CLINICAL RESEARCH STUDY

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Not FIT for Use: Fecal Immunochemical Testing in the Inpatient and Emergency Settings

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ABSTRACT

BACKGROUND: Fecal immunochemical testing (FIT) is widely used for colorectal cancer screening, its only indication. Its effect on clinical decision-making beyond screening is unknown. We studied the use of FIT in emergency and inpatient settings and its impact on patient care.

METHODS: Using electronic medical records, we reviewed all non-ambulatory FITs performed from November 2017 to October 2019 at a tertiary care community hospital. We collected data on demographics, indications, gastroenterology consultations, and endoscopic procedures. Multivariate logistic regression was performed to determine the effect of FIT on gastroenterology consultation and endoscopy.

RESULTS: We identified 550 patients with at least 1 FIT test. Only 3 FITs (0.5%) were performed for colorectal cancer screening. FITs were primarily ordered from the emergency department (45.3%) or inpatient hospital floor (42.2%). Anemia (44.0%), followed by gastrointestinal bleeding (40.9%), were the most common indications. FIT was positive in 253 patients (46.0%), and gastroenterology consultation was obtained for 47.4% (n = 120), compared with 14.5% (n = 43) of the 297 FIT-negative patients (odds ratio 3.28; 95% confidence interval, 2.23-4.82, $P < .0001$). A potential bleeding source was identified in 80% of patients with reported or witnessed overt gastrointestinal bleeding, a similar proportion (80.7%; $P = .92$) to patients who were FIT positive with overt gastrointestinal bleeding. Multivariate analysis showed that melena, hematemesis, and a positive FIT were associated with gastroenterology consultation (all $P < .05$), while only melena (odds ratio 3.34; 95% confidence interval, 1.48-7.54) was associated with endoscopy.

CONCLUSIONS: Nearly all emergency department and inpatient FIT use was inappropriate. FIT resulted in more gastroenterology consultation but was not independently associated with inpatient endoscopy.

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KEYWORDS: Anemia; Colorectal cancer screening; Gastrointestinal bleeding; Quality improvement; Stool testing

INTRODUCTION

Fecal immunochemical testing (FIT) and colonoscopy comprise the 2 most frequently used screening modalities for colorectal cancer in the United States. FIT, first described in 1978,[1] and guaiac-based fecal occult blood test (gFOBT), first described in 1967,[2] known collectively as fecal occult blood tests (FOBTs), were the first stool-based tests approved for the screening of colorectal cancer in average-risk patients by the US Food and Drug Administration and the US Multi-Society Task Force on Colorectal Cancer.[3]

FOBTs detect hemoglobin in the stool, which in principle originates from sources of gastrointestinal bleeding (eg, advanced colonic neoplasms, inflammation, angioectasias). As a noninvasive, easily administered, inexpensive test, FIT has become a mainstay of colorectal cancer screening throughout the world, as it is more specific for colonic bleeding.[4-6] The same factors that have led to success and widespread availability of gFOBT and FIT have also been

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extrapolated to uses beyond its sole indication for colorectal cancer screening. Most notably, these stool tests have been used to evaluate anemia of unclear etiology in the emergency department (ED) and inpatient hospital setting.[7-17]

Studies of FOBT (FIT or gFOBT) use for indications other than colorectal cancer screening have consistently shown that the tests are nearly always used inappropriately—often in the presence of confounding factors (such as certain medications for gFOBT) or contraindications, such as advanced age.[7-17] Such inappropriate use has led to high rates of both false-positive and false-negative results, with consequences such as delays in appropriate care (eg, colonoscopy for potential colorectal cancer or bleeding sources in the case of false-negative results) or unnecessary procedures and consultations from false-positive results and has little impact on clinical decision-making for hospitalized patients.[7-10,12-17] In this setting, it leads to added cost and has potential for inaccurate results without providing clinical value.

CLINICAL SIGNIFICANCE

- Nearly all fecal immunochemical testing (FIT) tests performed in the inpatient and emergency department settings at a tertiary care safety net hospital were inappropriate (99.5%).
- Multivariate analysis showed that while a positive FIT was more likely to lead to gastroenterology consultation, it did not predict which patients underwent endoscopic evaluation.
- FIT use in the inpatient and emergency department settings adds little value to patient care and should be eliminated.

Given the concerns about misuse of FOBT, our institution removed gFOBT from the electronic medical record in an attempt to eliminate its inappropriate use. However, FIT remained as an orderable test in the inpatient and emergency settings. In this study, our objective was to explore the appropriateness, consequences, and impact of FIT use in the non-ambulatory setting.

METHODS

Study Design

This single-center, retrospective, observational study was approved by the Institutional Review Board of Indiana University—Purdue University at Indianapolis and by Eskenazi Health as a Notice of Research Approval. STROBE (Strengthening the Reporting of OBservational studies in Epidemiology) guidelines for observational cross-sectional studies were followed. We reviewed the medical records of all patients evaluated with FIT while in the ED or any inpatient setting between November 2017 and October 2019. Eligible patients were identified through a search of laboratory results for FIT tests. We excluded outpatients and those younger than 18 years of age. Data were collected by 16 gastroenterology fellows, as part of a gastroenterology fellowship group quality improvement project, using a standardized data collection form developed on Microsoft Excel (Microsoft Corporation, Redmond, Wash). Data collected included demographics, setting where the test was performed, indication for FIT, test result, medical history, and whether gastroenterology consultation was obtained and endoscopic procedures were performed, along with their findings. All FITs were performed by the onsite laboratory at Eskenazi Hospital using the OC-light FIT (Polymedco, Cortlandt Manor, NY).

Analysis

Descriptive analyses are reported as means with standard deviations for normally distributed continuous variables. Categorical variables are reported as frequencies and percentages. FIT testing was stratified by results (positive or negative). Categorical variables were compared with the Fisher's exact test or chi-squared test. Continuous variables were analyzed utilizing the Student's *t* test. Univariate analysis was performed to assess the relationship between presentations of overt gastrointestinal bleeding (melena, hematochezia, coffee-grounds emesis, and hematemesis) and FIT result with obtaining gastroenterology consultation by the inpatient or ED teams, or obtaining endoscopy by the gastroenterology consult team. Age was also included as a variable for the endoscopy analysis. These were fitted with a univariate logistic regression model for each individual variable, after which a multivariate logistic regression model was developed, incorporating variables with univariate P value $< .25$; those variables with a multivariable P value $< .05$ were

Table 1 Baseline Characteristics of Patients Who Were Tested with FIT

Characteristic, n (%)	Total FIT Performed (n = 550)
Age, mean (SD)	55.9 (16.7)
Sex	
Male	284 (51.6%)
Female	266 (48.4%)
Race/ethnicity	
White	230 (41.8%)
Black or African American	248 (45.1%)
Hispanic	33 (6.0%)
Other or unreported	39 (7.1%)
Site of FIT testing	
Emergency department	249 (45.3%)
Hospital ward	232 (42.2%)
Intensive care unit	58 (10.5%)
Burn unit	11 (2.0%)
FIT result	
Positive	253 (46.0%)
Negative	297 (54.0%)
Overt gastrointestinal bleeding (reported/observed)	
Yes	155 (28.2%)
No	395 (71.8%)

FIT = fecal immunochemical testing.

retained in the final model. Odds ratios (OR), 95% confidence intervals (CI), and *P* values were reported. A *P* value < .05 was considered statistically significant. All analyses were done using SAS version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Cohort Characteristics

Between November 2017 and October 2019, 203,667 patients presented to Eskenazi Hospital in the non-ambulatory care setting (ED, inpatient ward, intensive care unit, and burn unit). FIT was performed 550 times during this time period, on 550 unique patients, 0.27% of all patients (550/203,667). The majority (87.5%) of FITs were performed in the ED (45.3%) or on the hospital ward (42.2%). Baseline characteristics of the study cohort are presented in Table 1. The most common indications for FIT were anemia (44.0%), suspected gastrointestinal bleed (40.9%), abdominal pain (5.6%), and change in bowel habits (3.5%). Only 3 of 550 patients (0.5%; 95% CI, 0.09%-1.52%) had FIT performed for colorectal cancer screening, the intended indication for this test, as shown in Table 2. These 3 patients were all tested on an inpatient unit.

Of the 550 patients, 133 (24.2%) were younger than 45 years old, and by age criteria alone, colorectal cancer screening with FIT was not indicated. In addition, among all tested patients, 28.2% had witnessed or reported overt gastrointestinal bleeding, effectively eliminating the need to test for occult bleeding.

Impact of FIT

Overall, FIT was positive in 253 of the 550 patients (46%). A gastroenterology consultation was requested for 47.4% (n = 120) of patients with a positive FIT, as compared with 14.5% (n = 43) of patients with a negative FIT (OR 3.28; 95% CI, 2.23-4.82; *P* < .0001) (Table 3). Based on gastroenterology consultation, 107 patients (19.5%) underwent at least one endoscopic procedure during their hospital stay. Those who were FIT positive were more likely to undergo an inpatient procedure (33.2%) than those who were FIT negative (7.7%) (*P* < .0001; OR 4.29; 95% CI, 2.62-7.00).

Table 2 Indications for FIT

Indication	n (%)
Colorectal cancer screening	3 (0.5%)
Anemia	242 (44%)
Suspected gastrointestinal bleed (total)	225 (40.9%)
Suspected upper gastrointestinal bleed	109 (19.8%)
Suspected lower gastrointestinal bleed	61 (11.1%)
Suspected gastrointestinal bleed, unclear source	55 (10%)
Abdominal pain	31 (5.6%)
Change in bowel habits	19 (3.5%)
Not documented/other	30 (5.5%)

FIT = fecal immunochemical testing.

Of the 120 FIT-positive patients for whom gastroenterology consultation was obtained, upper endoscopy was more likely to follow than was colonoscopy or flexible sigmoidoscopy (n = 70 [58.3%] vs n = 34 [28.3%]; OR 2.06; 95% CI, 1.27-3.33; *P* = .003). The majority of those with a positive FIT (66.8%) did not undergo inpatient endoscopy. However, of those who did, a potential bleeding source was found more often in the FIT-positive group (67/84, 79.8%) compared with the FIT-negative group (13/23, 56.5%) (OR 1.41; 95% CI, 0.67-2.99, *P* = .37). One colorectal cancer was identified in the FIT-positive group and none in the FIT-negative group, for a colorectal cancer prevalence of 0.18% (95% CI, 0.00-1.01%). One advanced adenoma was also found in the FIT-positive group.

Overt gastrointestinal bleeding was present by history or observation in 155 patients prior to obtaining a FIT (28.2%). Of those patients, 41.9% had inpatient endoscopy. Patients with both overt gastrointestinal bleeding and a positive FIT had the highest rate of endoscopy (49.6%), followed by those who had witnessed or reported overt bleeding (41.9%), followed by those with a positive FIT without overt bleeding (33.2%). Those who had both a negative FIT and no overt gastrointestinal bleeding had the lowest endoscopy rate, 6.2%. The likelihood of identifying a bleeding source among patients with overt gastrointestinal bleeding (regardless of FIT result) was 80% (52/65), similar to that among patients with overt gastrointestinal bleeding plus a positive FIT result (46/57, 80.7%) (*P* = .92). Univariate analysis revealed associations between inpatient endoscopy and positive FIT results, age, hematochezia, melena, and coffee-grounds emesis (Table 4).

Multivariate Analysis

In multivariate analysis, factors independently associated with obtaining gastroenterology consultation were melena (OR 6.00; 95% CI, 3.42-10.53), hematemesis (OR 4.59; 95% CI, 1.44-14.62), and a positive FIT (OR 3.78; CI, 2.42-5.89), while coffee-grounds emesis (OR 4.50; 95% CI, 0.74-27.33) and hematochezia (OR 1.72; 95% CI 0.95-3.11) were not. While univariate analysis revealed associations between inpatient endoscopy and a positive FIT, age, hematochezia, melena, and coffee-grounds emesis, in multivariate analysis the only factors independently associated with inpatient endoscopy were gastroenterology consultation (OR 922.25; 95% CI, 61.48-999.99) and melena (OR 3.34; 95% CI, 1.48-7.54) (Table 5); notably, FIT was not (*P* = .46).

DISCUSSION

This study evaluated the real-world use of FIT in the ED, inpatient wards, and intensive care unit at a large, urban, tertiary-care community hospital. The opportunity to study this issue arose after an institutional decision was made to remove gFOBT due to multiple concerns of misuse. FIT was not intended as a replacement, but as it remained an orderable test for colorectal cancer screening, it appeared to

Table 3 Association Between FIT Result and Subsequent Management

Management and Outcomes	FIT Positive (n = 253) n (%)	FIT Negative (n = 297) n (%)	Total (n = 550)
Inpatient gastroenterology consultation obtained	120 (47.4%)	43 (14.5%)	163 (29.6%)
Endoscopic procedure(s) performed (1 or more)	84 (33.2%)	23 (7.7%)	107 (19.5%)
Upper endoscopy	70 (27.7%)	19 (6.4%)	89 (16.2%)
Lower endoscopy	34 (13.4%)	5 (1.7%)	39 (7.1%)
Video capsule endoscopy	5 (2.0%)	1 (0.3%)	6 (1.1%)
Potential bleeding source identified	67 (26.5%)	13 (4.4%)	80 (14.5%)

FIT = fecal immunochemical testing.

Table 4 Univariate Logistic Regression Analysis of Bleeding Symptoms, FIT Results, and Inpatient Endoscopy

Variable	Endoscopy		Odds Ratio	95% CI	*P* Value
	Yes	No			
Gastroenterology consultation obtained, n (%)					
No	0 (0.0%)	387 (87.6%)	Ref		
Yes	108 (100.0%)	55 (12.4%)	>999.99	92.50-999.99	< .0001
FIT result, n (%)					
Negative	24 (22.2%)	273 (61.8%)	Ref		
Positive	84 (77.8%)	169 (38.2%)	5.65	3.46-9.25	< .0001
Hematochezia, n (%)					
Absent	89 (82.4%)	396 (89.6%)	Ref		
Present	19 (17.6%)	46 (10.4%)	1.84	1.03-3.29	.040
Melena, n (%)					
Absent	61 (56.5%)	408 (92.3%)	Ref		
Present	47 (43.5%)	34 (7.7%)	9.25	5.51-15.50	< .0001
Hematemesis, n (%)					
Absent	102 (94.4%)	433 (98.0%)	Ref		
Present	6 (5.6%)	9 (2.0%)	2.83	0.99-8.13	.053
Coffee-grounds emesis, n (%)					
Absent	104 (96.3%)	439 (99.3%)	Ref		
Present	4 (3.7%)	3 (0.7%)	5.63	1.24-25.52	.025
Age, mean (SD)	59.7 (16.0)	54.9 (16.8)	1.02	1.01-1.03	.008

CI = confidence interval; FIT = fecal immunochemical testing.

Table 5 Multivariate Logistic Regression Analysis of Factors Independently Associated with Inpatient Endoscopy

Variable	Odds Ratio	95% CI	*P* Value
Gastroenterology consultation	922.25	61.48->999.99	< .0001
Hematochezia	1.57	0.61-4.05	.350
Melena	3.34	1.48-7.54	< .004
Hematemesis	2.28	0.44-11.90	.328
Coffee-grounds emesis	1.66	0.20-13.62	.635
FIT result	1.33	0.62-2.87	.464
Age	1.01	0.99-1.04	.231

CI = confidence interval; FIT = fecal immunochemical testing.

have taken the place of gFOBT by some clinicians. Previous studies had sounded the alarm on the inappropriate use of FOBT in the acute hospital setting;[7-17] our study adds to this body of literature as the first study to exclusively evaluate FIT in this context.

Our primary finding was that similar to gFOBT, the inappropriate use of FIT in the inpatient and emergency settings was widespread: of the 550 tests done, 99.5% of tests were done for indications other than colorectal cancer screening. Ultimately, in this context, only 1 colorectal cancer and 1 advanced adenoma were found in patients with positive FIT who underwent endoscopy. In this study, 44% of FITs were performed for gastrointestinal bleeding and 40.9% done for anemia, which is consistent with prior studies showing these to be the most common non-ambulatory indications for FOBT, although anemia has more popularity.[12,15,17] While the absolute difference is small between the 2 indications and limited by occasionally unclear documentation about the indication of ordering a FIT, the popularity of FIT in evaluation of gastrointestinal bleeding is concerning. FIT is, in theory, more likely to be positive with large intestinal bleeding, as opposed to upper gastrointestinal bleeding, given the degradation of globin by proteolytic digestive enzymes from an upper gastrointestinal source. This has been a key feature of its specificity for colorectal cancer over gFOBT.[5] Even as FIT is able to sidestep many of the concerns about gFOBT, such as the effects of diet and medications, it should be avoided in the evaluation of upper gastrointestinal bleeding or anemia due to concerns for false-negative results.[18,19] Similarly, 28.2% of

the FITs in our study were done in the setting of reported/witnessed overt bleeding, consistent with reports from some recent studies of inpatient gFOBT use (range 19.2% to 26.4%).[12,13,16] This finding raises concerns of false-positive results and highlights inappropriate use of a test designed to evaluate for occult bleeding.

A related issue addressed by the study is the impact of a FIT result on clinical care, and specifically, whether it guides decisions for management. Multivariate analysis revealed that the presence of a positive FIT was more likely to lead to a gastroenterology consultation (47.4% vs 14.1%, $P = .0001$). However, while a greater proportion of FIT-positive patients underwent endoscopy, 33.2% vs 7.7% ($P < .0001$), FIT was not independently associated with inpatient endoscopy. Further, those with overt gastrointestinal bleeding had a source identified in 80.0% of cases, vs 80.7% ($P = .92$) in patients with positive FIT along with overt gastrointestinal bleeding, suggesting that FIT result did not affect the likelihood of identifying a source of bleeding on endoscopy.

We note that 66.8% of patients with a positive FIT did not undergo inpatient endoscopy following gastroenterology consultation, consistent with prior studies utilizing gFOBT (range 66%-70.3%[12,16,17]). This finding indicates that utilizing FIT did not alter practice regarding endoscopy, and that the presence of overt bleeding along with comprehensive clinical evaluation remains the cornerstone to evaluation of anemia and gastrointestinal bleeding.

A prospective study from Italy[20] evaluated 140 outpatients with iron deficiency anemia without overt bleeding and found that a potential bleeding source was identified by endoscopy in 79% of patients who had a positive FIT, vs 27% with a negative FIT ($P < .001$). The authors suggested a role for the use of FIT positivity in this context to help stratify patients for endoscopy. As this study was done in outpatients without overt bleeding, it is not directly comparable with the current study. Yet, if FIT alone were used as the determinant, 27% of bleeding cases among FIT-negative patients would have been missed. Given that these patients had unexplained iron deficiency anemia, bidirectional endoscopy was already indicated, and the results of a FIT test should not affect management, consistent with a recent American Gastroenterological Association guideline for the evaluation of iron deficiency anemia.[21] Finally, as these were outpatients already planned for end[1−28]oscopy immediately after their FIT test, this study does not provide guidance regarding triaging or timing of endoscopy, which is central to questions about inpatient FIT. This study recommended a role for evaluation of upper gastrointestinal pathology in patients with positive FIT, as 52.1% of their identified lesions were on upper endoscopy. However, several other studies have shown conflicting results and generally, a minimal role of FIT for the evaluation of upper gastrointestinal cancers.[22,23]

The concerns that our study raises about false-negative FIT results providing false reassurance is concordant with the results of a recent systematic review and meta-analysis,[10] which reported the sensitivity of FOBT to be 58% in identifying a cause of iron deficiency anemia on endoscopy. This translates to 42% of patients with iron deficiency anemia and a potentially endoscopically identifiable etiology having a negative FOBT; performance characteristics would clearly be inadequate for a screening test.

Clinicians should be sensitive to the many additional unintended consequences of FIT utilization in this context. In the setting of overt bleed there is a high risk of a false-positive test, while a negative test can provide false reassurance. A positive FIT may lead to patient anxiety and stress, as its only validated indication is for colon cancer screening.[24] Guidelines from the US Multi-Society Task Force recommend colonoscopy as the next step in this situation—a procedure that carries not insignificant risk. This potentially false-positive FIT also places physicians in a difficult position, as a subsequent negative FIT cannot be used to negate a positive test.[25] From a patient perspective, a positive FIT requires a colonoscopy that is now considered diagnostic and may require a copay, incurring additional health care expenses. A negative colonoscopy in a FIT-positive patient is a source of anxiety for gastroenterologists, as it raises concern for missed lesions. Prior studies already suggest widespread non-evidence-based practice among primary care physicians using gFOBT.[26] Protocols and processes must be established to ensure that patients are followed up after stool-based tests—with colonoscopy if positive and with repeat testing at 1 year if negative—in order that colorectal cancers are not missed; many large hospital systems such as the Veterans Affairs have these systems in place.[27] Many institutions, including ours, previously have divested from the use of gFOBT, citing many of these concerns.[19,28] While our study did not assess cost specifically, based on Medicare reimbursements for FIT during the time period, the estimated cost of performing the 550 FITs in this study was $9900- $12,000. Our study highlights the need for educational and quality improvement initiatives to be expanded to FIT use in the ED and inpatient settings.

Our study is unique in that it is the largest to examine the real-world use of FIT in a diverse patient cohort. The comprehensive chart reviews performed allowed us to examine subsequent patient management during hospitalization. Interpretation of our results is affected by several limitations. For the primary objective of appropriateness of FIT, we report data from a single institution. Data collection was performed by gastroenterology fellows who used their clinical judgment to infer the indications for FIT when documentation was insufficient. Our secondary aim is limited by the retrospective, observational study design and the narrow sampling frame of patients who (nearly all inappropriately) received FIT in the ED or inpatient setting. Not all patients tested with FIT had gastroenterology consultation or endoscopy, and there was no control group of patients presenting with the same distribution of symptoms and signs who did not receive FIT (and who represent the great majority of patients with these symptoms and signs). Given these limitations, we are unable to determine whether and to what extent FIT affects any management decisions in these

settings. While a (positive) FIT result was associated with gastroenterology consultation, we cannot conclude that this effect is causal because of the potential for confounding by indication, as well as several clinical factors that were not routinely recorded and thus, could not be included in the multivariable analysis. Our institutional culture is to not utilize gFOBT or FIT in decision-making for diagnostic endoscopy. Corroborating this practice, 14.1% of FIT-negative patients underwent gastroenterology consultation, 54.8% of whom underwent endoscopy, with 56.5% having a potential bleeding source identified. In addition, multivariate analysis did not show FIT to be associated with endoscopic evaluation. However, the ability to decipher the precise path of decision-making for any particular case was not possible. Further, the multivariate model does not include all clinically important variables such as the presence or degree of anemia, comorbidity, and hypotension, which may influence the decision to pursue endoscopy. Regardless, the use of FIT would still be inappropriate, as 99.5% of tests were ordered for indications other than screening for colorectal cancer. Overall, while there were some limitations for our study due to its retrospective nature, we were able to demonstrate that FIT was ordered inappropriately in the vast majority of cases.

CONCLUSION

We presented these data to hospital stakeholders, including the Chief Medical Officer and ED physician leadership. A decision was made to remove FIT as an orderable test from the electronic medical record in the inpatient and emergency settings. We believe FIT is not "fit" for inpatient and ED use, and more broadly, is not "fit" beyond its sole validated indication for colorectal cancer screening, which includes the inappropriate uses for the evaluation of gastrointestinal bleeding, abdominal pain, and iron deficiency anemia.

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