

Accuracy of Fecal Immunochemical Tests for Detecting Advanced Colorectal Neoplasia at Surveillance Colonoscopy

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INTRODUCTION: US guidelines recommend surveillance colonoscopy after polyp removal, but stool testing may offer a more efficient, acceptable strategy for patients with nonadvanced lesions. We conducted exploratory analyses to evaluate the diagnostic accuracy of quantitative fecal immunochemical testing (FIT) results to diagnose advanced colorectal neoplasia in patients undergoing surveillance colonoscopy.

METHODS: We classified patients by previous colonoscopy findings as having low, intermediate, or high risk polyps. We compared the diagnostic performance for detecting advanced colorectal neoplasia at an optimal cutoff identified by the Youden index vs the standard cutoff of 100 ng/mL. We also estimated cumulative sensitivity and specificity for serial FIT testing in patients with nonadvanced findings.

RESULTS: Among the 449 participants (mean $\pm$ SD age 65.4 ± 7.1 , 53.2% women, and 92.7% White), the median interval between colonoscopies was 5.0 years (IQR 3.5, 5.6); adequate or better bowel prep was achieved in 89.3%, and cecal intubation in 98.4%. We detected 55 advanced precancerous lesions, but no cancers. For patients with previous nonadvanced lesions ($n = 378$), the optimal cutoff was 26 ng/mL. Compared with the standard cutoff, the optimal cutoff increased sensitivity (14.3%–35.7%, $P < 0.01$) but reduced specificity (95.5%–79.2%, $P < 0.01$). Estimated cumulative sensitivity across 3 rounds of FIT testing was 73.4% at the optimal cutoff vs 37.1% with the standard cutoff.

DISCUSSION: Lowering the FIT hemoglobin cutoff markedly improved sensitivity for detecting advanced precancerous lesions in patients without previous advanced polyps. Serial testing could further enhance detection. FIT-based surveillance should be further evaluated as a potential strategy to prioritize, delay, or replace colonoscopy.

KEYWORDS: sensitivity and specificity; colorectal neoplasms; surveillance; fecal immunochemical test; colonoscopy

ABBREVIATIONS: ACN, Advanced colorectal neoplasia; APL, Advanced precancerous lesions; BMI, Body mass index; COOP, Colonoscopy vs. Stool Testing in Older Persons; FDA, Food and Drug Administration; FIT, Fecal immunochemical testing; g, Gram; Hb, Hemoglobin; mL, Milliliter; ng, Nanogram; OC, Occult blood; QR, Interquartile range; ROC, Receiver-operating characteristic; SD, Standard deviation; USMSTF, United States Multi-Society Task Force

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INTRODUCTION

The US Multi-Society Task Force (USMSTF) recommends colonoscopy as the preferred surveillance strategy after polypectomy (1). The surveillance interval depends on the histology, size, and number of polyps found on the previous colonoscopy.

However, the USMSTF noted the limited evidence demonstrating that polypectomy reduces the risk of incident and fatal colorectal cancer, particularly in the absence of high-risk features. Accordingly, the guideline now recommends longer surveillance intervals for individuals with lower risk polyps.

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By contrast, gastrointestinal guidelines from Canadian, British, and European societies, citing low to moderate quality observational evidence, recommend surveillance with a fecal immunochemical test (FIT) rather than colonoscopy after removal of low-risk adenomas (2–4). We are not aware of US observational studies evaluating the diagnostic performance of FIT testing for postpolypectomy surveillance. The Patient-Centered Outcomes Research Institute is funding the COOP trial (Colonoscopy vs Stool Testing in Older Patients with Colon Polyps) to investigate this strategy (5). The COOP trial is randomizing individuals whose most recent colonoscopy found ≤ 2 non-advanced polyps to surveillance with annual qualitative FIT testing or a one-time colonoscopy. The primary end point is the incidence of advanced colorectal neoplasia (ACN).

While awaiting results from the COOP trial, applying diagnostic performance data from observational FIT surveillance studies to US practice is challenging. Studies have either combined patients with previous polyps and personal and/or family history of colorectal cancer, did not report characteristics of the previous polyps, did not stratify diagnostic accuracy by polyp risk group, did not report diagnostic performance data, and/or included only intermediate-risk patients (6–17). The multicenter BestFIT study prospectively evaluated the diagnostic accuracy of 5 FIT tests for detecting ACN among patients undergoing scheduled elective colonoscopy (18). A substantial proportion of patients were undergoing surveillance procedures, and one of the studied FIT tests provided quantitative data. Consequently, we conducted a secondary exploratory analysis of study data to evaluate the diagnostic accuracy of quantitative FIT results for detecting ACN at a surveillance colonoscopy.

METHODS

BestFIT was a prospective, double-blinded study, comparing the diagnostic performance of 5 FITs using a reference standard of colonoscopy and histology reports (18,19). The study was conducted from 2017 to 2022 at 3 academic medical centers: the University of Iowa, University of North Carolina at Chapel Hill, and Texas Tech University Health Sciences Center El Paso. Investigators identified participants with upcoming elective screening or surveillance colonoscopies by medical record review. Consented participants completed FITs before starting their colonoscopy preparation. Colonoscopies were performed or supervised by board-certified gastroenterologists who categorized procedures as screening or surveillance examinations. The qualitative occult blood (OC)-Auto FIT (Polymedco Inc., Cortland Manor, NY) was run in the University of Iowa Hospitals and Clinics' Clinical Laboratory Improvement Amendment (CLIA)-certified clinical pathology laboratory. However, we analyzed quantitative results for the OC-Auto FIT tests for research purposes. This analysis is based on data from the consecutively enrolled Iowa Best-FIT participants with referrals for surveillance colonoscopy documented in the electronic medical record. We did not have access to previous colonoscopy reports for the other 2 study sites.

We used structured forms to abstract data from the surveillance colonoscopy, the most recent previous colonoscopy, and pathology reports. Colonoscopy data included procedure date; number, location, and size of any colon polyps; bowel preparation quality; procedure complications; cecal intubation; and scope withdrawal time. Pathology data included biopsy site, histology, number of polyps, polyp size, and morphology (18,19). We

classified risk among individuals referred for surveillance procedures based on findings from their most recent previous colonoscopy. We defined low risk if there were ≤ 2 small (<1 cm) polyps, intermediate risk if there were > 2 and < 10 small polyps, and high risk if there were advanced precancerous lesions (APL): adenomatous polyps or sessile serrated lesions (SSLs) ≥ 1 cm, tubulovillous or villous adenomas, traditional serrated adenomas of any size, or any lesion with high-grade dysplasia. We did not enroll patients with a previous colorectal cancer. For the surveillance procedures, we classified high-risk findings as APL, carcinoma-in-situ, or adenocarcinoma. When multiple polyps were identified, the most advanced lesion was considered the primary lesion to characterize findings.

Statistical analysis

We used standard descriptive statistics to summarize data and t-tests and χ^2 tests to compare participants with and without previous colonoscopy data. Diagnostic accuracy was evaluated according to the Standards for Reporting of Diagnostic Accuracy Studies guideline (20). We calculated test sensitivities based on the presence of an ACN whereas specificities were determined based on the absence of an ACN. We reported both values along with their exact binomial 95% confidence intervals (CIs).

The optimal cutoff point was determined using the Youden Index, defined as the value that maximizes the sum of sensitivity and specificity minus 100 (21). This corresponds to the point on the receiver operating characteristic (ROC) curve that is farthest above the diagonal line, indicating the best trade-off between sensitivity and specificity. We used the McNemar Test to compare the sensitivities and specificities for the standard and optimal cutoff points. We used standard formulas to calculate positive and negative predictive values for the standard cutoff point and the identified optimal cutoff point.

Given that multiple rounds of surveillance FIT testing would be recommended, we also evaluated the potential benefit of repeated testing by estimating cumulative sensitivity and specificity through 3 rounds of testing. These estimates assume independent and unbiased detection with each testing round and no disease progression. Cumulative sensitivity is calculated by the formula: sensitivity (x) = $1 - (1 - \text{sensitivity})^x$, where x represents the number of FIT rounds. Cumulative specificity is calculated by the formula specificity (x) = $(\text{specificity})^x$ (13,22).

All statistical analyses were performed using SAS, version 9.4 (SAS Institute).

Role of the funding source

The BestFIT study was funded by the National Institutes of Health, which had no role in the design, conduct, or analysis of the surveillance study or the decision to submit the manuscript for publication.

Human subjects protection

This study and the BestFIT study were approved by the University of Iowa Institutional Review Board.

RESULTS

The University of Iowa enrolled 1,489 individuals to the BestFIT study (19). Among these participants, 514 underwent surveillance colonoscopy and the rest underwent screening colonoscopy (Figure 1). We were able to abstract previous colonoscopy data for 449 surveillance participants (87.4%). Overall, 313 (69.7%) had

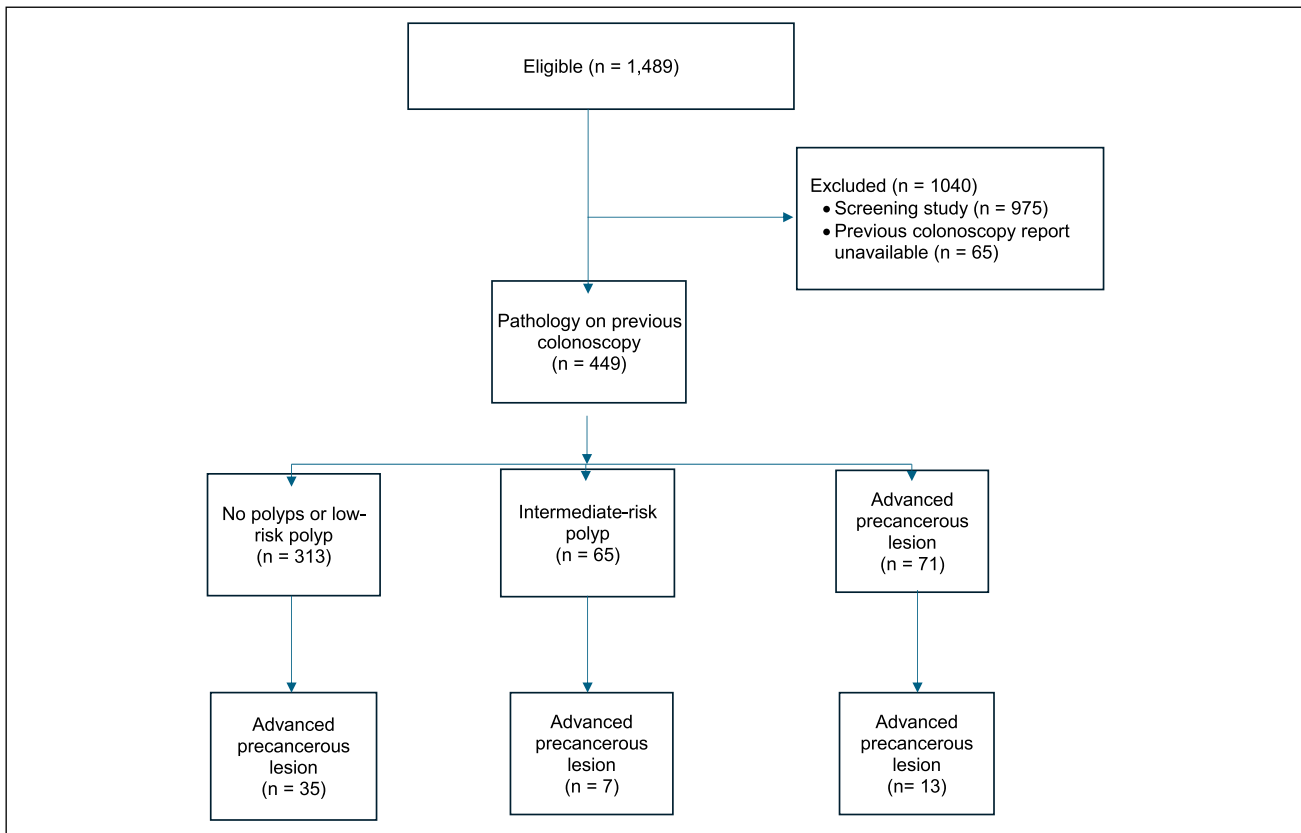


Figure 1. Study flow diagram.

low-risk adenomas or no findings on the previous colonoscopy, 65 (14.5%) had intermediate-risk adenomas, and 71 (15.8%) had an APL. Table 1 displays characteristics of participants with and without previous colonoscopy data. The mean ($\pm$ SD) age of those with colonoscopy data was 65.4 ($\pm$ 7.1) years, 53.2% were women, 2.9% were Black, 92.7% were White, and 1.3% were Hispanic. Seventy-seven percent had a college education or higher and 47.9% had an annual household income of $\geq$ \$80,000. There were no statistically significant differences between those with and without previous colonoscopy data.

Table 2 shows FIT hemoglobin levels and details of the surveillance colonoscopy stratified by risk categories from the previous colonoscopy. No FIT tests were unevaluable. The median (IQR) interval between FIT collection and colonoscopy was 11 (5–25) days. The median interval (IQR) between the most recent previous colonoscopy and the 449 surveillance colonoscopies was 5.0 (3.5, 5.6) years. For the 92 participants with a previous negative colonoscopy, the median interval (IQR) between procedures was 5.2 (4.9–5.8) years. Overall, 89.3% of the surveillance colonoscopies were described by the endoscopist as having an adequate/good/excellent bowel prep and cecal intubation was achieved in 98.4%. There were no complications related to the surveillance colonoscopy during or within one month of the procedure. An ACN was detected in 55 (12.3%) participants, although no cancers were found. Among the 71 participants with a previous APL, 13 (18.3%) had an ACN on the surveillance colonoscopy compared with only 42 of the 378 (11.1%) participants with no previous APL; however, the difference was not significant, $P = 0.09$.

The sample size was too small to estimate an optimal cutoff for participants whose previous colonoscopy showed only an intermediate-risk polyp. We calculated the Youden Index based on participants with previous low-risk findings and the combined cohort of patients with previous low-risk and intermediate-risk findings. We created the combined cohort to increase sample size and enable comparisons with previous studies that did not further characterize nonadvanced polyps. We identified a value of 26 ng/mL of hemoglobin (Hb) in buffer as the optimal cutoff. Table 3 shows the performance characteristics for the standard 100 ng/mL cutoff and the 26 ng/mL cutoff for participants with previous low-risk and low/intermediate-risk findings and the 100 ng/mL cutoff for the participants with either intermediate-risk or high-risk findings on the previous colonoscopy.

In the cohort with low-risk or intermediate-risk findings on the previous colonoscopy, the lower cutoff significantly increased the sensitivity for ACN (14.3%–35.7%, $P = 0.003$) and significantly decreased the specificity (95.5%–79.2%, $P < 0.001$). Lowering the cutoff was associated with a 0.9 percentage point increase in the negative predictive value, from 89.9% to 90.8%. The 100 ng/mL cutoff for the high-risk participants was associated with a sensitivity of just 15.4% and a negative predictive value of 83.6%.

Figure 2 displays the ROC curve for participants characterized as low/intermediate risk based on the previous colonoscopy. The ROC curve shows the point estimates for the 100 ng/mL and 26 ng/mL cutoffs (the associated diagnostic performance characteristics are shown in Table 3). Among participants in the combined low/intermediate-risk group, the area under the

Table 1. Characteristics of surveillance colonoscopy cohorts with and without previous colonoscopy data

Participant characteristic	Cohort with previous colonoscopy data (n = 449) n (%) or mean ($\pm$ SD)	Cohort without previous colonoscopy data (n = 65) n (%) or mean ($\pm$ SD)	P-value
Age (yr)	65.4 ($\pm$ 7.1)	66.6 ($\pm$ 6.7)	0.63
Age group (yr)			0.35
50–64	214 (47.6)	25 (38.5)	
65–74	188 (41.9)	33 (50.8)	
$\geq$ 75	47 (10.5)	7 (10.8)	
Sex			0.31
Female	239 (53.2)	39 (60.0)	
Male	210 (46.8)	26 (40.0)	
Race ^a			0.53
White	416 (92.7)	64 (98.5)	
Black	13 (2.9)	0	
Asian	6 (1.3)	1 (1.5)	
Native American	1 (0.2)	0	
More than one race	6 (1.3)	0	
Unknown	7 (1.6)	0	
Ethnicity ^a			0.44
Hispanic	6 (1.3)	0	
Education			0.30
8th grade or less	3 (0.7)	0	
High school	97 (21.6)	17 (26.2)	
College or higher	348 (77.5)	41 (72.3)	
Not reported	1 (0.2)	1 (1.5)	
Income			0.18
<\$40,000	92 (20.5)	13 (20.0)	
\$40,000 to < \$80,000	124 (27.6)	26 (40.0)	
$\geq$ \$80,000	215 (47.9)	23 (35.4)	
Not reported	18 (4.0)	3 (4.6)	
BMI (kg/m ²)	29.2 ($\pm$ 6.3)	28.5 ($\pm$ 6.0)	0.64
BMI category (kg/m ²)			0.50
Underweight (<18.5)	5 (1.1)	1 (1.5)	
Healthy weight (18.5–24.9)	112 (24.9)	22 (33.9)	
Overweight (25–29.9)	167 (37.2)	18 (27.7)	
Obese ($\geq$ 30)	164 (36.5)	24 (36.9)	
Smoker			0.36
Current smoker	29 (6.5)	4 (6.1)	
Former smoker	145 (32.3)	28 (43.1)	
Never been a smoker	273 (60.8)	33 (50.8)	
Previous colonoscopy result			
Low-risk or no polyp	313 (69.7)	—	
Intermediate-risk polyp	65 (14.5)	—	
APL	71 (15.8)	—	

APL, advanced precancerous lesion; BMI, body mass index.
^aSelf-reported by participants.

Table 2. Surveillance fecal immunochemical testing test and colonoscopy results stratified by risk classification based on most recent previous colonoscopy

Surveillance colonoscopy	Low risk ^a (n = 313)	Intermediate risk ^b (n = 65)	Advanced precancerous lesion ^c (n = 71)
Age at surveillance, yr (mean ± SD)	65.6 ± 7.0	64.1 ± 7.6	65.6 ± 7.1
Colonoscopies interval, yr (mean ± SD)	5.3 ± 1.6	4.0 ± 1.5	4.0 ± 1.6
Adequate/good/excellent bowel prep (n, %)	282 (90.1)	59 (90.8)	60 (84.5)
Cecal intubation (n, %)	309 (98.7)	63 (96.9)	70 (98.6)
OC-Auto FIT results (ng/mL) (median, IQR)	2.0, 0–20.0	7.0, 0–43.0	1.0, 0–13.0
Colonoscopy findings (n, [%])			
Adenocarcinoma	0	0	0
Advanced precancerous lesion	35 (11.2)	7 (10.8)	13 (18.3)
Low-risk or intermediate-risk polyp	143 (45.7)	30 (46.2)	29 (40.9)
Non-neoplastic findings ^d	56 (17.9)	9 (13.8)	12 (16.9)
Negative	79 (25.2)	19 (29.2)	16 (22.5)

^a≤2 tubular adenomas and no polyp size ≥10 mm, no dysplasia, no villous histology, no sessile serrated lesions.

^b>2 and <10 tubular adenomas; sessile serrated adenoma < 10 mm.

^cAdenomatous or sessile serrated lesions ≥10 mm; tubulovillous or villous adenoma; traditional serrated adenoma of any size; any lesion with high-grade dysplasia.

^dIncludes hyperplastic polyps, lymphoid aggregate, polypoid colonic mucosa, no diagnostic abnormality, and other.

receiver operating characteristic curve (AUC) was 0.57 (95% CI, 0.48–0.66) whereas in the low-risk group alone, the AUC was 0.60 (95% CI, 0.50–0.70).

Table 4 shows the estimated cumulative diagnostic performances among low/intermediate risk participants for detecting ACN with repeated testing for the manufacturer's hemoglobin cutoff of 100 ng/mL and the 26 ng/mL cutoff based on the Youden Index. We estimated diagnostic performance for 100% and 50% adherence with repeat testing in years 2 and 3. Surveillance FIT tests through 3 rounds of testing would achieve much higher sensitivities compared with 1-time testing with greater changes seen with the lower cutoff, even at 50% adherence during rounds 2 and 3. Specificity would decrease substantially, particularly for the lower cutoff.

DISCUSSION

We used quantitative data from the OC-Auto FIT to evaluate ACN detection among patients undergoing surveillance colonoscopies. For the cohort with low-risk or intermediate-risk findings on the most recent previous colonoscopy, we found that using a derived lower cutoff of 26 ng/mL would both significantly increase sensitivity (14.3%–35.7%) and decrease the positive predictive value (28.6%–17.7%) for detecting ACN compared with the US FDA-approved 100 ng/mL cutoff. The lower cutoff decreased specificity (95.5%–79.2%), although negative predictive values remained similar, approximately 90%. One-time testing had poor discriminant value for detecting ACN, with an AUC of 0.57. However, we estimated that serial testing using the lower cutoff could markedly improve the cumulative

Table 3. OC-Auto FIT performance characteristics for advanced colorectal neoplasia at > 100 ng/mL and > 26 ng/mL cutoffs by risk classification based on most recent previous colonoscopy

Test characteristic	Low-risk polyp N = 313		Intermediate-risk polyp N = 65	Low/intermediate-risk polyp N = 378		APL N = 71
	Positive at > 100 ng/mL	Positive at > 26 ng/mL	Positive at > 100 ng/mL	Positive at > 100 ng/mL	Positive at > 26 ng/mL	Positive at > 100 ng/mL
Positivity rate n (%)	15 (4.8)	65 (20.8)	6 (9.2)	21 (5.6)	85 (22.5)	4 (5.6)
Sensitivity % (95% CI)	14.3 (4.8–30.3)	40.0 (23.9–57.9)	14.3 (0.4–57.9)	14.3 (5.4–28.5)	35.7 (21.6–52.0)	15.4 (1.9–45.5)
Specificity % (95% CI)	96.4 (93.5–98.3)	81.7 (76.6–86.0)	91.4 (81.0–97.1)	95.5 (92.7–97.5)	79.2 (74.4–83.4)	96.6 (88.1–99.6)
PPV % (95% CI)	33.3 (11.8–61.6)	21.5 (12.3–33.5)	16.7 (0.4–64.1)	28.6 (11.3–52.2)	17.7 (10.2–27.4)	50.0 (6.8–93.2)
NPV % (95% CI)	89.9 (85.9–93.1)	91.5 (87.4–94.7)	89.8 (79.2–96.2)	89.9 (86.3–92.8)	90.8 (86.9–93.8)	83.6 (72.5–91.5)

APL, advanced precancerous lesion; NPV, negative predictive value; PPV, positive predictive value.

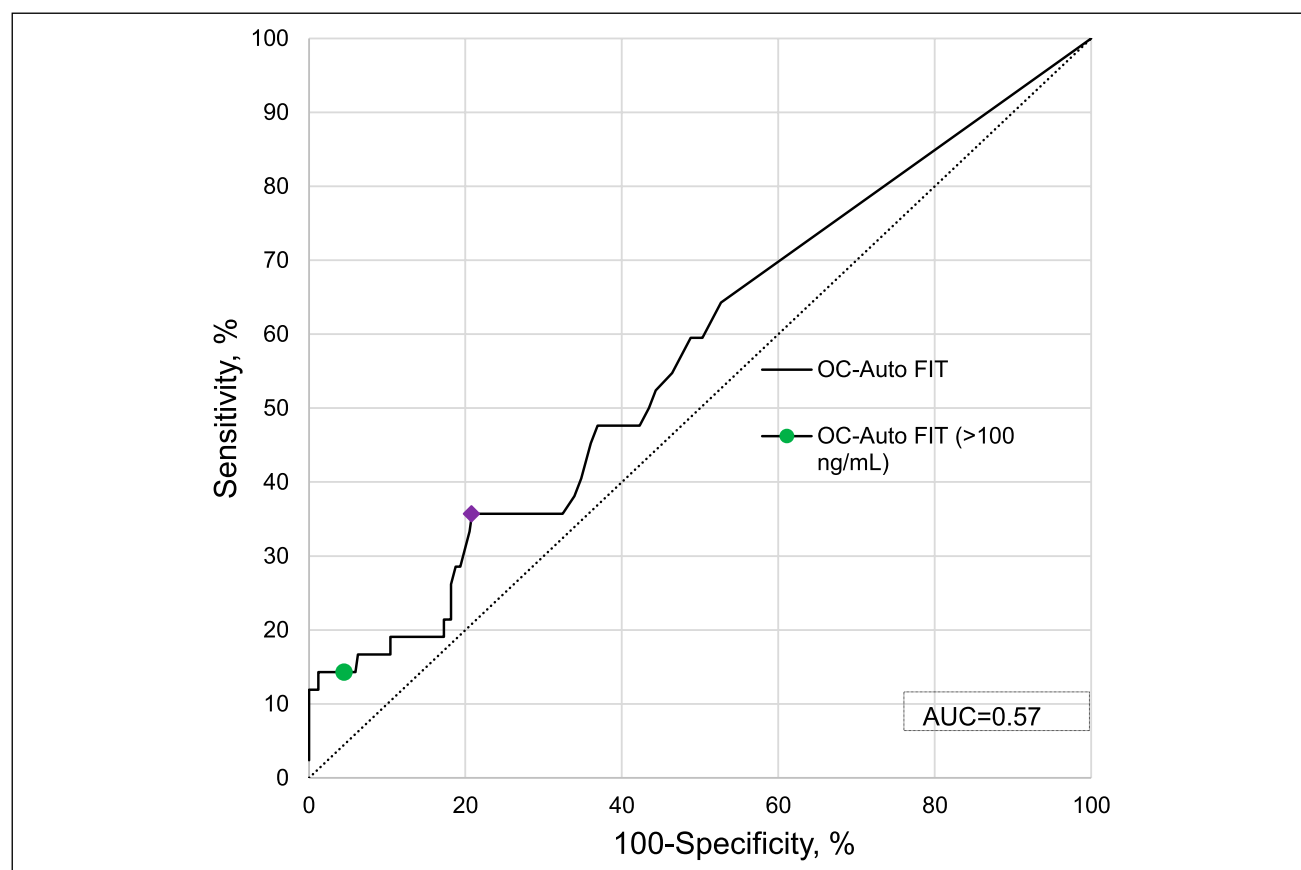


Figure 2. Receiver operating characteristic curve of OC-auto for detecting advance precancerous lesions on surveillance colonoscopy, showing manufacturer's cutoff and optimal cutoff determined from study data. Low/intermediate-risk cohort (N = 378). AUC, area under the receiver operating characteristic curve; FIT, fecal immunochemical testing.

sensitivity compared with the standard cutoff. The estimated cumulative specificity would substantially decrease with repeat testing.

Our findings agreed with other cross-sectional studies evaluating the diagnostic performance of postpolypectomy FIT for detecting ACN (6,7,9,13). These studies found ACN in 8%–14% of patients. A Dutch study reported that the FIT OC-Sensor had an AUC of 0.61 for detecting advanced neoplasia in a cohort of individuals with a history of colorectal neoplasia or familial risk (7). FITs with low cutoffs (10 μ g Hb/g feces [approximately 50 ng/mL of Hb in buffer]) achieved sensitivities ranging from 28% to

35% and specificities ranging from 81% to 89% (6,7,13). Two studies evaluated a cutoff of 2 μ g Hb/g feces (the limit of detection) and reported sensitivities ranging from 74% to 83% and specificities ranging from 41% to 59% (6,9). Although we did not detect any colorectal cancers, other studies reported higher (50%–80%) sensitivity for cancer, but estimates were imprecise because few cancers were diagnosed (<0.4%). No studies reported diagnostic performance for low-risk surveillance cohorts. Studies comparing FIT cutoffs consistently reported greater ACN sensitivity with lower detection cutoff values (6,8,9). Although cross-sectional data show limited sensitivity for ACN, the key

Table 4. Projected cumulative diagnostic performance of surveillance FIT testing for detecting advanced precancerous lesions over 3 sequential rounds stratified by hemoglobin cutoff and adherence with repeat testing^a

Testing rounds	OC-Auto FIT cutoff $\geq$ 100 ng/mL				OC-Auto FIT cutoff $\geq$ 26 ng/mL			
	100% adherence in yr 2 and 3		50% adherence in yr 2 and 3		100% adherence in yr 2 and 3		50% adherence in yr 2 and 3	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
1	14.3	95.5	14.3	95.5	35.7	79.2	35.7	79.2
2	26.6	91.2	20.4	93.4	58.7	62.7	47.2	70.9
3	37.1	87.1	26.0	91.2	73.4	49.7	56.6	63.6

FIT, fecal immunochemical test; OC, occult blood.

^aCalculations assume that tests are assumed to be independent and that disease did not progress.

diagnostic performance statistic is cumulative sensitivity which better reflects the risk of missing an ACN with programmatic FIT surveillance. A second Dutch study of high-risk patients, using cross-sectional data to calculate cumulative sensitivity (with the formulae and assumptions that we used), estimated a FIT sensitivity for ACN of 81% with 5 rounds of testing (13). More importantly, a prospective study in the United Kingdom, which evaluated programmatic interval FIT testing within colonoscopy surveillance protocols, found that sensitivity for ACN, using a 10 μg Hb/g feces threshold, increased from 33.0% at the first round of testing to a cumulative 58.7% over 3 rounds of testing. (8) A higher threshold (40 μg Hb/g feces) was associated with only a 35.0% cumulative sensitivity. A retrospective Australian study of interval surveillance FIT (20 μg Hb/g feces) in patients undergoing surveillance colonoscopy found that the ACN incidence decreased from 11.1% after one negative FIT to 5.7% after 4 negative FIT (23). While lowering the cutoff and serial testing increases test sensitivity, this has to be weighed against the decreased specificity leading to more diagnostic colonoscopies. However, given the current US recommendation for surveillance colonoscopies after polypectomy, FIT strategies could potentially substantially reduce the number of colonoscopies (7,8,24). A meta-analysis of FIT performance in individuals with a personal or family history of colorectal cancer concluded that FIT cutoffs between 15 and 25 μg Hb/g feces provided the best combination of sensitivity and specificity for diagnosing colorectal cancer (25).

Based on the observational United Kingdom data (8), a Health Technology Assessment performed for the National Institute for Health Research concluded that annual low-threshold (10 μg Hb/g feces) FIT surveillance of intermediate-risk patients post polypectomy would have a cumulative sensitivity of 84.6% for colorectal cancer and be cost saving compared with surveillance colonoscopy (24). By contrast, using a higher threshold (μg Hb/g feces) would substantially reduce sensitivity for colorectal cancer. The analysis excluded patients with ≤ 2 small adenomas and defined intermediate as 3 or 4 adenomas < 1 cm or at least ≥ 1 adenoma ≥ 1 cm. This definition does not directly align with our study because we classified patients with a polyp ≥ 1 cm as having an APL and classified patients with up to 9 small polyps as intermediate risk.

In clinical practice, the most recent surveillance intervals recommended by the USMSTF after detection of a low-risk adenoma have been increased (1). Guideline authors supported these changes by noting the uncertain impact of surveillance colonoscopy on colorectal cancer incidence or mortality after removal of low-risk adenomas. As shown by calculations simulating multiple rounds of testing and prospective cohort studies (7,8,13,23), repeating quantitative FIT tests annually or semi-annually could improve test sensitivity. Although the accuracy will be less than seen with colonoscopy, patients may consider being able to complete a home FIT test to be an acceptable trade off. This could lower health costs associated with colorectal cancer screening and minimize patient inconvenience and procedural risks, particularly for older patients (26). However, physicians need to realize that individual FIT tests have variable diagnostic performances (18). In addition, none of the tests currently used in the United States provides a quantitative result for hemoglobin, although the OC-Auto FIT can be set up to give a quantitative reading.

Studies have shown that adherence with initial and even one-time repeat stool testing can be low (27,28); however, patients

may be more motivated to complete stool tests to avoid or delay undergoing colonoscopy. We estimated a substantially increased sensitivity for detecting ACN through 3 rounds of screening, even assuming only 50% adherence. The United Kingdom prospective surveillance study reported FIT adherence of 74% with the initial test round and 97% for subsequent rounds (8). Several qualitative studies found that most participants in FIT surveillance programs would be comfortable completing a surveillance FIT every 2 years or less to supplement surveillance colonoscopy schedule at 3–5 years intervals; they were less likely to prefer a strategy of undergoing colonoscopy only if the FIT test was positive or undergoing colonoscopy without FIT (14,24,29,30). However, studies included participants with either a previous intermediate-risk or unspecified-risk adenoma, so results may be less applicable for patients with low-risk adenomas.

Patients will need to be informed about the potential risk of missing a cancer by using a less sensitive surveillance test. Fortunately, that risk seems to be low. A meta-analysis of 12 studies with 510,019 patients who underwent a baseline colonoscopy estimated that the incidence of colorectal cancer was 4.5 per 10,000 person-years among those with a low-risk adenoma and colorectal cancer mortality was 0.78 per 10,000 person-years (31). Although the incidence was slightly higher in the low-risk participants compared with the no-adenoma group (OR 1.26, 95% CI 1.06–1.51), the mortality was similar (OR 1.15, 95% CI 0.76–1.74). Compared with the no-adenoma group, however, those with a high-risk adenoma had significantly increased risks of incident colorectal cancer (OR 2.92, 95% CI 2.31–3.69) and colorectal cancer mortality (OR 2.69, 95% CI 1.87–3.87). Our diagnostic performance data would not support using FIT surveillance after detection of an ACN.

Our study had limitations. These exploratory results are from only one academic medical center with a largely White and socioeconomically advantaged population and would need to be confirmed in other settings. Quantitative FIT values are not currently available in clinical practice in the United States, and an optimal threshold for surveillance stool testing would need to be determined. Furthermore, the sample size was small, and none of the participants had a colorectal cancer found on surveillance colonoscopy. We included patients who were referred for surveillance colonoscopy even when the most recent previous colonoscopy was negative. However, these patients were being referred at a median 5-year interval consistent with their colonoscopy being a surveillance procedure and that they were representative of a low-risk population. Strengths of the study included using quantitative FIT data, having high-quality diagnostic colonoscopies performed by endoscopists blinded to the FIT result, and comprehensive medical record data on polyp characteristics from the most recent previous colonoscopy and the surveillance procedure.

Our study adds to the limited data on FIT surveillance in postpolypectomy patients by providing diagnostic performance data stratified by polyp risk category. We showed that lowering the hemoglobin detection cutoff for the OC-Auto FIT test markedly improved the sensitivity for detecting APL in patients undergoing surveillance colonoscopy after a previous colonoscopy with low/intermediate-risk findings. We estimated that serial testing in this population would further increase sensitivity. Although specificity would concomitantly decrease, a substantial proportion of surveillance patients could still avoid undergoing colonoscopy. Given the low risk of colorectal cancer incidence and mortality after removal of a low/intermediate-risk polyp, our

results suggest that serial quantitative FIT testing calibrated to a lower hemoglobin threshold might be an acceptable strategy to prioritize, delay, or replace surveillance colonoscopy. FIT testing would also be a less expensive strategy, given its estimated median total costs of \$20 compared with nearly \$1,800 for colonoscopy (32). The ongoing Patient-Centered Outcomes Research Institute COOP trial will provide more definitive evidence about the benefits and harms of surveillance FIT testing after polypectomy for nonadvanced polyps (5). The trial, which is enrolling nearly 9,000 adults aged 65–82 years, is scheduled for completion in 2029.

CONFLICTS OF INTEREST

Guarantor of the article: Barcey T. Levy, MD, PhD.

Specific author contributions: Planning and/or conducting the study: B.T.L., Y.X., S.D.C., J.M.D., R.M.H. Collecting and/or interpreting the data: B.T.L., J.M.D., Y.X., R.M.H. Drafting the manuscript: R.M.H., Y.X., S.D.C., J.M.D., G.D.C., B.T.L. All authors have approved of the final draft submitted.

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Potential competing interests: None to report.

The study's clinical trial registration number is NCT03264898 [https://clinicaltrials.gov/study/NCT03264898?](https://clinicaltrials.gov/study/NCT03264898?term=BEstFIT&rank=3) term=BEstFIT&rank=3.

Study Highlights

WHAT IS KNOWN

- ✓ US guidelines recommend surveillance colonoscopy at various intervals after removal of any adenomatous or sessile serrated polyps.
- ✓ The risk of cancer incidence and mortality after removal of low-risk polyps is very low.

WHAT IS NEW HERE

- ✓ Lowering the FIT hemoglobin threshold improves sensitivity for advanced precancerous lesions in a cohort with previous nonadvanced polyps.
- ✓ Serial FIT testing potentially could increase sensitivity for detecting advanced precancerous lesions with a concomitant decrease in specificity.

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