

# A NEW RAPID TEST FOR FECAL CALPROTECTIN (FC) PREDICTS MUCOSA HEALING IN CROHN'S DISEASE (CD)

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## INTRODUCTION

- Because of the poor correlation between clinical and endoscopic activity, objective markers of inflammatory activity are required for management and monitoring of the disease.
- FC has been proposed as a promising surrogate marker of inflammation. However, all previous studies in IBD patients have been performed with ELISA (> 80 samples, time-consuming).
- There is few data on quantitative rapid tests, which would permit us to have a quantitative result as ELISA but in minutes and by an easier method individually done for every patient.

## AIMS

- To assess the accuracy of FC to detect endoscopic activity/MH.
- To test the optimal thresholds of FC concentration for MH.
- To analyze reliability of rapid tests against ELISA.

## MATERIAL AND METHODS

- SETTING:** Inflammatory Bowel Disease Unit, Bellvitge University Hospital, Barcelona.
- DESIGN:** Transversal study.
- PATIENTS:** 45 patients with diagnosed Crohn's disease scheduled for colonoscopy between November 2010 and July 2011.
- Variables:**
  - Clinical indexes: Harvey-Bradshaw and CDAI.
  - Biomarkers : CRP, ESR, leucocytes and platelets.
  - Endoscopic indexes: CDEIS and SES-CD.
  - FC determined by both methods: ELISA (Bühlmann®) and quantitative rapid test based on immunochromatography (Bühlmann QUANTUM BLUE®).

TEST CHARACTERISTICS	BÜHLMANN ELISA®	BÜHLMANN QUANTUM BLUE® (normal / high range)
Technique	ELISA	Immunochromatography
Duration	3h	12 / 15 minutes
Number of samples	88	1
Amount of sample of feces	50-150 µl	60 µl / 80 µl
Range	10-3500 µg/g	30-300 µg/g / 100-1800 µg/g
Sensitivity	< 10 µg/g	< 10 µg/g



## RESULTS

Table 1. Baseline characteristics of CD patients	
Number of patients	45
Sex (male/female)	21/24 (46,70% / 53,30%)
Age ( years)	43,98 (+/- 15,31)
Disease duration ( years)	11,71 (+/- 9,00)
Monreal clasification:	
Age at diagnosis (A): A1/A2/A3	0 (0%) / 41 (91,10%) / 4 (8,9%)
Location (L): L1/L2/L3	5 (11,40%) / 21 (47,7%) / 18 (40,90%)
Behaviour (B): B1/B2/B3	33 (76,70%) / 5 (11,60%) / 5 (11,60%)
Pacientes with surgery	11 (37,93%)
Treatment	
No medicament	1/29 (3,45%)
Oral 5-ASA	14 (33,30%)
Steroids: budesonide/beclametasone/sistemic	3/1/1 (10,9%)
IMM( AZA, 6MP, MTX	14/1/1 (45,70%)
TNF-α inhibitor	3/6 (19,50%)
Indication for colonoscopy	
Post operative recurrence	14 (30,40%)
Flare	14 (30,40%)
Screening for dysplasia	11 (23,90%)
Confirm mucosa healing	2 (4,30%)
Extent study	Others
	5 (10,80%)
5-ASA, 5-amino salicylic acid; IMM, immunomodulators; AZA azathioprine; 6MP, 6 mercaptopurine; MTX, metotrexate; CyA, cyclosporine; TNF, tumor necrosis factor.	

Table 2. Biological markers, clinical and endoscopical activity.	
Leucocytes (10E9/L)	6930,44 (+/- 2351,39)
Platelets (10E9/L)	278572,18 (+/- 110126,38)
CRP (mg/dl)	6,57 (+/- 7,71)
ESR ( mm)	10,97 (+/- 10,12)
Fecal calprotectin (mg/kg) by ELISA	841,47(+/-998,69)
CDAI*	86,53 (+/- 121,95)
Harvey Bradshaw*	2,67 (+/- 2,93)
CDEIS*	4,50 (+/- 6,74)
SES-CD*	4,17 (+/- 6,14)
Extension to endoscopic activity	
Inactive	19 (39,10%)
Ileon	4 (8,70%)
Colon	6 (13%)
Ileon+colon	7 (15,20%)
Neoleon	4 (8,70%)
Incomplete assessment	7 (15,20%)

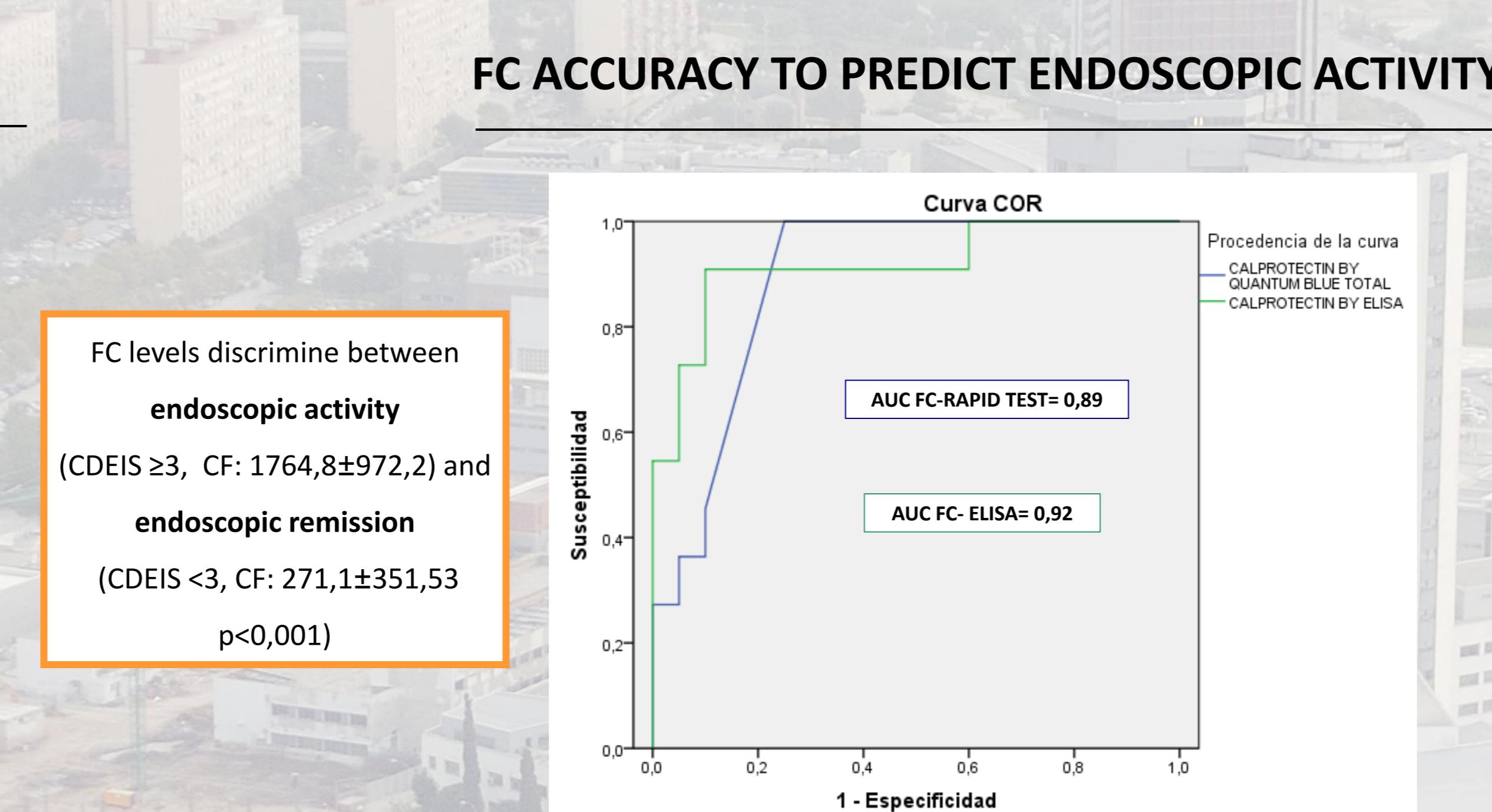
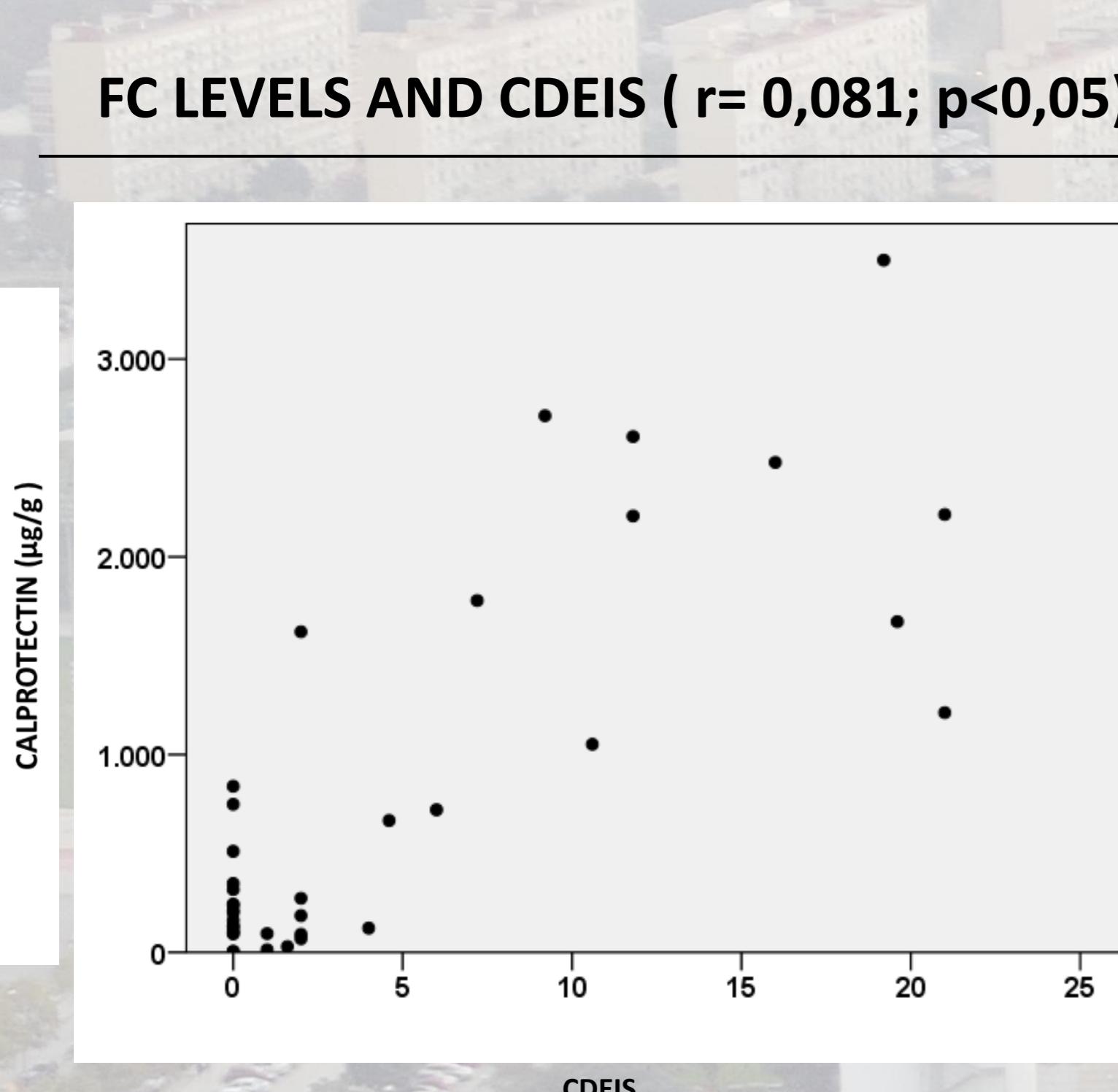
\*Correlation between indexes:  
-endoscopic: CDEIS-SES-CD = 0,96  
- clinical: CDAI-Harvey-Bradshaw = 0,77

Table 3. Pearson correlation between endoscopic activity and FC, clinical activity and biomarkers.							
	FC ELISA	CDAI	Harvey Bradshaw	CRP	ESR	Leucocytes	Platelets
CDEIS	<b>0,807</b> ( p<0,001)	0,199 ( p=0,237)	0,274 ( p=0,092)	0,541 ( p< 0,001)	0,397 ( p=0,022)	0,275 ( p=0,950)	0,218 ( p=0,813)
SES-CD	<b>0,752</b> ( p<0,001)	0,121 ( p=0,481)	0,203 ( p=0,222)	0,580 ( p=0,002)	0,516 ( p=0,115)	0,271 ( p=0,100)	0,210 ( p=0,207)
FC ELISA	- ( p=0,043)	0,322 ( p=0,014)	0,366 ( p< 0,001)	0,529 ( p< 0,001)	0,529 ( p=0,025)	0,235 ( p=0,125)	0,402 ( p=0,007)

## MULTIVARIATED ANALYSIS

	Coefficients		Beta Coefficient	P
	B	E.T		
FC	0,006	0,001	0,801	<b>&lt; 0,001</b>
CRP	0,044	0,111	0,051	0,695
CDAI	0,001	0,008	0,008	0,938

## FC AND CRP ACCURACY TO PREDICT ENDOSCOPIC ACTIVITY (CDEIS>3)



	Se (%)	Sp (%)	PPV (%)	NPV (%)	p
CRP	61,5	80,8	61,5	80,8	0,013
CalproELISA 500µg/g	92,3	88	80	95,7	< 0,001
CalproQB 500µg/g	80	90	80	90	0,017

Correlation ELISA- rapid test (Quantum Blue®)= 0,93  
Interclass correlation coefficient (ICC)= 0,90

## CONCLUSIONS

- Fecal calprotectin predicts MH more accurately than CRP and the rest of biomarkers.
- The good correlation between ELISA and this quantitative rapid test enables us to use the rapid one in order to take fast and adequate decisions.