



Poster (Mini-oral) presentation Code: PI-74

Evaluation and Comparison of a Rapid Semi-Quantitative Diagnostic Test With The ELISA Method For Detection of Fecal Calprotectin in Chronic Inflammatory Bowel Disease

Abdollahi P¹, Rasae MJ^{2*}, Farshid B¹, and Malek M¹

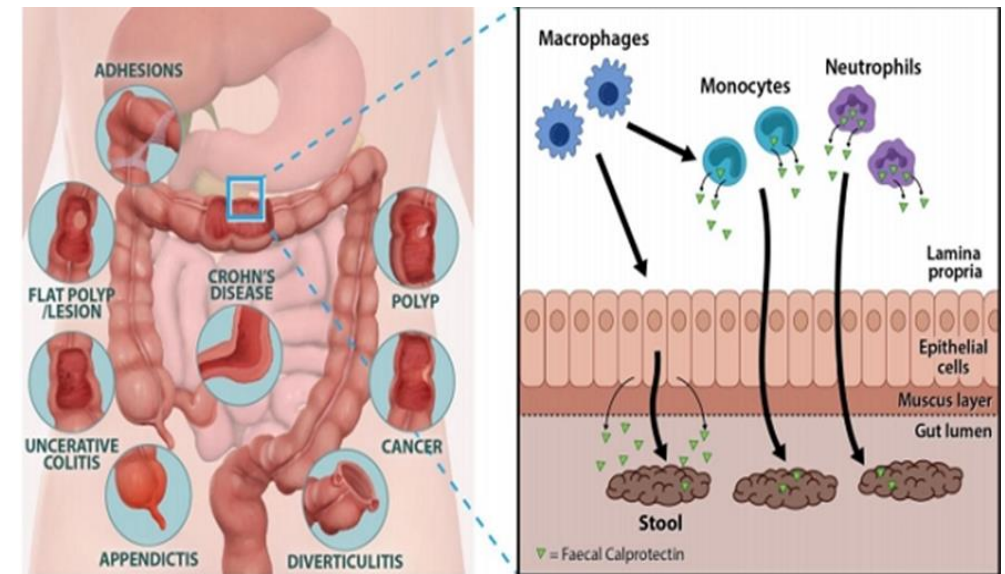
1. Department of Research and Development, Rojan Azma mfg, Alborz Iran
2. Department of Medical Biochemistry, Faculty of Medical Sciences, Tarbiat Modares University. Tehran Iran

*Corresponding Author: RasaeMJ ,rasae_m@modares.ac.ir



• Introduction

Calprotectin, a protein found in neutrophils, increases in stools during intestinal inflammation. This study contributes to the development of efficient diagnostic methods for UC, improving patient care. The traditional ELISA method, while accurate, can be resource-intensive and expensive. The rapid test offers a more convenient and immediate assessment. The study evaluated the Rojan rapid test and ELISA method for detecting Fecal Calprotectin (FC) in patients with Ulcerative Colitis (UC) and distinguishing between inflammatory and non-inflammatory bowel diseases. Results showed a high level of agreement between the two tests, indicating the rapid test potential as a valuable diagnostic tool.





- Materials & Methods

A total of 100 subjects of age above 60 years old were enrolled in the study. Fecal samples were collected from each participant. The rapid semi-quantitative diagnosis test for FC was performed. Simultaneously, FC levels were quantified using the ELISA method. Sensitivity, specificity, and diagnostic accuracy were calculated for both tests. The Fecal one step Calprotectin test device is a Semi-Quantitative, membrane based immunoassay for the detection of Calprotectin in Feces. The membrane is pre-coated with capture reagent (monoclonal antibody against calprotectin in different concentrations) to obtain a 3 test lines region of the test with detection limit for T1 (0~15ug/g), T1-T2 (15~60ug/g), T1-T2-T3 (>60ug/g). The traditional method of detecting Fecal Calprotectin involves Enzyme-Linked Immunosorbent Assay (ELISA), which, while accurate, can be time-consuming and resource-intensive. The development of a Rapid Semi-Quantitative Diagnosis Test offers the potential for a more convenient, immediate assessment and possibility of large number of samples.





• Results

The Rojan rapid semi-quantitative diagnosis test demonstrated a sensitivity of >99.9%, specificity of 94.6%, and diagnostic accuracy of 96%. The ELISA method exhibited comparable results. There was a strong correlation between the results obtained from the two methods. The study demonstrated a high level of concordance between the two diagnostic approaches, with the rapid test displaying notable accuracy in distinguishing between inflammatory and non-inflammatory bowel diseases. These findings indicate that the rapid semi-quantitative diagnostic test for fecal calprotectin holds significant promise as a valuable tool in the clinical assessment of ulcerative colitis patients. Its effectiveness, coupled with its expeditious nature, rapid performance and low cost may enhance diagnostic procedures and contribute to more timely and accurate treatment decisions for individuals suffering from bowel disorders.

Method		ELISA			Result
	result	0~15ug/g	15~60ug/g	>60ug/g	
ROJAN Calprotectin Rapid Test	0~15ug/g	70	0	0	70
	15~60ug/g	4	15	0	19
	>60ug/g	0	0	11	11
	Total Result	74	15	11	100
%Relative Accuracy		94,6%	100%	100%	%96
		100%			

Relative sensitivity: $26/26=100\%$
 Relative specificity: $70/74 =94.6 \%$
 Relative Accuracy: $96/100 =96.0 \%$



- Conclusion

The study evaluates a rapid semi-quantitative test for fecal calprotectin in ulcerative colitis, assessing its effectiveness in distinguishing between inflammatory and non-inflammatory bowel diseases. Comparison with the ELISA method provides valuable insights into diagnostic options. The rapid test shows excellent performance, correlating well with the ELISA results. This offers a convenient, reliable option for assessing mucosal inflammation, potentially aiding timely clinical decisions and enhancing patient care. The rapid semi-quantitative diagnosis test for FC showed excellent performance in differentiating UC from N-IBD.

- **Keywords:** Ulcerative Colitis; Fecal Calprotectin; Bowel Disease; Rojan Rapid Diagnosis Test.