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Effectiveness of Complete Diagnostic Examination in Clinical Practice Settings

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Abstract

Background—Thorough follow-up of a positive fecal occult blood test (FOBT) result, or a complete diagnostic evaluation (CDE), is recommended as routine care on the basis of findings from colorectal cancer (CRC) screening trials. CDE involves either colonoscopy or the combination of flexible sigmoidoscopy and double contrast barium enema x-ray. However, little evidence outside clinical screening trial settings has been reported in the literature to support CDE performance. The focus of this study was to determine the impact of CDE in primary care practice settings.

Methods—We determined diagnostic outcomes for 461 adult patients with a positive FOBT result in 318 primary care practices in southeastern Pennsylvania and southern New Jersey. Sociodemographic data were collected and CDE status was ascertained for these patients. Polytomous logistic regression models were used to identify whether having CDE was associated with subsequently being diagnosed with lower gastrointestinal “neoplastic disease” or “other gastrointestinal disease” as compared to “normal findings.”

Results—Patients who underwent CDE were significantly more likely to have a reported diagnosis of colorectal neoplasia than normal findings (adjusted odds ratio = 3.65, 95% confidence interval = 1.58–8.39, $p=0.02$). CDE performance did not result in the differential diagnosis of other gastrointestinal disease.

Conclusions—Patients with a positive screening FOBT who underwent CDE were more likely to be diagnosed with colorectal neoplasia than with less serious conditions or have normal findings. Results support the use of CDE in CRC screening.

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Keywords

Colorectal neoplasm; occult blood; fecal occult blood test; mass screening; cancer screening; follow-up studies; complete diagnostic evaluation; abnormal findings; chart audit; diagnosis

INTRODUCTION

Annual fecal occult blood test (FOBT) screening is endorsed by the major medical organizations, including the American Cancer Society and U.S. Preventive Services Task Force, as an important colorectal cancer (CRC) screening strategy [1,2]. Previous large, randomized controlled trials have shown that FOBT screening can significantly lower colorectal cancer incidence and mortality [3,4,5]. In these trials, over 80% of patients with positive FOBT results [FOBT (+)] underwent appropriate diagnostic evaluation, referred to as complete diagnostic evaluation (CDE). CDE consists of either colonoscopy or the combination of flexible sigmoidoscopy and double contrast barium enema x-ray. Use of other procedures (e.g., flexible sigmoidoscopy alone, barium enema x-ray alone, repeat FOBT) is not considered to be adequate follow up.

Surprisingly, however, CDE rates are low in clinical practice. Recent studies have shown CDE rates ranging from 39 to 59% [6-11]. As a result, it may be the case that many opportunities to diagnose early CRC and colorectal polyps are being missed. Evidence from primary care practice settings to support this assumption is sparse; however, the study presented here addresses the need for information in this area.

We obtained data on CDE performance from a randomized trial designed to evaluate the impact of a physician intervention (i.e., CDE reminder-feedback and educational outreach) on CDE recommendation and performance rates in primary care practices. For patients with an FOBT (+) result who underwent CDE [CDE(+)] and those with an FOBT(-) result who did not undergo CDE [CDE(-)], we determined frequency of occurrence for the three diagnostic outcomes: colorectal neoplastic diseases, non-neoplastic gastrointestinal diseases, and normal findings. The purpose of the study was to determine if FOBT (+) patients who undergo CDE have higher rates of neoplasia detected than patients who do not have CDE.

MATERIALS and METHODS

In the late 1990's, a research team from Thomas Jefferson University initiated a randomized trial funded by the National Cancer Institute to evaluate the impact of a physician-oriented intervention on CDE recommendation and performance rates in primary care practices [12]. In this study, 318 primary care practices in southeastern Pennsylvania and southern New Jersey were randomly assigned either to a Control Group (N=198) or an Intervention Group (N=120). Practice *administrative arrangement* (e.g., solo versus group practice, practice geographic location, and participation in an integrated delivery system) and *physician background and experience* (e.g., age, gender, race/ethnicity, specialty, board certification status, median years in medical practice, number of newly diagnosed CRC and polyp patients seen in prior year, and percent of CRC and polyp patients diagnosed by FOBT screening) are shown in Table IA, Table IB.

Patients in Control Group and Intervention Group practices who were 50 or more years of age routinely received a standard CRC screening program sponsored by a managed care organization (MCO). In the screening program, MCO subscribers aged 50 years and over were mailed an annual FOBT kit, which contained an introductory letter, information about colorectal cancer, three Hemoccult II FOBT slides with instructions, and a postage-paid return envelope. Printed instructions regarding diet and medication restrictions during the test period

were also provided. FOBT cards were returned directly to Thomas Jefferson University Hospital Clinical Laboratory for analysis. The laboratory notified the patient and the patient's primary care practice of the test results. Physicians in Intervention Group practices also received CDE reminder-feedback plus educational outreach. This included reminder notes to physicians on patients with FOBT (+) results, CDE feedback reports, in-office education, and follow-up letter and phone calls. The study was approved by the institutional review board (IRB) at Thomas Jefferson University. Written consent for participation was obtained from physicians involved in the study in accordance to the directions provided by the IRB.

From January 1999 through January 2000, the screening program central laboratory identified 1508 FOBT (+) patients in study practices identified via the MCO screening program. Of this number, 920 (61%) were men and 588 (39%) were women. The study research team requested follow-up information on FOBT (+) patients by sending patient-specific internal chart audit (ICA) forms to the individual's primary care practice. For each FOBT (+) patient, the ICA form asked for information on procedures that were recommended and performed within 180 days after the FOBT (+) result date. The 180-day time frame was viewed as adequate for the completion of initial follow-up procedures. The ICA forms were sent to Intervention Group practices during the study, as these mailings were part of the reminder-feedback component of the study intervention. The forms were sent to Control Group practices in the final year of the study. It is possible that this study design feature may have resulted in differential diagnosis between study groups. However, such an artifact would have had little influence, if any, on the reporting of diagnostic outcomes for patients with CDE.

Practice physicians were asked to report follow-up procedures recommended, reasons that CDE was not recommended in cases where such a recommendation was not made, and diagnostic results for patients who were followed up (with CDE and non-CDE procedures) during the defined 180-day timeframe. If a follow-up procedure had been performed, the procedure date was requested. Space was provided on the form to allow the physician to explain why CDE was not advised or not performed. Physicians were able to check off any of 10 items on the chart audit form for the diagnostic outcome: colon cancer, rectal cancer, polyp, diverticulosis, diverticulitis, peptic ulcer disease, arteriovenous malformation, hemorrhoids, no pathology, or other. For the "other" category, we asked the responding physician to provide details. Completed ICA forms were returned to the study central office. More complete data on patient diagnostic outcomes may have been reported for Control Group practice patients due to the fact that by design those practices received the ICA forms later than Intervention Group practices.

As presented elsewhere, decision rules were developed to determine patient eligibility for CDE [13]. Reasons that a patient was deemed ineligible for CDE included the following: patient was deceased before CDE could be recommended, patient left the practice before CDE could be recommended, patient was unknown to the practice, patient's medical condition contraindicated CDE, or patient had CDE performed within three years prior to the FOBT (+) result. Patients determined to be ineligible for CDE were excluded from further analysis.

For patients considered eligible for CDE, the research team reviewed ICA forms and MCO administrative claims data on CDE performance. By combining data from the ICA forms and administrative claims, determined CDE recommendation and performance status for each patient were determined. This method for measuring CDE recommendation and performance is highly sensitive and specific (≥ 0.90) compared with the "gold standard" for assessing CDE rates (i.e., external chart audit and ADR) [13]. Diagnostic outcomes for each patient were determined solely on the basis of ICA data.

For patients with and without CDE, we grouped reported diagnostic outcomes into the following categories: “Neoplastic Diseases” (which consisted of colorectal cancer and polyps), “Other Diagnoses,” “Normal Findings,” and “No Diagnostic Information”. Conditions included in “Neoplastic Diseases” were: colorectal cancer (malignant neoplasm of colon; malignant neoplasm of rectum, rectosigmoid junction, and anus); benign neoplasm of colon; benign neoplasm of rectum and anal canal; neoplasm of uncertain behavior of stomach, intestines, and rectum; neoplasm of uncertain behavior of other and unspecified digestive organs (anal canal/sphincter/NOS); and anal and rectal polyp.

The “Other Diagnoses” category included conditions that could account for an FOBT positive result, such as gastric ulcer and hemorrhoids. This category was further divided into upper and lower GI tracts. Conditions grouped into the “Other Diagnoses” category were: upper gastrointestinal (GI) sources (*Helicobacter pylori* infection; esophagitis; ulcer of esophagus; esophageal reflux; gastric ulcer; duodenal ulcer; peptic ulcer, site unspecified; gastrojejunal ulcer; gastritis and duodenitis; stenosis/stricture of duodenum; hiatal hernia), lower GI sources (hemorrhoids, regional enteritis, ulcerative colitis, gastroenteritis and colitis due to radiation, other and unspecified noninfectious gastroenteritis and colitis, diverticula of colon, irritable bowel syndrome, unspecified functional disorder of intestine, anal fissure, stenosis of rectum and anus, ulceration of intestine, angiodysplasia of intestine, melanosis coli, unspecified disorder of intestine, gastrointestinal vessel anomaly), and one non-GI related diagnostic information (metastatic prostate cancer).

The “Normal Findings” category included physician report of normal findings. Finally, the “No Diagnostic Information” category included patients for whom the physician did not report the diagnostic outcomes on the ICA or reported too little information to determine the diagnostic outcome. Patients for whom no diagnostic information was available were excluded from further analysis. Patients with missing data for race were also excluded from the final modeling.

We compared the age and gender of the excluded group with the final study population. This step was accomplished with univariable logistic regression modeling. Logistic models were corrected for clustering of patients within practices using generalized estimating equations (GEE). The p-values reported relate to the Type 3 hypothesis for the overall association. When a patient had more than one GI diagnosis, the most serious condition was used as the primary diagnostic outcome. For example, for a patient with two reported diagnostic outcomes of colorectal cancer and hemorrhoids, colorectal cancer was selected as the diagnostic outcome, and the patient was included in “Neoplastic Disease” rather than “Other Diagnoses” category.

Polytomous logistic regression modeling was used to identify predictors of being in the “Neoplastic Diseases” and “Other Diseases” outcome groups. The reference group was FOBT (+) patients reported to have “Normal Findings.” Since patients were not randomized to CDE performance versus non-performance, we modeled diagnostic outcomes using a multivariate, controlled comparison. We controlled for age, race, gender, CDE group, and study group in the logistic model and report results as adjusted odds ratios with two-sided 95% confidence intervals, and p-values, with statistical significance considered for $p < 0.05$. All results from the polytomous model were adjusted for the clustering of patients within practices using the jackknife regression procedure in IVEware [14].

RESULTS

ICA form data or administrative data were obtained for 1468 (97%) of the 1508 FOBT(+) patients initially considered for inclusion in data analysis. From this number, 175 patients were excluded from analysis, because they did not meet the CDE performance eligibility criteria. Of the remaining 1293 CDE-eligible patients, 34 had administrative data only and did not have

an ICA form returned. Because we used ICA forms for determining diagnostic outcomes, patients for whom the form was not returned were also excluded from data analysis. Thus, 1259 patients with ICA forms, or 84% of the original study population, were available. Of these, 608 patients had no reported diagnostic information. These patients were assigned to the “No Diagnostic Information” category. Given that planned analyses focused on patients with a reported diagnosis, we also excluded these patients from further analyses.

The distribution of diagnostic outcomes reported for the remaining 651 patients was as follows: Five hundred eleven patients (78.5%) had CDE and 140 patients (21.5%) did not have CDE. A total of 224 patients (88.2%) with CDE and 30 patients (11.8%) without CDE were reported to have neoplastic disease. Of the 224 patients with CDE who had neoplastic disease, 18 had colorectal cancer and 206 had colorectal polyps but no cancer (124 with polyps only; 82 with polyps and other diagnoses). Of the 30 patients without CDE who had neoplastic disease, seven had colorectal cancer and 23 had colorectal polyps without cancer (15 with polyps only; eight with polyps and other diagnoses). Two hundred and twenty-six patients (72.0%) with CDE and 88 patients (28.0%) without CDE were reported to have other diagnoses. Sixty-one patients (73.5%) with CDE and 22 patients (26.5%) without CDE had normal findings. For the regression analysis, 190 patients without information on race were excluded, since these patients could not be controlled for age, gender, race, CDE group, and study group. Thus, there were 461 patients in the final data analyses. Figure 1 summarizes these steps and provides further breakdown of the numbers.

Table 2 shows the demographic characteristics and CDE status of FOBT (+) for the 461 patients included in the regression analysis. Three hundred sixty-two patients (78.5%) had CDE and 99 patients (21.5%) did not have CDE. A total of 154 patients (89.0%) with CDE and 19 patients (11.0%) without CDE were reported to have neoplastic disease. One hundred sixty-four patients (73.2%) with CDE and 60 patients (26.8%) without CDE were reported to have other diagnoses. Forty-four patients (68.7%) with CDE and 20 patients (31.3%) without CDE had normal findings.

To check for potential bias, we compared this final group of 461 patients to the group of 798 patients who were excluded from the final logistic regression analysis due to lack of data on diagnostic outcome or race. Both groups had similar gender distributions: 39% men and 62% women for the final included group and 39% men and 61% women for the excluded group ($p=0.937$). However, the final included group was younger than the group that was excluded: 39% were aged under 65 years and 61% were aged 65 years or over for the final included group of 461 patients, and 32% were aged under 65 years and 68% were aged 65 years and over for the excluded group of 798 patients ($p=0.0016$).

Findings from multivariable analyses are displayed in Table 3. Findings show that FOBT (+) patients who underwent CDE were substantially and significantly more likely to have a reported diagnosis of colorectal neoplasia than normal findings (odds ratio = 3.65, 95% confidence interval = 1.58 to 8.39, $p=0.02$). CDE performance was not significantly associated with a diagnosis of conditions other than colorectal neoplasia versus normal findings. No other covariates were found to be significantly associated with outcome.

To check for data quality, we analyzed the proportion of 461 patients who had their ICA forms confirmed by MCO administrative data. We performed a Fisher's exact test on the 362 patients who had CDE. We did not apply this analysis to the patients without CDE, since the administrative data included colonoscopy claims only. All 362 patients had ICA data. For the Control Group, CDE status for 8% of patients was determined from ICA only and 92% from both ICA and administrative data. For Intervention Group, CDE status for 14% were

determined from ICA only, and 86% were from ICA and administrative data, respectively ($p=0.08$). Thus, data sources used for this parameter were similar for both study groups.

DISCUSSION

We found that the completion of CDE for a positive screening FOBT was associated with a higher likelihood of reported neoplastic disease (i.e., colorectal cancer and polyps) but not other diseases among community physician practices. Previous studies have shown that FOBT screening decreases CRC incidence and mortality [3,4,5]. This was attributed to CDE of positive FOBT results leading to the diagnoses of early, treatable, colorectal neoplastic diseases. However, these studies were done in controlled trial settings, and the CDE completion rate was high. It was unclear whether lower rates of CDE typically found in non-trial practice settings would actually lead to a meaningful increase in the diagnosis of neoplastic diseases of colon and rectum. This study showed a statistically significant correlation between CDE and the diagnosis of neoplastic disease of colon and rectum and, thus, highlights the effectiveness and amplifies the importance of CDE performance for patients with positive FOBT results in the community. In particular, if patients are diagnosed with colorectal polyps and, thus, are subsequently surveyed more frequently and polyps removed, it would lead to lower incidence, morbidity and mortality from advanced CRC [3].

Previous studies in non-trial settings have shown an association between CDE and the finding of significant colorectal disease [8,9]. However, this association was not substantiated by statistical analysis. We show for the first time that the performance of CDE for patients with positive FOBT in practice-based CRC screening is significantly associated with reported diagnostic outcomes of colorectal neoplastic disease (cancers and polyps). The very high return rate of the internal chart audit forms by the physicians (97%) lends further support that the study results closely reflect the actual CDE performance in the community.

In our study, the CDE performance rate was 60.4% (781 out of 1293 eligible patients who had positive FOBT result). This is lower than the CDE rates of over 80% reported in the randomized controlled trials (3,4,5). However, our rates of colorectal neoplasm among those with positive FOBT results were comparable with the published trials. Another key finding from our study was that CDE performance was significantly associated with neoplastic diseases but not other diagnoses. Since the purpose of CDE is to detect colorectal neoplasms in patients who test positive in screening FOBT, our study finding lends further support to this recommendation. Table 4 compares the rates of CDE, CRC, and colorectal polyps in patients with positive FOBT results with the published trials by Mandel, Kronborg, and Hardcastle.

In an analysis of a subset of patients from the same trial, over three-quarters of the reasons for CDE nonperformance could be attributed to physician factors, such as normal findings from non-CDE procedures completed after FOBT (+) date, non-CDE procedures completed before FOBT (+) date, and medical history or medications before or during FOBT suggesting reason for FOBT(+) (15). In a national physician survey conducted in 2000, only 52% and 7% of primary care physicians would recommend colonoscopy or flexible sigmoidoscopy and barium enema, respectively, to FOBT (+) patients in hypothetical cases, for a total CDE recommendation rate of 59% (16). Also, a recent study has shown that a substantial proportion of primary care physicians continue to practice CRC screening methods not recommended by current guidelines (e.g., single stool sample obtained by digital rectal examination) and follow up abnormal results with methods other than CDE (e.g., repeat FOBT, sigmoidoscopy only) (17). Non-CDE procedures such as repeat FOBT and sigmoidoscopy only are not considered to be adequate evaluations. Indeed, even a combination of FOBT and sigmoidoscopy would miss 24% of advanced colonic neoplasia (defined as adenoma 10mm or more in diameter, villous adenoma, adenoma with high-grade dysplasia, or invasive cancer) detected by

colonoscopy (18). Thus, efforts should be renewed to increase CDE of positive FOBT patients in CRC screening to maximize the public health impact of this screening modality.

The diagnostic outcome groups that were used for the final analysis in our study were not randomly assigned to have or not to have CDE. We addressed this issue by controlling for age, gender, race, and whether the patient's affiliated practice had received feedback and educational outreach interventions, in the final analysis. The diagnostic outcome was not significantly associated with any of these factors.

The patients who were excluded from the final analysis, due to lack of information on race, were significantly older than the patients who were included in the final analysis. Although this may affect the generalizability of our study, it should not affect the analysis. Indeed, since older age is associated with greater incidence and prevalence of colorectal neoplasm, our analysis may underestimate the true impact of CDE.

Several limitations exist to our study. First, the diagnostic outcomes were based on physician-reported internal chart audit forms. Thus, we do not have information on polyp size, the complete histological information about the polyps, the stage information about the cancers that were detected, or the way in which the patients without CDE were diagnosed. However, the use of physician-reported internal chart audit forms is also a strength of this study, since it reflects how physicians acted on the FOBT (+) results and the resulting diagnostic outcome that they would then base their clinical decision-making on. Second, our data may underestimate the number of diagnoses due to the fact that data on CDE performance were limited to within 180 days from the positive FOBT result. The time interval may not have been long enough to capture all of the CDE performance events. However, this would equally affect the diagnostic outcomes of those who had CDE to those who did not. Third, we do not know if physicians were more likely to perform CDE on patients whom they viewed as being of higher risk of having colorectal cancer. For instance, physicians' decisions about CDE may have been influenced by patient self-report of certain symptoms or risk factors. We do not have the data to either support or refute this possibility.

We noted that CDE performance for patients with positive FOBT in community practices was associated with higher diagnostic outcome of significant disease, i.e., colorectal neoplasia. This finding further supports the importance of completely evaluating patients who have an abnormal (positive) FOBT result in colorectal cancer screening. Special attention needs to be directed toward assuring CDE performance in order to realize the maximal benefit for colorectal cancer screening.

Glossary

Abbreviations Used:

CDE, complete diagnostic evaluation; FOBT(+), positive fecal occult blood test; ICA, internal chart audit; ADR, administrative data review.

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Figure 1.
Flow of patients in the CDE diagnostic outcomes study

Table IA**Physician Practice Attributes**

Practice Environment	N*	%
Administrative arrangement		
Solo	147	46.2
Group	171	53.8
Geographic location		
Pennsylvania	216	67.9
New Jersey	102	32.1
Participation in an integrated health care delivery system		
No	210	66.7
Yes	105	33.3

Total number (N) may be lower than 318 due to missing data.

Table IB**Physician Practice Attributes - Continued**

Physician Background & Experience	N*	%
Median age		
≤45.5 years	148	47.6
> 45.5 years	163	52.4
Gender		
All male	242	76.6
All female or male+female	74	23.4
Race/ethnicity		
All Caucasian	248	79.7
Other	63	20.3
Specialty		
Family Medicine	228	72.2
General Internal Medicine	88	27.8
Board certification status		
100% board certified	251	79.7
< 100% board certified	64	20.3
Median years in medical practice		
≤ 18.5 years	149	47.2
> 18.5 years	167	52.8

*
Total number (N) may be lower than 318 due to missing data.

Table II
Frequency of diagnostic outcomes among FOBT+ patients (N=461)

Variable	Neoplastic Disease N=173 Number (%; 95% CI)	Other Diagnoses N=224 Number (%; 95% CI)	Normal Findings N=64 Number (%; 95% CI)
CDE performance *	154 (89.0; 83.4 - 93.3)	164 (73.2; 66.9 - 78.9)	44 (68.7; 55.9 - 79.8)
Yes	19 (11.0; 6.7 - 16.6)	60 (26.8; 21.1 - 33.1)	20 (31.3; 20.2 - 44.1)
No			
Age	70 (40.5; 33.1 - 48.2)	86 (38.4; 32.0 - 45.1)	25 (39.1; 27.1 - 52.1)
65 years and over 50-64 years	103 (59.5; 51.8 - 66.9)	138 (61.6; 54.9 - 68.0)	39 (60.9; 47.9 - 72.9)
Race			
White	161 (93.1; 89.3 - 96.9)	207 (92.4; 88.1 - 95.5)	57 (89.1; 78.8 - 95.5)
Non-white	12 (6.9; 3.2 - 10.7)	17 (7.6; 4.5 - 11.9)	7 (10.9; 4.5 - 21.3)
Gender			
Male	68 (39.3; 32.0 - 47.0)	89 (39.7; 33.3 - 46.5)	23 (35.9; 24.3 - 48.9)
Female	105 (60.7; 53.0 - 68.0)	135 (60.3; 53.5 - 66.7)	41 (64.6; 51.1 - 75.7)
Study group			
Intervention group	65 (37.6; 30.3 - 45.2)	97 (43.3; 36.7 - 50.1)	26 (40.6; 28.5 - 53.6)
Control group	108 (62.4; 54.8 - 69.7)	127 (56.7; 49.9 - 63.3)	38 (59.4; 46.4 - 71.5)

Footnote:

* CDE: complete diagnostic evaluation

Table III

Multivariable analysis of diagnostic outcomes

Variable	Neoplastic Diseases vs. Normal Findings			Other Diagnoses vs. Normal Findings
	Odds ratio (95% CI)	(n = 237) P value	Odds ratio (95% CI)	(n = 288) P value
CDE performance (Yes/No)*	3.65 (1.58 - 8.39)	0.002	1.22 (0.66 - 2.27)	0.516
Age (65 years and over/50-64 years)	0.98 (0.51 - 1.87)	0.944	1.03 (0.56 - 1.90)	0.926
Race (Non-white/White)	1.53 (0.58 - 4.07)	0.387	1.48 (0.52 - 4.18)	0.459
Gender (Male/Female)	1.16 (0.67 - 2.01)	0.591	1.17 (0.67 - 2.07)	0.579
Group (Study/Control)	1.17 (0.59 - 2.30)	0.651	0.89 (0.46 - 1.75)	0.743

Footnote:

* CDE: complete diagnostic evaluation

Table IV

Comparison of CDEM* rates and diagnoses

Variable	Current Study % of FOBT(+)	Mandel 1993 % of FOBT(+)	Hardcastle 1996 % of FOBT(+)	Kronoborg 1996 % of FOBT(+)
CDE performance	60.4	82.7	Not Available	83.9
Neoplasia detection	43.8	29.4	35.8	39.6
Colorectal cancer	3.5	1.9	1.2	12.2
Colorectal polyp	40.3	27.5	34.6	27.4

Footnote:

*

CDE: complete diagnostic evaluation