European Crohn's and Colitis Organisation

Minimal additional benefits in adding fecal hemoglobin to fecal calprotectin in predicting endoscopic disease activity in patients with inflammatory bowel disease

LY Mak, LJ Chen, T Tong, KS Lau, WK Leung

Dr. Lung-Yi Mak (MBBS, PDipID, MRCP, FHKCP, FHKAM)

Specialist in Gastroenterology & Hepatology

Department of Medicine, Queen Mary Hospital, Hong Kong

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HKU Med LKS Faculty of Medicine Department of Medicine 香港大學內科學系

瑪麗醫院 Queen Mary Hospital

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Conflict of interest: None

Background and Aim

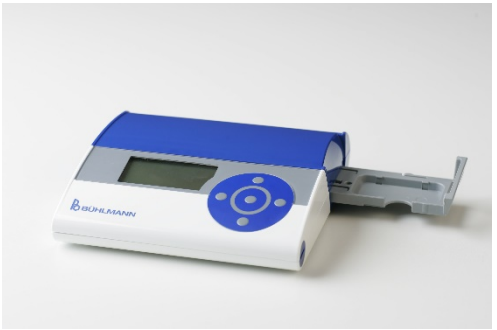
- Accurate evaluation of disease activity is essential in patients with inflammatory bowel disease (IBD).

- While endoscopic remission is the ideal therapeutic goal, non-invasive serum and fecal biomarkers are potential surrogate markers for monitoring disease activity.

- We aimed to evaluate the performance of these non-invasive biomarkers on prediction of endoscopic disease activity in IBD patients.

Methods

Patients with ulcerative colitis (UC) or Crohn's disease (CD)



Assessment:

1. Clinical activity scores (Partial Mayo scoring index or HBI)
2. Serum biomarkers included C-reactive protein (CRP), albumin and haemoglobin
3. Fecal biomarkers:
   - Fecal calprotectin (FCT) – Quantum Blue Calprotectin Extended (Buhlmann, Basal, Switzerland) with extended range from 30-1000 ug/g
   - Quantitative fecal immunochemical test (FIT) – Orion Diagnostica with range from 15-200 ug/g
4. Endoscopic disease activity in patients who had recent sigmoidoscopy or ileocolonoscopy within one year

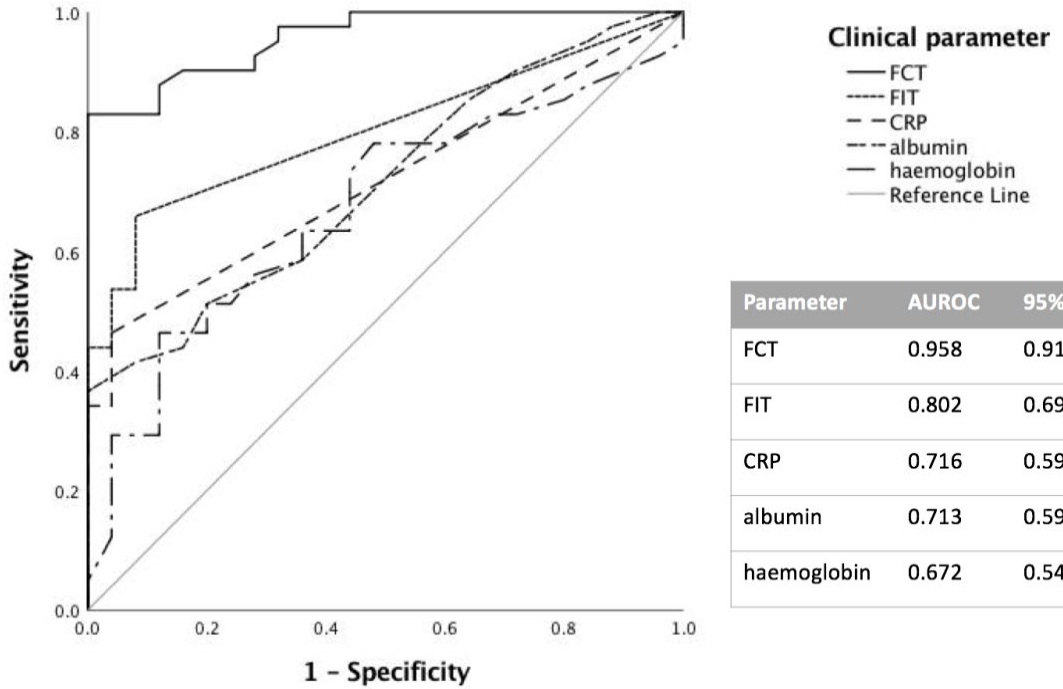
Statistical analysis:

- Receiver-operating characteristic analysis for best cut-off value of the biomarkers for endoscopically active disease

Results

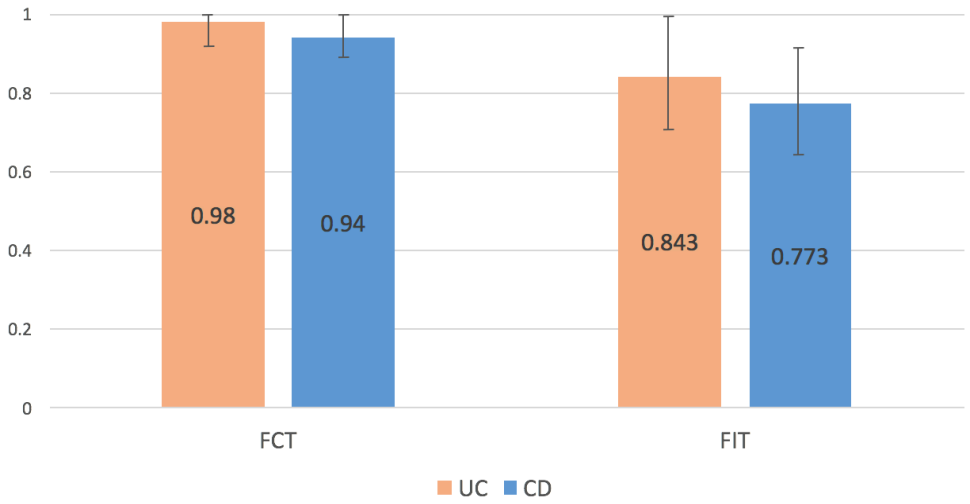
- 113 patients: mean age 44.7±17.6; 63.7% male; 54.9% UC:45.1% CD

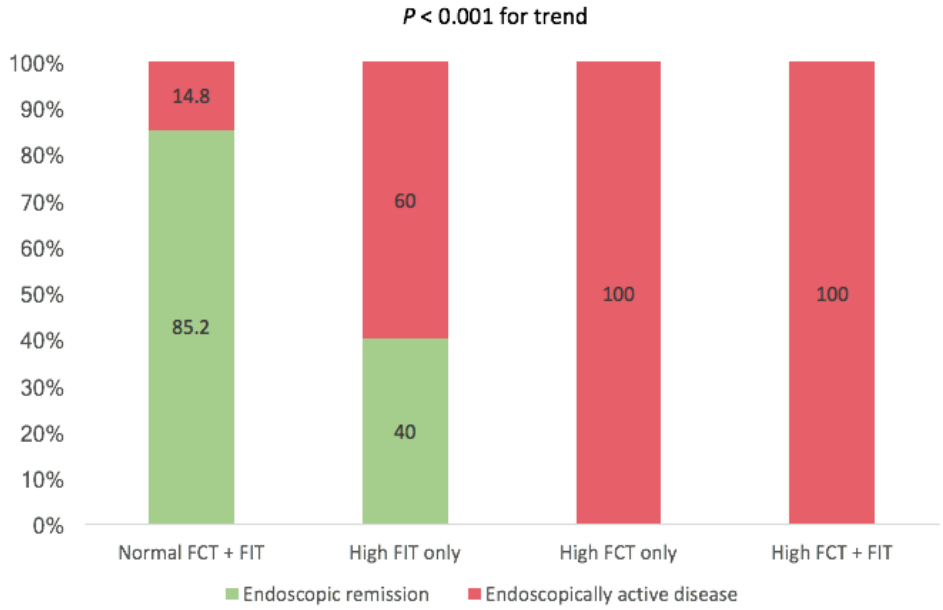
	Endoscopically active disease (62.1%)	Endoscopic remission (37.9%)	P value
Age (years)	36.4 ± 20.2	47.2 ± 15.1	0.025
Gender (male)	28 (68%)	18 (72%)	0.790
Clinical remission (yes)	16/27 (59%)	16/25 (64%)	0.781
Use of thiopurines (yes)	18 (43.9%)	7 (25%)	0.296
Use of biologics (yes)	7 (17.1%)	1 (4%)	0.143
FCT (ug/g)	632 ± 394	49 ± 30	<0.001
FIT (ug/g)	65 ± 65	16 ± 4	<0.001
CRP (mg/dL)	1.15 ± 1.34	0.37 ± 0.10	0.005
Albumin (g/L)	41± 6	45 ± 3	0.001
Hemoglobin (g/dL)	12.7 ± 1.8	13.7± 1.2	0.024



Parameter	AUROC	95% CI	P value
FCT	0.958	0.917 – 0.999	<0.001
FIT	0.802	0.697 – 0.906	<0.001
CRP	0.716	0.595 – 0.837	0.003
albumin	0.713	0.591 – 0.835	0.004
haemoglobin	0.672	0.541 – 0.803	0.020

	FCT	FIT
Cut-off (ug/g)	168	16
Sensitivity	82.9%	65.9%
Specificity	100%	92%
PPV	100%	99.1%
NPV	78.1%	62.2%





Conclusion

- Among the 5 biomarkers, **fecal calprotectin** demonstrated the best performance characteristics for endoscopically active disease (AUROC 0.96).

- Elevated **fecal calprotectin** *per se* accurately identified all patients with endoscopically active IBD.

- Combination of fecal calprotectin and fecal immunochemical test only further increased the NPV for endoscopically active disease.