prospective cohort study, 70 patients who had FC ordered as part of standard clinical care also received FLE testing. FLE levels were compared to various FC cut-off values, endoscopy and pathology findings as gold standard.

**Results:** As the FC cut-off increased from 50 to 500  $\mu\text{g/g}$ , FLE sensitivity increased from 67% to 95% while the specificity decreased from 86% to 76%. The area under the receiver operating characteristic (AUROC) increased from 0.79 to 0.90. An FLE of  $\geq 1+$  had the best test characteristics. Amongst patients who underwent endoscopic evaluation, FLE demonstrated an identical sensitivity (75%) and specificity (86%) to FC in predicting endoscopic inflammation. AUROC was 0.80 for FLE and 0.85 for FC with an optimal cut-off of  $\geq 2+$  and 301  $\mu\text{g/g}$ , respectively. When used to distinguish between active IBD and no/inactive IBD patients, FLE had a sensitivity of 84% and specificity of 90%, comparable to the 84% and 83%, respectively, of FC. AUROC was 0.88 for FLE and 0.91 for FC with an optimal cut-off of  $\geq 2+$  and 145  $\mu\text{g/g}$ , respectively.

**Conclusions:** FLE demonstrates adequate correlation and comparable accuracy to FC in predicting endoscopic inflammation and distinguishing between patients with active versus inactive IBD.

**Table 2. FLE sensitivity and specificity values derived from receiver-operator characteristic curves. A)** FLE relative different FC cut-offs. N = 70 for all cut-offs. FLE of 1+ or greater is the optimal cut-off value. **B)** FLE relative to presence of inflammation on colonoscopy. N = 27 (n = 20 inflammation vs 7 no inflammation). FLE of 2+ or greater and FC of 301 µg/g is the optimal cut-off value. **C)** FLE relative to presence of active IBD. N= 59 (n = 19 active IBD vs 40 no/inactive IBD). FLE of 2+ or greater and FC of 145 µg/g is the optimal cut-off value.

**A**

	FC ≥50 µg/g	FC ≥100 µg/g	FC ≥250 µg/g	FC ≥500 µg/g
Sensitivity (%)	67	74	88	95
Specificity (%)	86	83	78	76
Positive likelihood ratio	4.67	4.33	3.96	3.89
Negative likelihood ratio	0.39	0.31	0.15	0.06

**B**

	FLE ≥2+	FC >301 µg/g
Sensitivity (%)	75	75
Specificity (%)	86	86
Positive likelihood ratio	5.25	5.25
Negative likelihood ratio	0.29	0.29

**C**

	FLE ≥2+	FC >301 µg/g
Sensitivity (%)	84	84
Specificity (%)	90	83
Positive likelihood ratio	8.42	4.81
Negative likelihood ratio	0.18	0.19

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