

The Use of the Fecal Immunochemical Test in the Acute-Care Hospital Setting

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Objective: The fecal immunochemical test (FIT) is indicated for colon cancer screening in asymptomatic average-risk patients. However, the inclusion of orders for non-indication-based FITs in medical records has led to increased inappropriate use in emergency department (ED) and inpatient settings. This study aimed to evaluate the clinical impact of FIT results when the test is used for purposes other than routine screening.

Methods: We conducted a single-center, retrospective chart review using electronic medical records, analyzing patients who underwent the FIT in the ED or while admitted to the VA Hospital from September 2013 through December 2016. The collected data included demographics; clinical symptoms and signs; medications; and information on digital rectal examinations, gastroenterology consultations, and endoscopic procedures.

Results: Of the 1,354 patients included, most were men. Among FIT-positive patients, the mean age was 73.7 years. The majority of FITs were done in the ED. Positive FIT results were statistically significantly associated with rectal bleeding, weakness, and diarrhea. Anticoagulants were associated with positive FIT results. Patients with positive tests often received gastroenterology consultations and were more likely to undergo endoscopic procedures.

Conclusion: None of the evaluated FITs were used for screening, confirming that they had been ordered inappropriately. This indiscriminate use can lead to unnecessary interventions and prolonged hospitalizations. Additionally, negative tests may lead to underestimate worrisome symptoms or features that require further investigation. In conclusion, our study does not support the indiscriminate use of the FIT in inpatient or ED settings.

[P R Health Sci J 2025;44(4):189-194]

Key words: Quality improvement, Colorectal cancer screening, Fecal immunochemical test, Anemia, Gastrointestinal bleeding

Colorectal cancer (CRC) is a leading cause of cancer-related death. However, it is also one of the most preventable malignancies when detected early, which has led to the development of numerous screening tests. Prevention strategies have improved and evolved in recent decades, but they are sometimes used in place of basic physical examination skills (1). Several CRC screening options are available, including non-invasive tests and invasive procedures. The fecal occult blood test (FOBT) is a well-established community-based screening tool for the early detection of CRC. Two types of tests are used: the guaiac-based version, which detects the pseudoperoxidase activity of hemoglobin, and the fecal immunochemical test (FIT), an immunological test that uses antibodies against human hemoglobin (2). The latter is currently preferred over the older FOBT because it has higher sensitivity and specificity for detecting cancerous and precancerous lesions and does not require any dietary preparation before testing (3). It is important to note that FIT is validated only for CRC screening in asymptomatic patients; in addition, its effectiveness requires strict patient adherence during repeated testing (3).

Although strong evidence supports the use of the FIT as a screening tool for colorectal neoplasia in the outpatient population, its commercial availability has led to broader use, including its

application in the evaluation of altered stool color and anemia, even though such use falls outside its validated role (2). There is currently a paucity of data regarding its application in the inpatient setting (4). The availability of imaging and endoscopic interventions has rendered the FIT irrelevant to the acute inpatient setting, but its use has persisted and at times has been inappropriately substituted for physical and rectal examinations (4). The most common indications for ordering a FIT include patients' self-reported rectal bleeding or dark stools and anemia, and the preemptive initiation of anticoagulant therapy. However, its impact on clinical decision-making beyond the context of screening remains uncertain (2). Inappropriate testing and the misinterpretation of results often lead to increased costs and may

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The authors have no conflict of interest to disclose.

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expose patients to harm caused by poor disease-management decisions or the initiation of unnecessary procedures (4). Moreover, it is important to note that the results of this test frequently do not alter the management plan, but instead delay appropriate care. Studies have suggested that the use of the FIT in inpatient and emergency department (ED) settings adds little value to patient care and should be eliminated (5). Nevertheless, the discontinuation of ineffective clinical interventions has been focus of limited research and remains difficult to carry out, even when evidence support on doing so (4).

This study aimed to assess and describe which presenting symptoms and/or signs would trigger the inappropriate ordering of non-indication-based FITs in the ED and inpatient settings and describe the actions and outcomes associated with the results of such tests.

Methods

We conducted a single-center, retrospective chart review approved by the VA Caribbean Healthcare System Institutional Review Board in San Juan, Puerto Rico. We examined the medical records of patients who, from September 2013 through December 2016, underwent FIT screening in the ED or while hospitalized. The study population was identified via the Veterans Affairs Caribbean Healthcare System Laboratory Department, which provided an electronic list of all the patients who underwent FIT screening at the hospital during this period. Those patients younger than 18 or over 89 years of age were excluded. Patients who had a FIT that was ordered for screening purposes were also excluded. The data were collected using a standardized Microsoft Excel spreadsheet. Data collection included age, sex, the location where the FIT was ordered, the FIT result, the patient's subjective complaint(s), a list of active medications, the presence of orthostatic changes in vital signs, the findings of any rectal examination (including documentation of hemorrhoids), hemoglobin levels, platelet count, international normalized ratio, the endoscopic procedures performed during hospitalization, and whether the gastroenterology service was consulted.

The primary outcome of this study was to describe the signs and symptoms that prompted the use of the FIT in the ED and inpatient settings and to characterize these findings. Included were the patient's subjective complaint(s), comorbidities (with a focus on gastrointestinal [GI] pathology), medications (antiplatelets, anticoagulants, non-steroidal anti-inflammatory drugs [NSAIDs], and iron supplements), physical examination findings, and laboratory results. We also evaluated whether the result of the FIT was a factor involved in the clinical decision-making process and whether said result prompted either further testing or consultation with additional medical specialists.

Results

A total of 1,354 patients were included in this single-center retrospective study at the VA Caribbean Healthcare System. Most of the subjects in our study were men (99%). Most of the tests were performed in the ED (865/1354 [63%]) rather than in the inpatient setting (489/1354 [36%]). The mean ages of the

FIT-positive and FIT-negative patients were 73.7 and 71.7 years, respectively. Of the FIT results, 43.3% were positive. Overall, 45.9% of the tests were performed in the context of overt GI bleeding. None of the FITs were ordered for screening purposes. Refer to Table 1 for baseline characteristics.

Table 1. Baseline characteristics of patients who were tested with fecal immunochemical test

Characteristic, n (%)	Total FITs Performed (n = 1,354)
Age (years), mean (SD)	72.6 (12.5)
Sex	
Male	1335 (98.6)
Female	19 (1.4)
Site of FIT testing	
Emergency department	865 (63.9)
Inpatient	489 (36.1)
FIT result	
Positive	586 (43.3)
Negative	768 (56.7)
Overt gastrointestinal bleeding (reported/observed)	
Yes	621 (45.9)
No	733 (54.1)

Abbreviation: FIT, fecal immunochemical testing.

The most common symptom for which a FIT was ordered was rectal bleeding. Notably, a significant association between gastroenterology consultation and rectal bleeding was found; among the patients who had a gastroenterology consultation, 74% presented with rectal bleeding (Table 2). Nearly 17% of the patients with positive FIT results were taking anticoagulants. We found statistical significance in the association between the use of anticoagulants and having a positive FIT; on the other hand, neither the use of antiplatelet therapy nor NSAIDs was associated with a positive FIT. Iron supplementation was more frequently associated with negative results, although that association was without statistical significance. Those patients who had a positive FIT most commonly had a history of rectal bleeding, dark blood, port-wine stools, or hemorrhoids on physical examination. These associations were statistically significant.

Table 2. Association between overt gastrointestinal bleeding and gastroenterology consultation

	Gastroenterology consultation		P value
	Yes	No	
Overt GI Bleeding			<.001
Yes	355 (74%)	266 (30%)	
No	126 (26%)	607 (70%)	

Abbreviation: GI, gastrointestinal. Data presented as n (%).

Approximately 72.1% of the patients with a negative FIT had hemoglobin levels above 10 g/dL, while lower hemoglobin levels (<10 g/dL) were associated with FIT-positive results; both results were statistically significant. Refer to Table 3 for additional details.

Of the study sample, only 36% of the patients who underwent a FIT as part of their evaluation at the ED or during hospitalization received a consultation by the gastroenterology service. Interestingly, when evaluated in terms of test result, about 60% of those with positive tests received a consultation, compared to only 17.2% who had a negative result. This difference in consultation rates was statistically significant. Refer to Table 4.

Of the total number of patients referred to the gastroenterology service, 37% had an endoscopic procedure performed during hospitalization. Overall, 146 upper endoscopies and 152 colonoscopies were performed. Forty-two patients underwent both procedures.

Of the 349 patients with positive FITs who had been referred to gastroenterology for consultation, only 22% had a colonoscopy, while 17.6% had an upper endoscopy. The most common finding on positive FIT-related colonoscopy was hemorrhoids (18.9%), followed by diverticulosis and polyps, representing 15.7% and 11.3%, respectively. Colon cancer was diagnosed in 12 patients, representing 2% (12 out of 586) of all the positive FIT results and 9% (12 out of 130) of those in our study group who underwent a colonoscopy following a positive FIT. None of the patients who underwent a colonoscopy and had a negative FIT result were diagnosed with colon cancer. Out of the 12 patients diagnosed with CRC, 11 (91.6%), presented with signs and symptoms. The single patient with no signs or symptoms had a spinal cord injury with bowel dysfunction requiring bowel manipulation. In this type of patients the use of FIT is not recommended. Refer to Tables 4 and 5 and Figure 1 for additional details.

Discussion

The current guidelines for using the FIT vary by country and healthcare organization. However, the U.S. Preventive Services Task Force, American College of Gastroenterology, and American Gastroenterological Association guidelines recommend this test for screening asymptomatic individuals at average risk who are aged 45 years and over (3).

In hospitals, the FIT is sometimes used inappropriately outside the approved indications. There are few studies evaluating the merit of using this test for purposes other

than screening. None so far has demonstrated a clinical benefit. Multiple variables can affect the test's performance outside its routine use for screening. One of these variables is improper sample collection, which can lead to false-negative or false-positive results. False-positive results may occur if the probe is inserted improperly during stool collection, possibly causing minor injury or bleeding

Table 3. Patient demographics, test-order location, subjective complaint(s), medications, rectal exam findings, platelet counts, and international normalized ratio values, according to FIT results

	Positive		Negative		P value
	n	%	n	%	
Age (years), mean (SD)	73.7	11.8	71.7	12.9	.003
Sex					.300
Male	580	99.0	755	98.3	--
Female	6	1.0	13	1.7	--
Location					<.001
Emergency department	427	72.9	438	57.0	--
Inpatient setting	159	27.1	330	43.0	--
Subjective complaint					
Rectal bleeding	252	43.0	78	10.2	<.001
Dark or black stools	114	19.5	128	16.7	.185
Hematemesis	9	1.5	4	0.5	.058
Coffee-ground emesis	14	2.4	24	3.1	.417
Bright red blood per rectum	18	3.1	2	0.3	<.001
Fatigue	13	2.2	15	2.0	.734
Weakness	14	2.4	47	6.1	.001
Syncope	3	0.5	8	1.0	.367
Diarrhea	51	8.7	101	13.2	.010
Abdominal pain	36	6.1	98	12.8	<.001
Other	117	20.0	320	41.7	<.001
Antiplatelets	256	43.7	326	42.5	.663
Anticoagulant	99	16.9	92	12.0	.010
NSAIDs	76	13.0	170	22.2	<.001
Iron supplements	109	18.6	155	20.2	.467
Orthostatism	36	6.2	21	2.7	.002
Rectal examination findings					
Red blood	86	14.7	2	0.3	<.001
Dark blood	88	15.0	21	2.7	<.001
Port-wine-colored blood	15	2.6	0	0.0	<.001
Hemorrhoids	81	13.8	69	9.0	.005
Mass	0	0.0	0	0.0	--
Normal	171	29.2	290	37.8	.001
Not done	154	26.3	386	50.3	<.001
Presence of hemorrhoids	148	32.5	78	17.6	<.001
Hemoglobin					<.001
>10 g/dL	350	59.7	554	72.1	--
<10 g/dL	326	40.3	214	27.9	--
Platelets					.092
≥100,000	547	93.3	733	95.4	--
<100,000	39	6.7	35	4.6	--
INR					.162
>1.5	87	15.4	92	12.7	--
≤1.5	477	84.6	632	87.3	--

Abbreviations: INR, international normalized ratio; NSAIDs, nonsteroidal anti-inflammatory drugs.

Table 4. Gastroenterology consultation, endoscopic interventions, and colonoscopy findings, according to FIT results

	Positive		Negative		P value
	n	%	n	%	
Gastroenterology consultation	349	59.6	132	17.2	<.001
Procedure performed					
Endoscopy	103	17.6	43	5.6	<.001
Colonoscopy	130	22.2	22	2.9	<.001
Both	18	3.1	24	3.1	.955
Findings					
Normal	0	0.0	0	0.0	–
Hemorrhoids	111	18.9	22	2.9	<.001
Polyps	66	11.3	14	1.8	<.001
Diverticula	92	15.7	16	2.1	<.001
Colorectal cancer	12	2.0	0	0.0	<.001
Angiodysplasia	2	0.3	0	0.0	.187
Radiation proctitis	8	1.4	1	0.1	.013
No abnormal findings	2	0.3	1	0.1	.582
Other	6	1.0	0	0.0	.006

Table 5. Signs/symptoms of positive FIT patients diagnosed with colorectal cancer (N = 12)

Age (years)	FIT Indication	Signs/Symptoms Present?
89	Rectal bleeding	Yes
85	Anemia	Yes
84	Anemia, melena	Yes
79	Rectal bleeding, anemia	Yes
82	Rectal bleeding, anemia	Yes
86	Rectal bleeding	Yes
86	Rectal bleeding, melena, anemia	Yes
83	Rectal bleeding	Yes
87	Rectal bleeding, anemia	Yes
86	Anemia	Yes
67	SCI; inpatient	No
75	Rectal bleeding, anemia	Yes

Abbreviation: SCI, spinal cord injury.

(6). In our study, we could not assess the method of collecting the FIT samples; therefore, this variable could not be evaluated.

Most of the patients with a negative test but having GI symptoms were not referred to the gastroenterology service. This likely led to the mistaken belief that further evaluation was unnecessary, even though many of these patients had clear indications for a gastroenterology referral and likely required endoscopic or other diagnostic procedures (7).

It was also noted that among the patients referred to gastroenterology because of a positive FIT, the clinical decision on whether to perform a colonoscopy or an upper endoscopy

was largely guided by symptoms and clinical presentation rather than test results, highlighting the fact that a positive FIT in the ED or an inpatient setting does not always lead to a colonoscopy. It must also be emphasized that, given the clinical presentation, FIT screening was inappropriately ordered for this group of patients. In patients with signs or symptoms suggestive of GI bleeding and a high pretest probability, a negative FIT result does not alter the clinical decision to refer such patients for further evaluation (5). A literature review suggests that the FIT is of limited utility in the inpatient setting to diagnose obscure GI bleeding, as results do not impact immediate medical decision-making. Patients suspected of GI bleeding should undergo endoscopic evaluation, regardless (7). This finding highlights that a careful history, physical examination, and visual inspection remain the foundation of establishing the etiology of a suspected GI hemorrhage (8).

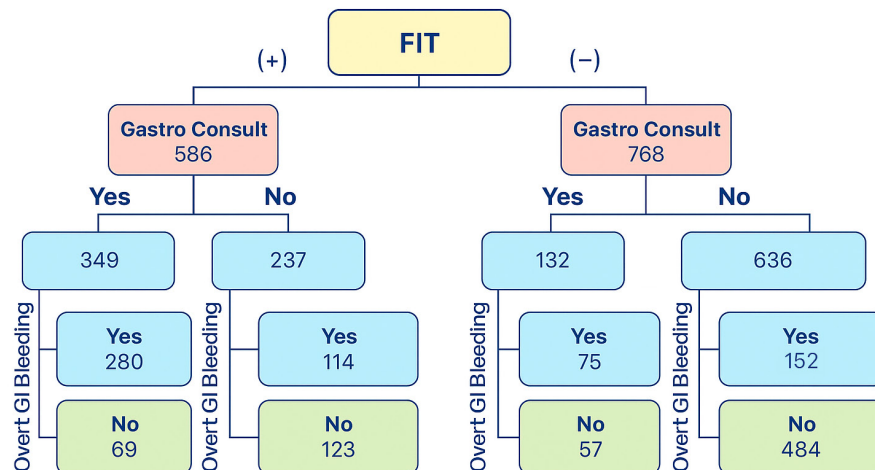
The costs associated with the inappropriate use of the FIT is also an important factor to consider. Medicare reimbursement rates for a FIT are approximately \$24 per test (9). The inappropriate use of FIT during our study period alone resulted in over \$30,000 in unnecessary costs. Some unmeasurable costs include repeated testing or inaccurate diagnoses—which latter can result in unnecessary endoscopic procedures—delayed or incorrect treatment, and an increased length of stay. In addition to the aforementioned medical costs, these factors may take a physical and emotional toll on the patient.

It is difficult to estimate the exact cost of the inappropriate use of the FIT, as that cost depends on various factors, such as the extent of the misuse, the patient population, and the healthcare system in which the test was performed. The inappropriate use of FIT may also have additional negative impacts, reflected in prolonged lengths of stay and potentially leading to delays in treatment and the inefficient use of institutional resources. However, it is important to minimize inappropriate use by ensuring adherence to established protocols and by training healthcare professionals to identify the proper indications for implementing the test. Some studies have questioned the utility of having the FIT be an orderable test in the acute-care hospital setting (4). Despite some limitations in our study, given its retrospective nature, the inappropriate use of the FIT was demonstrated to be occurring in our institution's ED and inpatient setting. Although disinvestment (that is, the discontinuation of ineffective clinical interventions) is very difficult, we aimed to reduce the number of unnecessary FIT orders within the inpatient and ED settings by developing a campaign to remove FIT orders from the electronic medical record's laboratory order set.

Conclusions

In conclusion, our study does not support the indiscriminate use of the FIT in the inpatient and ED settings and furthermore raises

Figure 1. This diagram illustrates the distribution of patients who underwent FIT and had gastroenterology consultations and details the findings of overt gastrointestinal (GI) bleeding.



awareness about the possible negative impact of such use on patient-care decisions. In our study, most of the patients admitted with GI symptoms and a negative FIT did not receive a gastroenterology consultation. When making clinical decisions, healthcare providers should carefully consider a patient's clinical presentation, signs, and symptoms, as well as the results of other diagnostic tests rather than relying on the FIT. Our study demonstrated that the results of a FIT may be irrelevant in determining the next step in management or, at times, may compel a physician to perform low-yield, unnecessary interventions. In our study, many of the patients required evaluation of a possible upper GI tract cause of symptoms, regardless of the test results. A similar pattern was observed with colonoscopy. This finding is consistent with those of Narula et al., who reported that a positive FIT result did not appear to affect clinical decisions, but was associated with delayed investigations and increased lengths of stay, suggesting that the test may not have been appropriate in some cases (5). The improper use of the FIT in the acute hospital care setting is a significant concern, as it can lead to missed diagnoses and inappropriate treatment, which can lead to consequences for patient outcomes, lengths of stay, and overall quality of life. After having explored the use of the FIT at our institution, we consider it reasonable to discontinue its use in our acute inpatient and ED setting. By doing so, we can ensure that patients receive appropriate care and can decrease costs associated with medical care in the inpatient setting and ED. As stated by Gupta et al., it is time to "write the obituary" for in-hospital fecal immunochemical testing (4).

Resumen

Objetivo: La prueba inmunoquímico fecal (FIT, por sus siglas en inglés) está indicada para cernimiento de cáncer colorrectal en pacientes asintomáticos de riesgo promedio. La disponibilidad de una orden para una prueba aleatoria ha llevado al uso inapropiado en pacientes hospitalizados y en sala de emergencias (SE). Evaluar

el impacto clínico de los resultados de FIT aleatorios cuando se utilizan fuera del propósito de cernimiento. **Método:** Realizamos una revisión retrospectiva de registros médicos electrónicos, analizando pacientes que se sometieron a FIT en SE o estando ingresados en el Hospital de Veteranos entre septiembre de 2013 y diciembre de 2016. Los datos recopilados incluían demografía, síntomas y signos clínicos, medicamentos, información sobre exámenes rectales, consultas de gastroenterología y procedimientos endoscópicos. **Resultado:** De los 1,354 pacientes incluidos, la mayoría eran hombres. La edad media de los pacientes positivos era 73.7 años. La mayoría se realizaron en SE. Los resultados positivos mostraron significancia

estadística en pacientes con sangrado rectal, debilidad y diarrea. Los anticoagulantes se asociaron con resultados positivos. Los pacientes con una prueba positiva a menudo recibían consultas a gastroenterología y eran más propensos a someterse a procedimientos endoscópicos. **Conclusión:** Ninguna de las pruebas se utilizaron para el cernimiento de cáncer de colon, confirmando su uso inapropiado. Este uso puede llevar a intervenciones innecesarias y hospitalizaciones prolongadas. Además, las pruebas negativas pueden resultar en la subestimación de signos y síntomas preocupantes que requieran investigación. En conclusión, nuestro estudio no apoya el uso indiscriminado del FIT en entornos hospitalarios y de emergencias.

Acknowledgments

This material is based on work supported by the Gastroenterology Section and the Research and Development Service at the of the VA Caribbean Healthcare System, San Juan, PR. We would like to extend our gratitude to Gerardo G. Jovet-Toledo, MS, whose expertise in statistical analysis was invaluable to our study. His contribution in the efforts designing the statistical framework, guiding data analysis, and interpreting the results was crucial to the successful completion of this research. We deeply appreciate his dedication and meticulous attention to detail. We would also like to extend our gratitude to Ms. Loriany Alcocer-Rodriguez, BS, whose diligence and contributions, including the extensive revision of the article, reanalysis of the data, resubmission, table corrections, and creation of a new figure, were crucial to finalizing the manuscript.

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