Usability of a home-based test for the measurement of fecal calprotectin in IBD patients

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Introduction

Fecal calprotectin correlates well with endoscopic inflammation and is a useful biomarker to adapt treatment strategies in IBD. However it requires that the patients bring stools to the hospital which is not always well acepted Home-based tests may overcome this limitation and favour borader and more regular measurement of fecal calprotectin, fostering at the same time tight disease control and patients' empowerment.

The aim of our work was to assess the usability of one of these home-based test: IBDoc (Buhlmann)

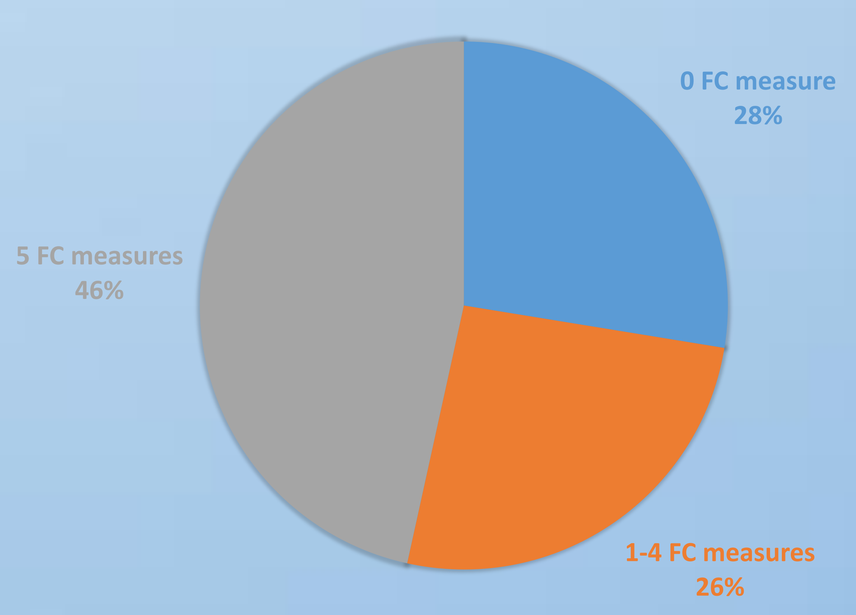
Methods

- Patients with quiescent or mildly active CD (HBI<7) or UC (Partial Clinical Mayo <3) were prospectively reruited from 3 IBD centres (Oslo, Barcelona, Liège).
- They received a standardized training and were instructed to measure FC with a dedicated tool and smartphone application, 5 times at two weeks intervals over an 8 weeks period.
- The included patients had to fill in a usability questionnaire at the first and the last FC measurement. A System Usability Scale (SUS: 0-100) and the Global Score of Usability (GSU: 0-85) were calculated.
- FC was also centrally measured by ELISA.

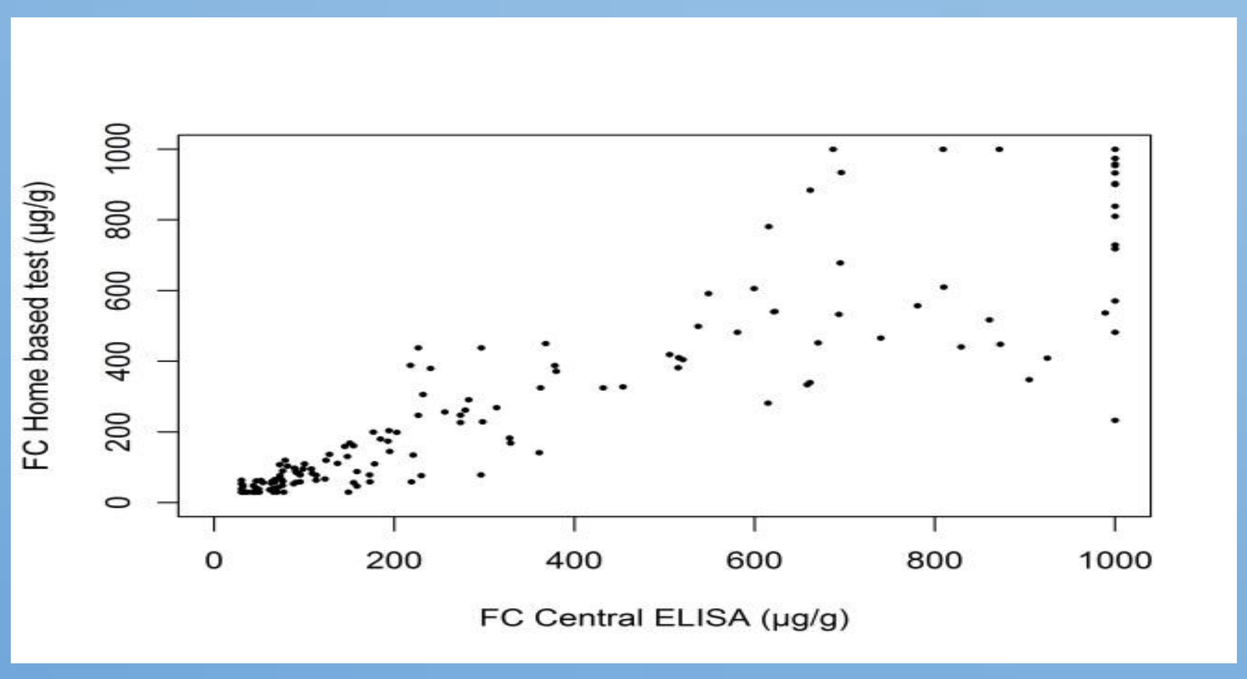
Results

Patients' demographic and clinical characteristics

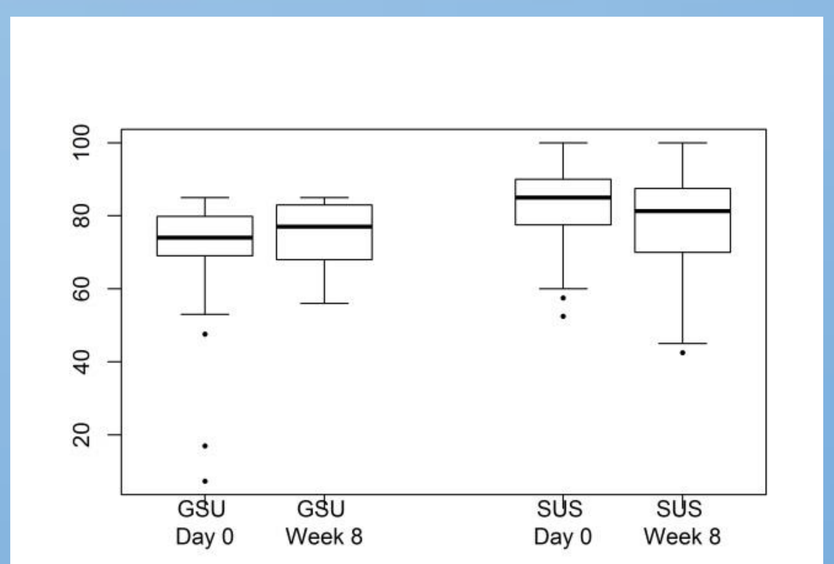
Sex	***F***	***M***		
	30 (51.7%)	28 (48.3%)		
Origin	*Oslo*	*BCN*	*LG*	
	18 (31%)	15(25.9%)	25(43.1%)	
IBD	*CD*	*UC*		
	40(69%)	18(31%)		
Age	*Median* 35.00 (IQR : 26.5-40)			
HBI	*Median* 0.00 (IQR : 0.0-4.0)			
Mayo	*Median* 0.00 (IQR : 0.0-1.0)			
Treatment	***5-ASA***	***IS***	***Corticoïds***	***Biologics***
	17 (32.1%)	21 (39.6%)	4 (7.5%)	25 (47.2%)



72,5% of patients performed at least 1 FC measurement; 46,6% performed the 5 measurements. The adherence to the planned FC measurements was significantly higher in females (p=0.034), in 5ASA treated patients (p=0.027). It significantly increased with lower disease activity in CD (p=0.016) and higher GSU at day 0 (p=0.010). It differed between centres (p=0.025); it was higher in Barcelona compared to Liège. It was also higher in patients declaring that this tool would help them to better manage their disease at day 0 (p=0.016). In multivariate analysis, it was higher in females (p=0.0077) and in 5ASA treated patients (p=0.042).



The intra-class correlation coefficient between measures was 0.88 with an inferior limit of the coefficient at 0.82. The values obtained with the central ELISA were significantly higher than with the home-based test (158 (63 – 581) vs 120 (49 – 419); p<0.0001). Bland and Altman method showed that the greater the FC value, the greater the difference between the central ELISA and the home-based test (r=0.90, p<0.0001). When categorized in normal (≤100 microg/g), borderline (101-299 microg/g) and elevated values (≥ 300 microg/g), 140/169 measures (82.8%) were similarly classified with the two methods and the Cohen Kappa coefficient was 0.73 (0.65 – 0.82)



The median (IQR) SUS (0-100) at the first and last use were 85 (78-90) and 81 (70-88), respectively; the median (IQR) GSU (0-85) at the first and last use were 74 (69-80) and 77 (68-83), respectively. The GSU at day 0 differed between centres (p=0.013); it was significantly higher for Barcelona patients as compared to Liège. It also inversely correlated with disease activity assessed by HBI in CD (r=-0.47, p=0.015). No factor was associated with GSU in multivariate analysis at day 0.
The SUS was only significantly higher in females at day 0 in univariate (p=0.040) and multivariate analysis (p=0.042).

Conclusion:

The adherence to home-based measurement of FC was fair. Usability scores for the home-based test were high. There was a good correlation with the centrally measured FC by ELISA.