Diagnostic Utility of Flexible SigmoidoscopyAs An Aid In Diagnosis of Colorectal Disease

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Abstract:Background: Colorectal disease is one of the main areas of research interest. Several benign colorectal and anorectal conditions may be precancerous, or may warrant evaluation to rule out cancer as a cause of symptoms. Sigmoidoscopy is highly sensitive and specific for detection of lesions within reach of the instrument. The effectiveness of combined screening strategy in reducing colorectal disease mortality has not been studied directly, it is likely that the combination of screening methods is more effective than the use of any method alone. **Aim of the work:** Study the utility of flexible sigmoidoscopy with other parameters (fecal occult blood testing (FOB), Iron profile, CBC, ESR, clinicopathological findings) for early diagnosis of colorectal lesions. **Patients and methods:** This study included 160 patients who were clinically suspected to have colorectal disease. Iron profile, CBC, ESR, FOBT, liver and kidney function tests were done. Also Flexible sigmoidoscopy and abdominal US were done. Patients were divided into 2 groups Group I: comprised 100 patients with +ve FOBT, Group II: comprised 60 patients with -ve FOBT. **Results::** There was significant increase of ESR in group I in comparison to group II and positive correlation of histopathological findings in relation to ESR. The sensitivity of FOBT was 78.5% and specifity was 55% with a total accuracy 67.5%. The sigmoidoscopy reveled findings in 52.5% of patients (polyps, CRC, inflammation, infection, internal piles, rectal ulcer). Also the pathological changes showed highly significant difference in group I compared to group II. **Conclusion:** Flexible sigmoidoscopy equipment is easy to acquire; therefore the procedure may be offered in small, remote communities in which colonoscopy may not be readily available. Combined flexible sigmoidoscopy, FOBT, and ESR are important in the diagnosis of rectal disease especially in patients with anorexia and weight loss. They play a role in decreasing incidence and early diagnosis of colorectal cancer as they detect precancerous lesions before turning malignant.
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Keywords: Sigmoidoscopy, Fecal occult blood test,Colorectal disease.

1. Introduction

Several benign colorectal and anorectal conditions can be discovered by colonoscopy but it is an invasive and costly procedure with a risk of serious complications. It would therefore be useful to priorities colonoscopies by identifying people at higher risk of either cancer or premalignant adenomas (**Barbara et al., 2011**).

First time sigmoidoscopic screening in asymptomatic persons detects about 7 cancers and 60 huge or high-risk adenomas per 1,000 examinations **(Atkin et al., 1998).** The 60-cm instrument has an average depth of insertion of 40 to 50 cm. It will reach the proximal end of the sigmoid colon in 80% of examinations **(Winawer et al., 2003).**

Flexible sigmoidoscopy screening is associated with reduced mortality for colorectal cancer (CRC). It was reported that it reduce CRC mortality by two thirds for lesions within reach of the sigmoidoscope**(Kavanagh et al., 1998).**

Early CRC (with submucosal invasion) and advanced adenomas (size > or =10mm, with severe dysplasia or >20% villous component) produce intermittent microscopic blood losses that can be detected through chemical and immunological testing for fecal occult blood (C-FOBT and I-FOBT**) (Servicio, 2009).**

Normal fecal blood loss varies from 0.5 to 1.5 ml per day. Faecal occult blood testing (FOBT) have sufficient sensitivity to detect bleeding that is not visible in the stool. This periodic stool testing is considered a low-priced, non-invasive test. Although most tests for fecal occult blood become positive when about 2 ml of blood is lost per day, for consistent positivity higher levels of fecal blood are required **(Ouyang et al., 2005).**

The likelihood of detecting fecal blood depends not only on the sensitivity of a particular test, but also on the frequency and rate at which the causative lesion bleeds, bowel motility, and the anatomic level of bleeding, all of which influence intraluminal metabolism of hemoglobin. Fecal occult blood tests clearly detect blood loss from many different lesions at many different locations in the gastrointestinal tract **(Burt, 2000).**

Evidence to support FOBT combined with sigmoidoscopy came from a nonrandomized trial suggesting a 43 percent reduction in CRC-mortality after nine years from combined testing compared with rigid sigmoidoscopy alone **(Whitlock et al., 2008).**

The American Cancer Society, (2008) guidelines distinguish between test that can detect cancer at early treatable stage (e.g.,FOBT) and tests that also detect adenoma leading to cancer prevention(e.g., Flexible sigmoidoscopy). The guidelines stress that prevention rather than early detection should be the 1ry goal for most patients **(Levin et al., 2008).**

Aim of the work:

The aim of this study was to study the utility of flexible sigmoidoscopy with other parameters (fecal occult blood testing (FOB), Iron profile, CBC, ESR, clinicopathological finds) for early diagnosis of colorectal lesions.

2. Subjects and Methods:

This study was conducted on 160 patients (who complete the study from 200 patients) who were suspected clinically to have colorectal disease and they admitted to the Tropical Medicine Department of Al-Zahraa University Hospital. The patients were 104(65%) males and 56 (35%) females. Their ages ranged from 45 to 68 years with a mean ± SD of 54.73± 6.765.

The inclusion criteria include: adult patients with one or more of the following clinical picture: diarrhea, constipation, alternating bowel habit, abdominal pain, weight loss, anorexia and or unexplained anemia.

The exclusion criteria include: Patients with local causes of bleeding per-rectum e.g. piles, fissure, history of non-steroidal anti- inflammatory drugs intake, melena or hematemesis, women with vaginal bleeding, bleeding tendency; as hemorrhagic blood diseases or patients on anticoagulants, patients with advanced diseases as (hepatic, renal or cardiac), known cases of malignancy, anemia of known causes, peptic ulcer, worm infestation, alcohol, or iron supplementation.

Patients were divided into 2 groups according to FOBT:

Group I: comprised 100 patients with positive FOBT, they were 68 males (68%) and 32 females (32%). Their ages ranged from 45- 68 years with mean ± SD of 58.600±6.123.

Group II: comprised 60 patients with negative FOBT, they were 36 males (60%) and 24 females (40%). Their ages ranged from 46 - 67 years with mean± SD of 53.280 ±6.633.

All patients were subjected to the following:

Eligible patients who provide an informed consent were subjected to the following:

- **Clinical part of the work**:
  - **Detailed history:** with special emphasis: Symptoms of lower GIT: diarrhea, constipation, alternating bowel habit, abdominal pain and its relation to bowel motions, bleeding per rectum, history of weight loss, anorexia, peptic ulcer, worm infestation, alcohol, use of NSAID, steroids or iron supplementation and symptoms of anemia.

B. Complete physicalexamination: with special emphasis on presence of pallor, nail changes, tachycardia. Examination of the abdomen, chest, heart and neurological examination: to exclude other system affection.

- **P R examination:** to examine the tone of the sphincter, determine if the endoscopic preparation has been adequate and exclude any obvious lesions at the anus and lower rectum.

II. Laboratory investigations: Blood samples were taken. Each blood sample was divided into three portions as follows:

• First portion was collected into Na citrate -containing tube, and used for estimation of prothrombin time (PT) immediately.

• The second portion was collected into EDITA containing tube for CBC estimation using folly automated cell counter, and for ESR estimation by Westegren method.

• The third portion was put in a plan tube, left to clot then centrifuged at 1600 rpm for 20minutes and serum was separated and used for estimation of:

-Liver and kidney function tests.

-Serum iron profile (iron, ferritin and total iron binding capacity).

Fecal occult blood testing (FOBT): The test contains a specially prepared stabilized guaiac paper and is ready for use without additional preparation. The fecal occult blood test which we used was Haemoccult (Beckman Coulter Diagnostic, Palo Alto, CA, USA):

Principle of the test

▪Seven days before the stool collection period non steroidalanti inflammatory drugs are to be avoided, three days before the stool collection period vitamin C in excess of 250 mg/day from supplements and citrus fruits, juices and red meat are to be avoided. A well balanced diet including fiber such as bran cereals, fruits and vegetables is encouraged.

▪Patients were requested to submit 3 stool samples. The samples were not rehydrated. The stool sample should be collected before contact with the toilet bowel water. Any clean dry container can be used. Slides should be protected from heat, light and volatile chemicals. The patients were instructed to submit the stool samples upon arrival at the endoscopy unit prior to the endoscopic procedure. The samples are taken from formed non-bloody stool to be put on the 2 windows of

the test card and this is repeated for two more times. If any of the six windows on the three cards is positive, then the test is interpreted as positive **(Winawer et al., 2003).**

III. Abdominal ultrasongraphy: Was done using using FLUKUDA FF sonic machine.

VI. Flexible sigmoidoscopy and rectal snip examination: We used fiberopticsigmoidoscopy OLYMPUS. Patients were given a date with instructions for bowel preparations. We reached up to 60 cm into the colon. In patients with positive FOBT and no abnormality on their sigmoidoscopy, we proceeded into the whole colonoscopy examination but in another session. Three rectal snips were taken from each patient and examined by direct transparency technique to demonstrate schistosomal ova (living or dead ova) **(Sherman and Finlayson, 1982).**

During examination, the location and size of all polypoid lesions or masses were noted and described. All polyps were excised (polypectomy) and biopsies were taken from any abnormal mucosa and from all masses for histopathology.

Statistical analysis:

Data were collected, reviewed and fed to the computer where statistical analysis was done using the Statistic Package for Social Science Version 17 (SPSS 17.0) for windows. Comparing groups was done using Student's t- test, Chi-square, ROC curve. .The level of significance was taken at P-value of < 0.05. Study of the relationship between variables was done using correlation coefficient (Pearson correlation).The level of significance was taken at P-value of <0.05" and P-value of < 0.001. The results were presented in tables and figures.

3. Results:

As regard the personal data of the studied groups **(Table 1):** There was highly significant difference in age between the two groups at p< 0,001 and no significant difference in sex. They were 68 males (68%) and 32 females (32%). Their ages ranged from 45- 68years with mean ± SD of 58.600±6.123 in group I, while in group II there were 36 males (60%) and 24 females (40%). Their ages ranged from 46 - 67 years with mean± SD of 53.280 ±6.633.

As regard the clinical pictures, anorexia was highly significant increased in group I, while weight loss is significant increased in group I, with no significant difference in the rest of symptoms and signs between the two groups.

ESR mean level was 48.740±30.340 and 32.500±28.173 in groups I and II respectively. There was a highly significant increase in ESR level in GI compared to GII at P≤0.01 **(Fig 1)**.While there was no significant difference in the rest of blood picture parameters. There was positive relation of histopathological findings in relation to ESR **(Fig 2)** and negative correlation of histopathological findings in relation to the rest of blood picture was detected. **Table (2) &Fig (3):** Lesions were detected in 52.5% of the studied cases and the pathological changes in group I compared to group II were highly significant at p< 0.001.

Our results revealed that no significant difference in the two studied groups as regards the liver function tests, kidney function tests and iron profile.

Concerning the sensitivity of FOBT **(Table3)** it reaches 78.5% with specifity 55% and a total accuracy 67.5%. The positive predictive value (PPV) was 66% and the negative predictive value (NPV) was 70%.

As regard the sigmoidoscopic findings of the studied groups (**Table4**), It revealed that: 25% of patients had polyps, 15% had inflammation, 10% had CRC, 3.75% with infection, 3.75% with rectal ulcer, 2.5% with internal piles, and 47.5% had no mucosal abnormality on examination. In patients with positive FOBT and no abnormality on their sigmoidoscopy (8 patients), we proceeded into the whole colonoscopy examination but in another session.

Result of histopathological examination of the polyps **(Table 5):** The 40 polyps found on sigmoidoscopic examination of the studied patients was as follows: 28 polyp (70%) was adenomatous polyp, 6 (15%) hyperplastic polyp, 2 (5%) adenocarcinomatous polyp, 2 (5%) bilharizial polyp while 2 patient (5%) had hyperpolyposis syndrome ''HPS''.

Table (1) Age and sex distribution of the studied groups:

	Groups							
	Group I			Group II			T-test	
	Mean	±	SD	Mean	±	SD	t	P-value
Age	58.600	±	6.123	53.280	±	6.633	-3.572	0.001** HS
	N	%		N	%		X^2	
Sex	Female	32	32.00	24	40.00		0.527	0.468 NS
	Male	68	68.00	36	60.00			

** HS highly significant at p< 0.001 NS: non significant at p>0.05

It shows highly significant difference in age between the two studied groups at p< 0.001 and no significant difference of sex.

Fig (1) ESR of the studied groups

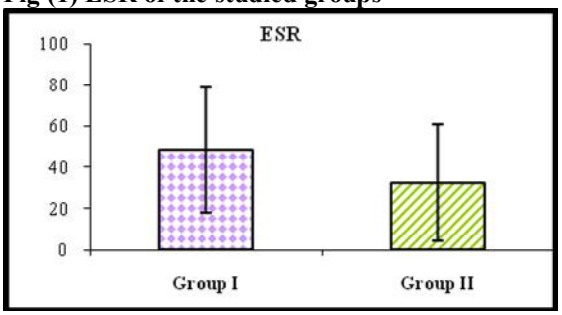
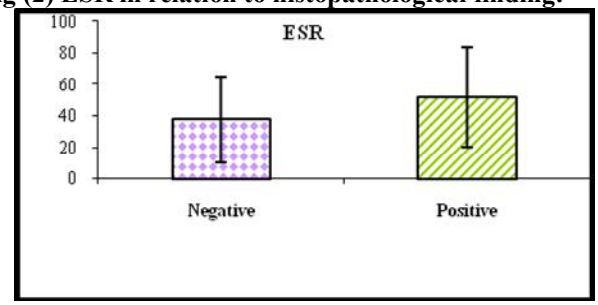


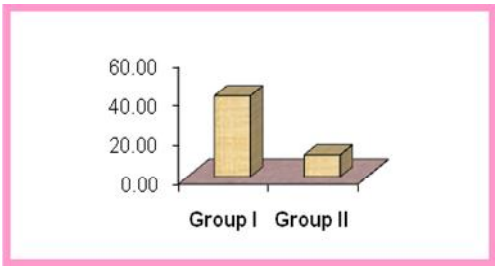
Fig (2) ESR in relation to histopathological finding:



Fig(1) shows significant increase of ESR in group I in comparison to group II at p< 0.05.
Fig(2) shows positive correlation of histopathological finding in relation to ESR.

Table (2) &Fig (3): Number and percentage of positive sigmoidoscopy findings in relation to FOBT

Groups		Histopathology	
		N	%
Group I(100)		66	41.25
Group II(60)		18	11.25
Total(160)		84	52.50
Chi-square	X^2	9.744	
	P-value	0.002**HS	



** HS: highly significant at p< 0.001

It shows that pathological changes in group I compared to group II is highly significant at p< 0.001.

Table (3): Specifity and sensitivity of FOBT in relation to pathological lesions

FOBT		Histopathology		
		Positive	Negative	Total
Group I	N	66	34	100
	%	41.25	21.25	62.50
Group II	N	18	42	60
	%	11.25	26.25	37.50
Total	N	84	76	160
	%	52.50	47.50	100.00
Sens.	Spec.	PPV	NPV	Accuracy
78.571	55.263	66.000	70.000	67.500

PPV: positive predictive value NPV: negative predictive value

It shows sensitivity of FOBT 78.5% and specifity 55% with a total accuracy 67.5%

Table (4) Sigmoidoscopy findings in relation to FOBT:

Lesions	+ve FO BT Group I		-ve FOBT Group II		total	
	NO	%	NO	%	NO	%
Polyp	28	28%	12	20%	40	25%
CRC	16	16%	0	0%	16	10%
Inflammation(U.C, C.D, div., nonspec .colitis)	18	18%	6	10%	24	15%
Infection''Bilhaziasis. Amabiasis''	6	6%	0	0%	6	3.75%
Piles	4	4%	0	0%	4	2.5%
Ulcers	6	6%	0	0%	6	3.75%
Normal	34	34%	42	70%	76	47.5%

Some patients had double lesions

Table (5) Results of histopathological examination of the polyps :

Polyps	No & %	
Adenomatous Polyp	28	70%
hyperplastic polyp	6	15%
Adenocarcinoma	2	5%
Bilharzial polyp	2	5%
HPS (hyperpolyposis syndrome)	2	5%
total	40	100%

4. Discussion

Endoscopic screening has a potentially large effect, and can theoretically prevent CRC **(Bretthauer and Hoff, 2007) and (Atkin et al.,2010).** In the mid-1970s, the flexible sigmoidoscope was introduced for the first time. The entire recto-sigmoid and potentially as high as the splenic flexure could be examined comfortably **(Winawer, 2001).**

Screening for CRC can impact both primary prevention (finding precancerous polyps that could later become malignant) and secondary prevention (detecting early cancers that can be more effectively treated) **(Whitlock et al., 2008)**.

As regard the personal data of our patients, we found that there was a high significant difference in age in group I compared to group II and the age group from 50 -60 years had the highest percent of lesions (50%), while age group above 60 years had the highest incidence of CRC (62.5%). This was in agreement with **(Rundle et al., 2008)** and (**Barbara et al., 2011**) who stated that the age is a dominant risk factor for cancer and for adenomas of all sizes and rationale for 50 years as the age of screening inception is that the risk of clinically significant neoplasia.

As regard the clinical symptoms and signs in relation to FOBT, we found that anorexia was highly significant increased in group I, while weight loss is significant increased in group I with no significant difference in the rest of symptoms and signs between group I and II, and there was no relation between clinical symptoms and signs in relation to pathological changes in the studied patients. This was in agreement with **(Banaszkiewicz et al., 2004)** who studied 346 subjects with abdominal symptoms of unclear etiology, he found that colorectal pathology was found in 34.6% and colorectal neoplasia was recognized in 9%.

Our study demonstrated a highly significant increase in ESR level in GI in comparison to GII, this was in agreement with **(Cankurtaran et al., 2010)** who examined retrospectively the 139 old patients with high ESR and accompanying anemia to lighten the cause. In 57.6% a specific underlying pathology was found. Malignancy was the leading cause (21.6%), followed by infectious disorders (10.1%), collagen vascular diseases (9.4%), and non-neoplastic hematologic disorders (5.0%). In 42.4% of patients no specific pathology could be found. Also we found positive relation of histopathological finding in relation to ESR.

As regard the FOBT results the test shows sensitivity of 78.5% and specifity of 55% with a total accuracy of 67.5% and sensitivity to CRC 100%. Positive and negative predictive values were 66% and 70% respectively. **Banaszkiewicz et al., 2004** found that the great majority of neoplastic conditions were found in FOB positive subjects. And the sensitivity of the test was 90%, while its specificity reached 84%. Diagnostic accuracy was 84%. Positive and negative predictive values were 15% and 99% respectively. He concluded that FOB testing appears highly sensitive and specific for colorectal cancer.

In Egypt, colorectal carcinoma is one of the most common malignant neoplasms, it is the fourth most common malignancy, representing 6.1% of cancers in Egypt **(Zalata et al., 2000).**

Ulcerative colitis and Crohn's disease are Inflammatory bowel disease about one third of its deaths of Ulcerative colitis are due to CRC, and both diseases risk depends on disease duration and extent of inflammation **(Itzkowitz and Hapraz, 2004).** We have detected Inflammation (Ulcerative colitis and Crohn's disease ,non specific colitis in 15% of the studied groups . Also Polyps, and CRC were detected in 25%, 10% of patients in group I,II respectively while **(Baxter et al., 2009)** recorded 9.2% and 7% of patients respectively.

Also we have found 2 cases (1.25%) of amebic colitis. This was nearer to the result reported by **(Naoki et al., 2010)** who examined patients with chronic diarrhea alternating with constipation, unidentified hematochezia and with positive fecal occult blood test by conventional colonoscopy. Also **(Okamoto et al., 2005)** found four cases of amebic colitis among 5,193 subjects who underwent colonoscopy because of positive fecal occult blood test results in a mass screening. All of four cases did not have any abdominal symptoms while in our study the patients had diarrhea.

We have reported 4 cases (2.5%) of colonic Schistosomiasis patients. This was in agreement with **(Wakid, 2010)** who in his examination of 1238 Arabic patients for occult GIT bleeding by FOBT; he found 34 patients (2.7%) with colonic Schistosomiasis.

However it worth noting that we found 9% of the lesion beyond the sigmoidoscopy feasibility and was discovered on the continuation of endoscopy into

whole colon, of which the malignant lesions and polyps accounted only for 2% and 4% respectively of all lesions. They were all discovered in a positive FOBT result patients. Also **(Smith et al., 2009)** found that 91.3% of the lesions were located distal to the splenic flexure and of the remaining proximal lesions, polyps and carcinoma accounted for only 2.2%, so he stated that sigmoidoscopy is suggested as the first line of investigation for patients suspected to have colonic diseases, total colonoscopy should be reserved for sigmoidoscopy negative patients with persistent symptoms and high risk cases for malignancy.

In our study flexible sigmoidoscopy (FS) was able to diagnose 88% of cancer cases and this was approximately as the results of **(Thompson et al., 2008)** who studied over 16 years 16433 patients, and found that FS detects 95 per cent of cancers, and that the diagnostic yield of whole colon imaging after FS is very low. In other hand in our study the sigmoidoscopy failed to discover 12% of malignant lesions as they were proximal lesions while with **(Singh et al., 2009)** 8% of total malignant lesions was missed. As colorectal cancer was diagnosed in 86.2%in the rectum or sigmoid (distal) and 13.8 % in the proximal colon.

As 70% of the polyp discovered during our study turned out to be adenomatous polyp, 15% hyperplastic polyp, 5% adenocarcinomatous polyp, 5% bilharizial polyp while only 5% hadhyperpolyposis syndrome . **Levin et al., 2008** suggested that left-sided hyperplastic colonic polyps (generally within the reach of a screening sigmoidoscopy) serve as a marker for neoplastic polyps.

We have found that the pathological changes in group I (FOBT+ve) showed highly significant increase in comparing to group II (FOBT-ve). **Denis et al., 2009** mentioned that the detection rate for advanced neoplasia was by the combined procedure, three times more than with FOBT alone. So a population-based screening programme with the addition of FS to FOBT is feasible and safe.

Smith et al., 2006 added that FOBT screening offers no benefit without appropriate follow up diagnostic testing and treatment. It is an indirect screening test that identifies a subgroup of the average risk, asymptomatic population sufficiently likely to have clinically important CRC to justify more expensive, invasive diagnostic tests (e.g. endoscopy). The screening test by itself neither rules in nor rules out colonic neoplasia.

5. Conclusion:

Sigmoidoscopy is an efficient screening test for most colorectal diseases (especially CRC). FOBT shows high sensitivity as screening test for colorectal diseases FOBT results the test shows sensitivity of78.5% and specifity of 55% with a total accuracy of 67.5% and sensitivity to CRC 100%. Positive and negative predictive values were 66% and 70% respectively. Combined FOBT and flexible sigmoidoscopy are important in the diagnosis of rectal diseases especially their role in decreasing incidence and diagnosis of CRC as they detect precancerous lesions before turning malignant. ESR is highly increased in patients with malignant lesions. Gender has no relation to the incidence of GIT lesions or to the affection with CRC.

6. Recommendation

Combined FOBT and flexible sigmoidoscopy are recommended for the diagnosis of rectal diseases. Upper endoscopy and colonoscopy in patients with iron deficiency anemia and negative sigmidoscopy examination are highly recommended. Screening for CRC should start at the age of 50 years. Further studies are recommended to figure out the benefit and role of both FOBT and sigmoidoscopy for diagnoses of rectal diseases and to compare and determine the value of using colonoscopy versus sigmoidoscopy as a screening test for colorectal diseases.

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