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Study of cut-off level for Fecal Calprotectin and Its Relation to Endoscopic and Histological Remission in IBD Egyptian Patients

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Abstract

Background: Inflammatory bowel disease [IBD] poses diagnostic challenges. Fecal calprotectin [FCP] shows promise as a biomarker for intestinal inflammation and disease activity, but its optimal cut-off values and correlation with remission need further exploration in Egyptian patients

The aim of the work: The objective of this research was to investigate the optimal cut-off level for fecal calprotectin and its correlation with endoscopic and histological remission among Egyptian patients with inflammatory bowel disease [IBD].

Patients and Methods: A cross-sectional study was conducted with IBD patients from Menoufia University's Endoscopy Unit. Retrospective data included demographics, clinical history, and laboratory results. Fecal calprotectin levels were measured using ELISA, and disease activity was evaluated using established scoring systems like the Mayo Endoscopic Score and modified Riley score.

Results: Analysis revealed that a fecal calprotectin [FC] threshold value of 164 mcg/g accurately predicted histologic remission [HR] based on the Nancy index. This threshold appeared to be indicative of overall endoscopic remission [ER] and histologic remission [HR] in UC patients, as determined by the Mayo clinical endoscopic Score [MES=0] and The Ulcerative Colitis Endoscopic Index of Severity [UCEIS≤1], with a sensitivity of 85.7%, specificity of 87.2%, and accuracy of 87%.

Conclusion: In UC patients, a fecal calprotectin [FC] value below 164 mcg/g was found to effectively identify both endoscopic and histological remission, as evidenced by the Mayo clinical endoscopic Score [MES=0], The Ulcerative Colitis Endoscopic Index of Severity [UCEIS≤1], and the Nancy Index. Similarly, in CD patients, an FC value below 105 mcg/g was indicative of endoscopic remission as per the Simple Endoscopic Score for Crohn's Disease [SES-CD≤2], while a value below 220 mcg/g identified histological remission based on the modified Riley score [mRS=0]

Keywords: Crohn's Disease; Endoscopic Remission; Fecal Calprotectin; Histological Remission; Ulcerative Colitis.

INTRODUCTION

Inflammatory bowel disease [IBD], encompassing both Crohn's disease [CD], intermediate colitis and ulcerative colitis [UC], is a chronic, idiopathic inflammatory disorder affecting the partial gut inflammation [1]. It manifests with a relapsing–remitting course and diverse clinical presentations, often accompanied by extraintestinal manifestations [2].

Assessing disease activity and achieving mucosal healing [MH] are crucial, as MH is linked with sustained remission and a decreased risk of surgery in IBD. Currently, endoscopy with biopsy serves as the gold standard for evaluating the site, extent, and severity of intestinal inflammation [3, 4]. However, endoscopic procedures are invasive and carry a significant risk of complications. They can be painful and frequently necessitate general anesthesia, which poses potential dangers to patients [5, 6]. Bowel preparation for colonoscopy is also unpleasant and may pose risks in certain situations [7, 8].

Routine clinical practice often involves a combination of clinical examination, laboratory biomarker levels, and endoscopic and microscopic findings [9, 10]. Fecal calprotectin concentrations exhibit a strong correlation with intestinal inflammation and are utilized as a biomarker in gastrointestinal disorders. It is highly sensitive to inflammation in the gastrointestinal tract and aids in distinguishing between inflammatory bowel disease [IBD] and irritable bowel syndrome [IBS] [11, 12]. Fecal calprotectin is employed for various purposes, including diagnosis, monitoring disease activity, guiding treatment, and predicting disease relapse and post-operative recurrence in IBD. Additionally, it may have potential applications in managing infectious gastroenteritis, acute appendicitis, peptic ulcer disease, cystic fibrosis, coeliac disease, transplant rejection, and graft versus host disease [13, 14].

In this study, we aimed to investigate the optimal cut-off level for fecal calprotectin and its correlation with endoscopic and histological remission among Egyptian patients with inflammatory bowel disease [IBD].

PATIENTS AND METHODS

All patients included in the study were recruited from the Endoscopy unit of the Internal Medicine department at Menoufia University. Patient data were collected from medical records, which included details from history-taking, clinical examinations, investigations, and a history of anemia or gastrointestinal [GIT] bleeding to identify any associated risk factors.

Clinical and Laboratory Data: Data of the patients were gathered from files regarding to: Full history. Thorough clinical examination. Histopathology and Colonoscopy imaging. Fecal calprotectin [FCP] was typically measured using an enzyme-linked immunosorbent assay [ELISA], a common method that is highly sensitive and specific for detecting calprotectin levels in stool samples. Routine investigations [CBC- INR- CRP-LFT-US]. Myoclinic score, Activity Score and Monteral classification.

Inclusion Criteria: All patients had a confirmed diagnosis of inflammatory bowel disease [IBD]. Patients had disease limited to colon and/or terminal ileum. Age from 18-70 years old.

Exclusion Criteria: Colorectal cancer or colon polyps. Indeterminate colitis. History of colorectal surgery. Pregnancy. Infectious colitis. Primary immunodeficiency [HIV, etc.]. Urinary and stool incontinence.

Colonoscopic Assessment: To evaluate the extension and activity of the disease in patients with ulcerative colitis [UC] and Crohn's disease, several scoring systems were utilized, including the Mayo Endoscopic Score, Ulcerative Colitis Endoscopic Index of Severity, and Disease Activity Index for Ulcerative Colitis, Simple Endoscopic Score for Crohn's Disease [SES-CD], and Crohn's Disease Activity Index [CDAI].

Histologic Assessment: Targeted biopsies were obtained from the most inflamed area in Colon and terminal ileum which were identified during colonoscopy and subjected to analysis, by using Hematoxylin and Eosin [H&E] and Periodic Acid-Schiff [PAS] stains. Histologic activity was evaluated using the Nancy Index for UC patients, with a score of 0 indicating histological remission. For patients with Crohn's disease, the modified Riley score was employed to assess disease activity, with a score of 0 indicating histological remission. All samples were evaluated by an expert gastrointestinal pathologist [DZ].

Statistical analysis: Data were collected, tabulated, and statistically analyzed using IBM compatible personal computer software, specifically the Statistical Package for the Social Sciences [SPSS] version 26. Continuous variables were presented as mean ± standard deviation, and differences were assessed using the Chi-square test or Kruskal Wallis test. Proportions were utilized to identify discrepancies. Receiver Operating Characteristic [ROC] curves were generated to determine the optimal fecal calprotectin [FCP] cut-off values for predicting endoscopic remission [ER] as evaluated by the Ulcerative Colitis Endoscopic Index of Severity [UCEIS] and the Simple Endoscopic Score [SES-CD] in Crohn's disease [CD] patients. Similarly, ROC curves were employed to predict histological remission [HR] using the Nancy Index for UC patients and the modified Riley score for Crohn's disease [CD] patients.

RESULTS

This cross-sectional study enrolled 59 patients with ulcerative colitis [UC] and 33 patients with Crohn's disease [CD], as detailed in Tables 1 and 2. Endoscopic remission, defined as a Mayo clinical endoscopic Score [MES] of 0 in UC and a Simple Endoscopic Score for Crohn's Disease [SES-CD] ≤2 in CD, was predicted by fecal calprotectin [FC] levels below 164 mcg/g and 105 mcg/g, respectively. A total of 92 patients were included in the study, and the findings were consistent across both UC and CD patients.

Age distribution of the included UC patients according to Montreal Classification was as the following 69.5% were from 16-40 years, 25.4% were <16 years, 5.1% were>40 years. Most of the included patients were males [52.5%], and 47.5% were females. According to type of treatment 77.9% used 5aminosalicated, 18.6% on Steroid, 18.6% on Biological therapy and 10.2% not used any treatment. Patients distributed according to UCEIS was 39% had no symptoms, 23.7% with mild, 22% with moderate and 15.3 with severe symptoms. Patients distributed according to MES was 42.4% was normal, 22% with mild activity, 20.3% with moderate and 15.3 with severe activity. Histological assessment [NI] revealed that was 39% was normal, 23.7% with mild activity, 20.3% with moderate and 16.9

with severe activity. The mean of fecal calprotectin was 445.8±342.97 mcg/g as 40.7% with activity. 42.4% had HB >14 g/dL, 22% were from 12-14 g/dL, 20.3% were 9-11 g/dL and 15.3 were 6-8 g/dL. According to C. Reactive Protein 39% were <8 mg/L, 23.7% were from 9-199 mg/L, 20.3% were from 200-699 mg/L and 16.9 %were 700-1000 mg/L [Table 1, Figure 2].

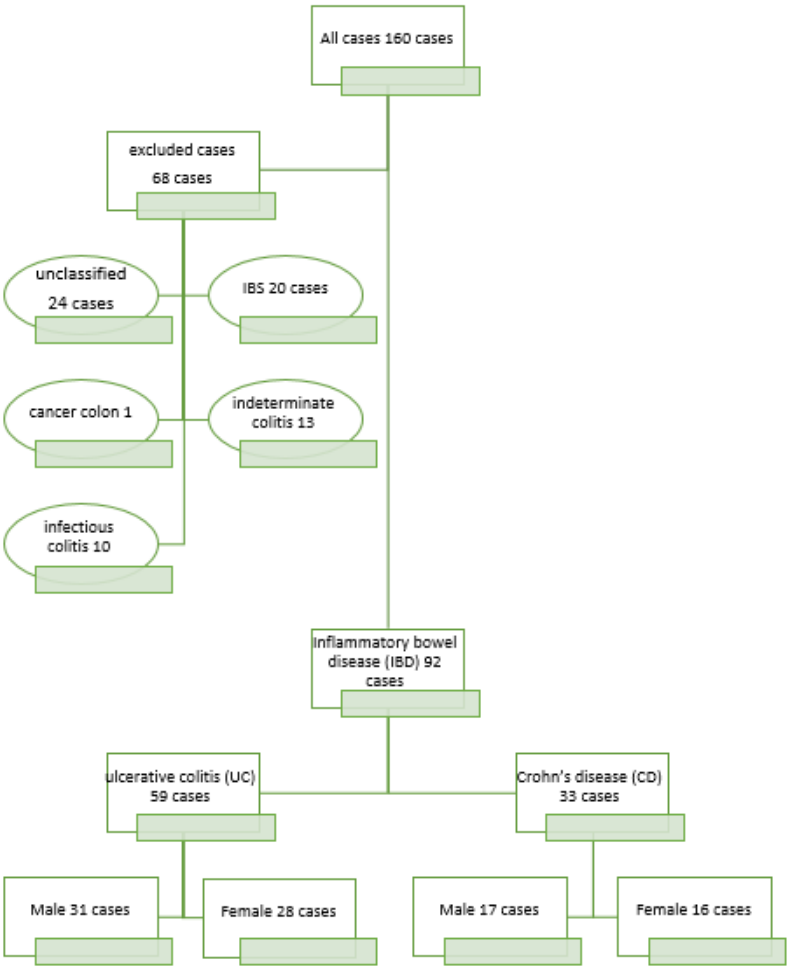

Figure [1]: Follow chart of cases

Age distribution of the included CD patients according to Montreal Classification was as the following 69.7% were from 16- 40 years, 24.2% were <16 years, 6.1% were>40 years. Most of the included patients were males [51.5%], and 48.5% were females. According to type of treatment 42.4% used 5aminosalicated, 24.2% on Steroid, 39.4% on Biological therapy and 18.2% not used any treatment. Patients distributed according to HBI was 18.2% had no symptoms, 24.2% with mild, 24.2% with moderate and 33.3 with severe symptoms. Patients distributed according to SES-CD was 21.2% was normal, 24.2% with mild activity, 39.4% with moderate and 15.2 with severe activity. Histological assessment [Modified Riley score] revealed that was 63.6% was normal, 9.1% with mild activity, 18.2% with moderate and 18.2 with severe activity. The mean of fecal calprotectin was 349.5±306.3mcg/g as 36.4% with activity. 21.2% had HB >14 g/dL, 24.2% were from 12-14 g/dL, 39.4% were 9-11 g/dL and 15.2 were 6-8 g/dL. According to C. Reactive Protein 63.6% were <8 mg/L, 9.1% were from 9-199 mg/L, 18.2% were from 200-699 mg/L and 9.1% were 700-1000 mg/L [Table 2, Figure 3].

The analysis revealed that an FC threshold value of 164 mcg/g accurately predicted histologic remission [HR] using the Nancy index [NI≤1]. This threshold was indicative of both overall endoscopic remission [ER] and histologic remission [HR] in UC patients, as determined by a Mayo clinical endoscopic Score [MES] of 0, with a sensitivity of 85.7%, specificity of 87.2%, and accuracy of 87%. Similarly, an FC threshold value below 220 mcg/g defined endoscopic remission as SES-CD≤2 and modified Riley score [mRS=0] in CD patients, with a sensitivity of 85.2%, specificity of 87.9%, and accuracy of 87%. There was a statistically highly significant association between levels of Fecal calprotectin and severity the UC assessed clinically assessment by UCEIs, endoscopic assessment by [MES] and Histological assessment by [NI] [p value<0.001]. there was a statistically highly significant association between levels of Fecal calprotectin and severity the disease assessed clinically assessment by HBI, endoscopic assessment by [SES-CD] and Histological assessment by Modified Riley score [p value<0.001] [Tables 3, 4; Figure 4,5].

Table [1]: Demographics and Characteristics of studied UC patients

		UC Group N=59	
		No.	%
Age According to Montreal classification	<16 years	15	25.4
	16- 40 years	41	69.5
	>40 years	3	5.1
Gender	Male	31	52.5
	Female	28	47.5
Therapy	No	6	10.2
	5aminosalicated	46	77.9
	Steroid	11	18.6
	Biological	11	18.6
Clinical assessment According to The Ulcerative Colitis Endoscopic Index of Severity [UCEIs]	Remission [no symptoms]	23	39.0
	Mild symptoms	14	23.7
	Moderate symptoms	13	22.0
	Severe symptoms	9	15.3
Endoscopic assessment According to Mayo clinical endoscopic Score [MES]	Remission [normal]	25	42.4
	Mild activity	13	22.0
	Moderate activity	12	20.3
	Severe activity	9	15.3
Histological assessment According to Nancy index [NI]	Remission [normal]	23	39.0
	Mild activity	14	23.7
	Moderate activity	12	20.3
	Severe activity	10	16.9
Fecal calprotectin	Mean ± SD	445.8±342.97	
	Range [Minimum – Maximum]	90 - 1120	
	Remission	24	40.7
	Activity	35	59.3

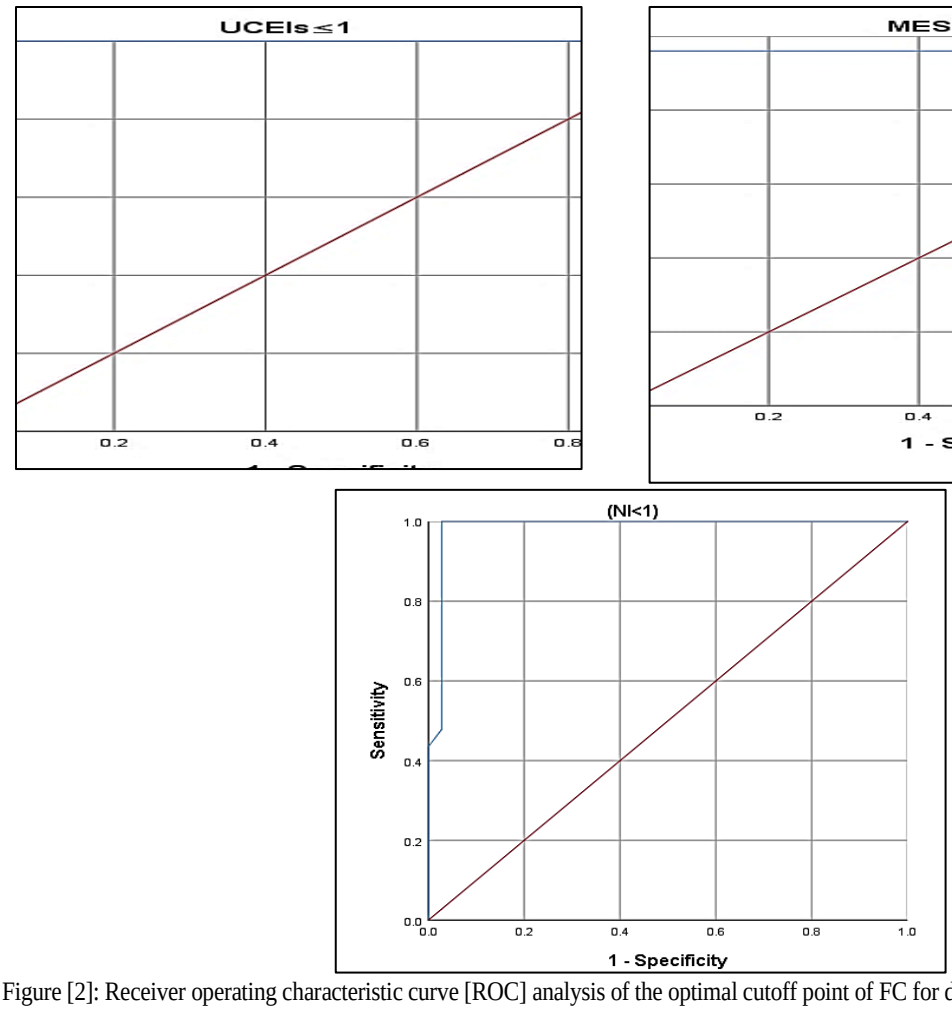

Figure [2]: Receiver operating characteristic curve [ROC] analysis of the optimal cutoff point of FC for defined Endoscopic and Histological Remission in UC

Table [2]: Demographics and Characteristics of studied CD patients

		CD Group N=33	
		No.	%
Age According to Monteral classification	<16 years	8	24.2
	16- 40 years	23	69.7
	>40 years	2	6.1
Gender	Male	17	51.5
	Female	16	48.5
Therapy	No	6	18.2
	5aminosalicated	14	42.4
	Steroid	8	24.2
	Biological	13	39.4
Clinical assessment According to Harvey-Bradshaw Index [HBI]	Remission [no symptoms]	6	18.2
	Mild symptoms	8	24.2
	Moderate symptoms	8	24.2
	Severe symptoms	11	33.3
Endoscopic assessment According to Simple Endoscopic Score for Crohn's Disease" [SES-CD]	Remission [normal]	7	21.2
	Mild activity	8	24.2
	Moderate activity	13	39.4
	Severe activity	5	15.2
Histological assessment According to Modified Riley score	Remission [normal]	21	63.6
	Mild activity	3	9.1
	Moderate activity	6	18.2
	Severe activity	3	9.1
Fecal calprotectin	Mean ± SD	349.5±306.3	
	Range [Minimum – Maximum]	95 - 985	
	Remission	21	63.6
	Activity	12	36.4

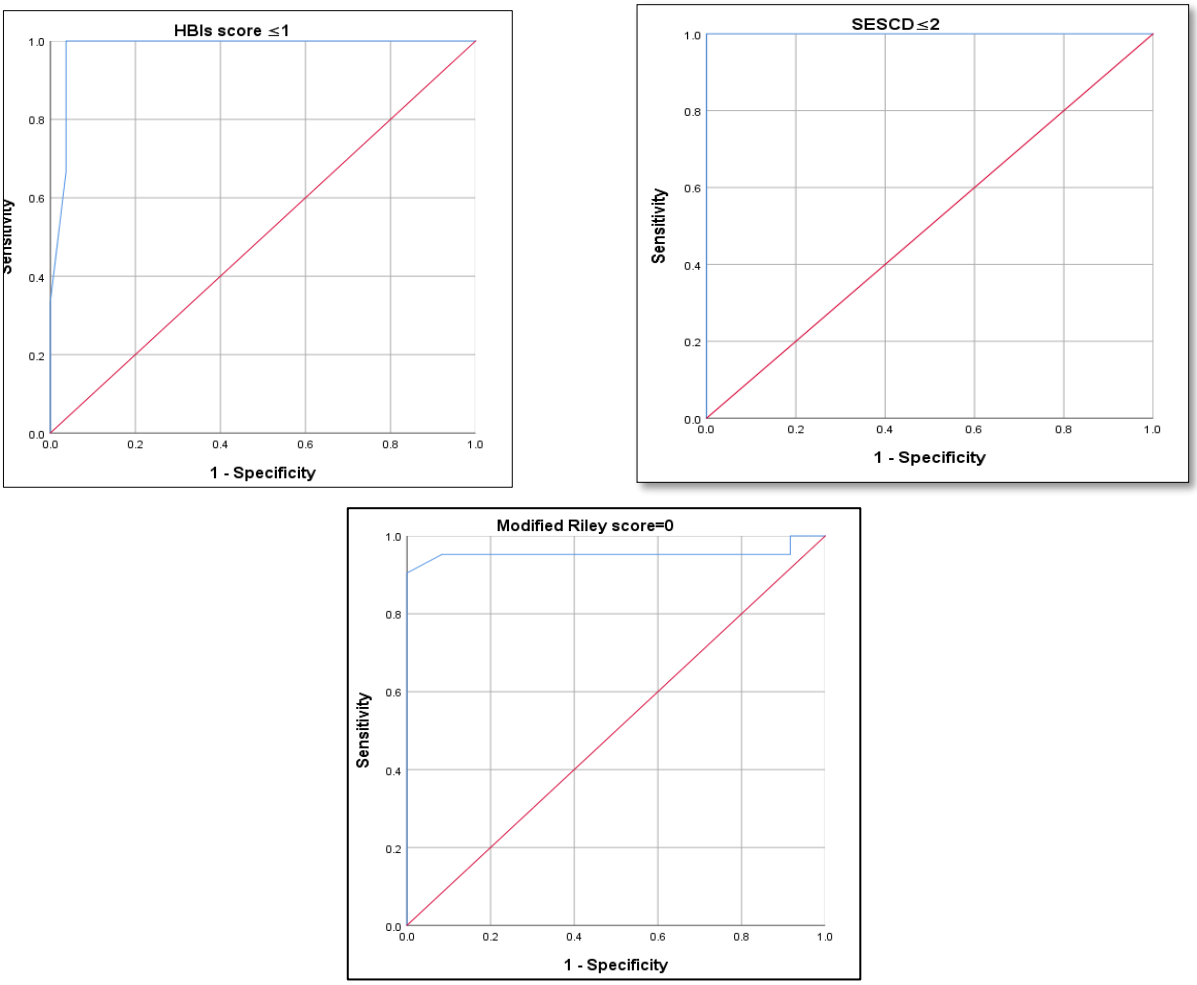

Figure [2]: Receiver operating characteristic curve [ROC] analysis of the optimal cutoff point of FC for defined Endoscopic and Histological Remission in CD

Table [3]: Clinical, Endoscopic, and Histologic Activity and Fecal Calprotectin in Ulcerative Colitis Based on the Scores Used

Variable		Fecal calprotectin	Test of Sig.	P value	Post hoc
		Mean ± SD			
Clinical assessment According to The Ulcerative Colitis Endoscopic Index of Severity [UCEIs]	**Remission [no symptoms]**	129.5±25.15	KW=38.837	<0.001**	P1=<0.001** P2=0.003*; P3=0.004* P4=0.396; P5=1 P6=0.759
	Mild symptoms	724.5±256.7			
	Moderate symptoms	527.69±300			
	Severe symptoms	702.4±316.6			
Endoscopic assessment According to Mayo clinical endoscopic Score [MES]	**Remission [normal]**	161.52±162.93	KW=38.695	<0.001**	P1=<0.001** P2=0.013*; P3=0.004* P4=0.093 P5=0.996; P6=0.630
	Mild activity	765.46±194			
	Moderate activity	499.3±294.7			
	Severe activity	702.4±316.9			
Histological assessment According to Nancy index[NI]	**Remission [normal]**	129.5 ±25.15	KW=22.411	<0.001**	P1=<0.001** P2=0.006*; P3=0.002* P4=0.628 P5=1; P6=0.922
	Mild activity	716.14±249.4			
	Moderate activity	544.9±325.13			
	Severe activity	676±309.99			

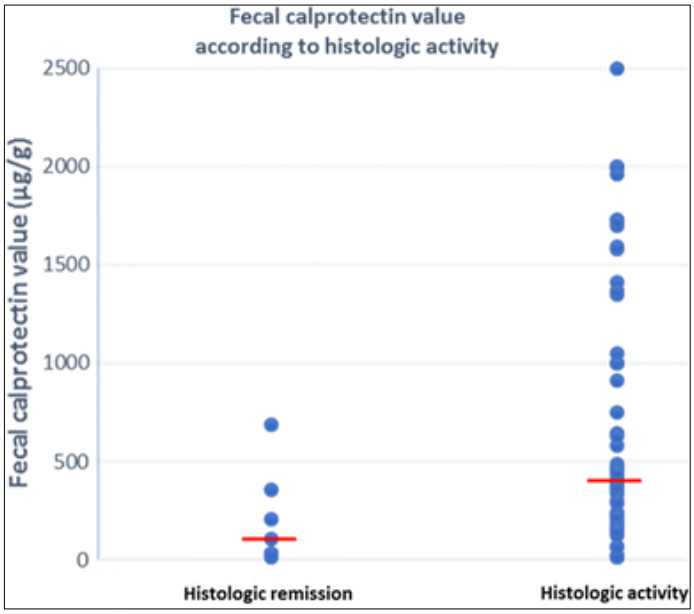

Figure [3]: comparison of fecal calprotectin level in patients with ulcerative colitis with histological activity or remission

Table [4]: Clinical, Endoscopic, and Histologic Activity and Fecal Calprotectin in Crohn's disease Based on the Scores Used

		Fecal calprotectin	Test of Sig.	P value	Post hoc
		Mean ± SD			
Clinical assessment **According to Harvey-Bradshaw Index [HBI]**	Remission [no symptoms]	105±17.9	KW=27.826	<0.001**	P1=0.005*; P2=0.381; P3<0.001** P4=0.667 P5<0.001**; P6=0.064
	Mild symptoms	154.87±24.19			
	Moderate symptoms	299.6±265.3			
	Severe symptoms	660.7±275			
Endoscopic assessment **According to Simple Endoscopic Score for Crohn's Disease" [SES-CD]**	Remission [normal]	104±16.56	KW=26.797	<0.001**	P1<0.001** P2=0.014* P3=0.025*; P4=0.05 P5=0.036*; P6=0.376
	Mild activity	167.73±14.5			
	Moderate activity	449.77±323.77			
	Severe activity	724±236			
Histological assessment **According to Modified Riley score**	Remission [normal]	157.6±44.1	KW=22.411	<0.001**	P1=0.006*; P2=0.027* P3=0.329 P4=1; P5=0.990 P6=0.991
	Mild activity	611.3±370.2			
	Moderate activity	665.5±256.5			
	Severe activity	799±297.4			

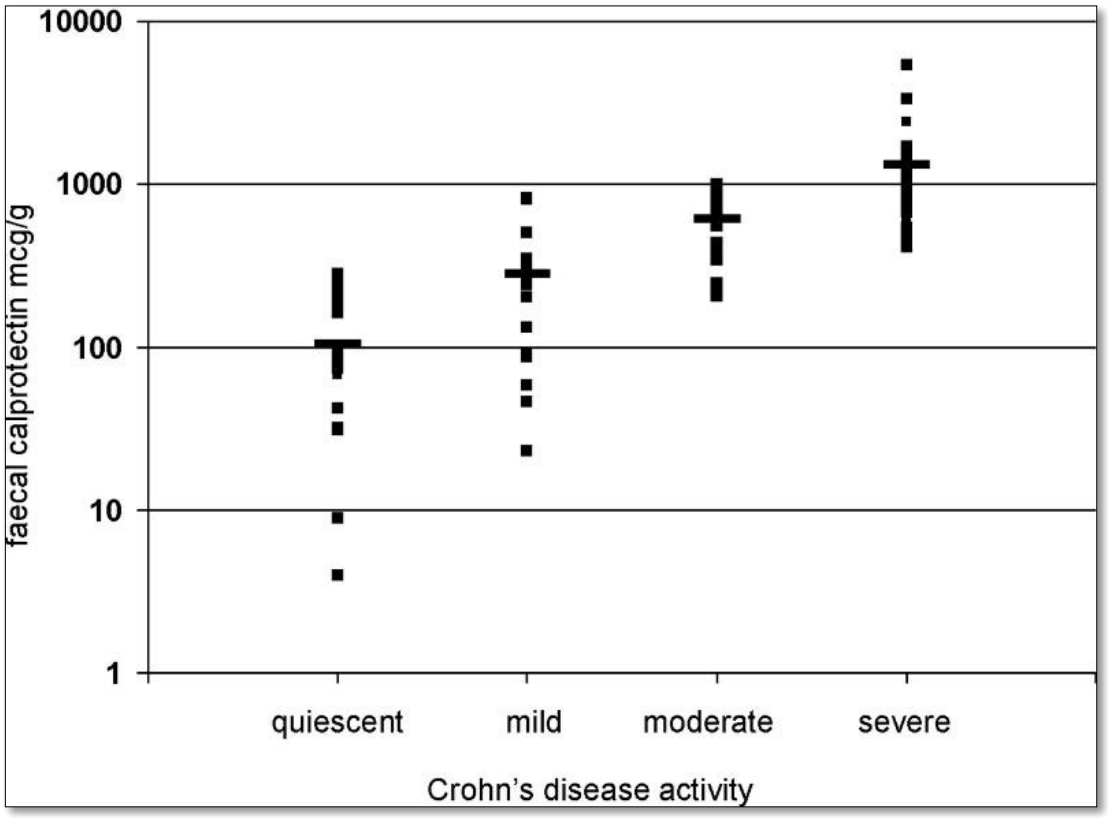

Figure [4]: comparison of fecal calprotectin level in patients with Crohn's disease with histological activity or remission

DISCUSSION

Though The International Organization for the Study of Inflammatory Bowel Disease [IOIBD] [15] has proposed fecal calprotectin [FC] as a surrogate marker of endoscopic remission [ER], recently histological remission [HR] in ulcerative colitis [UC] is increasingly used as an exploratory or secondary endpoint [16]. In Crohn's disease [CD], a higher fecal calprotectin [FC] concentration was associated with Simple Endoscopic Score for Crohn's Disease [SES-CD] scores indicating endoscopic remission [ER], suggesting that the relationship between fecal calprotectin [FC] and endoscopic healing is not very tight [17].

Other studies have shown that a fecal calprotectin [FC] value of >200 mcg/g has sensitivity and specificity for relapse of 80% and 65%, respectively, and a 4 times higher risk of relapse compared with patients with lower values. However, a threshold of fecal calprotectin [FC] 250 mcg/g to predict endoscopic remission [ER], measured as SES-CD ≤3, with 94.1% sensitivity and 62.2% specificity, has also been reported [18]. These cut-offs correspond to the threshold for fecal calprotectin [FC] to predict histologic remission [HR] found in this study, which is 220 mcg/g.

The study also explored whether the combination of fecal calprotectin [FC] and endoscopic scores could be useful in clinical practice to better predict histological remission [HR] compared with each endoscopic score alone. However, the combination showed no statistically significant advantages and did not support such a combination, likely due to the wide range of fecal calprotectin [FC] results. However, this study disagrees with **Serrano *et al.*** [19], whose review finds that fecal calprotectin [FC] has some disadvantages in predicting mucosal healing for inflammatory bowel disease [IBD]. Factors such as dietary supplements such as vitamin D, fatty acids, zinc, environmental influences [intestinal bacterial flora], and genetic influences can affect fecal calprotectin [FC] levels [20].

Thresholds of FCP that predict endoscopic remission in our cohort of Egyptian adult patients were assessed the thresholds of fecal calprotectin [FC] that predict endoscopic remission [ER] using not only the Mayo clinical endoscopic Score [MES] but also new endoscopic validated scores such as The Ulcerative Colitis Endoscopic Index of Severity [UCEIS]. This study utilized, for the first time, the histological remission [HR] cut-off of Nancy index ≤ 1. Additionally, this study explored the fecal calprotectin [FC] cut-off value to predict endoscopic remission [ER] with the modified Riley score for Crohn's disease [CD].

Diet significantly influences IBD management by affecting the inflammatory response while Supplementing with fatty acids, omega-3, or proteins did not consistently improve patient outcomes or reduce inflammation [21].

Hormonal contraceptive [HC] use among women with IBD was linked to a reduced likelihood of IBD-related symptoms but an increased risk of intestinal inflammation [FCAL > 250 µg/g] over one year [22].

Conclusion

In UC patients, a fecal calprotectin [FC] value below 164 mcg/g was found to be a strong indicator of both endoscopic and histological remission. Similarly, in CD patients, an FC value below 105 mcg/g was indicative of endoscopic remission, while a value below 220 mcg/g identified histological remission. However, these findings should be interpreted with caution. Further studies are needed to validate these thresholds and assess their impact on clinical practice

and patient outcomes, including how they influence real-life decision-making and long-term disease management.

Limitations of the study: A computerized patient registry system was not available. This study was conducted at a single center and performed by a single operator. Due to missing investigations in some files, certain patients were excluded from the analysis.

Data sharing statement: All data and materials included in this work are available

Ethics approval and consent to participate: Our local Ethics Committee approved our study and a written consent for participation was obtained from all patients.

Authors' contributions: All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure: The authors declare no competing interests in this work.

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