Colorectal Cancer Screening After Changes in US Preventive Services Task Force Guidelines With Increased Screening Options

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ABSTRACT

Introduction: In 2016, the US Preventive Services Task Force (USPSTF) added multitarget stool DNA and computed tomography colonography (CTC) as accepted colorectal cancer screening modalities to the already recommended tests: fecal immunochemical test (FIT), sigmoidoscopy, and colonoscopy. The aim of our study was to determine trends in screening after the USPSTF update, with the effect of additional tests on the use of existing colorectal cancer screening modalities and overall screening rates.

Methods: We prospectively compared monthly colorectal cancer overall screening rates and the mean total numbers of patients screened by multitarget stool DNA, colonoscopy, sigmoidoscopy, CTC, and FIT 6 months prior to the new USPSTF guidelines until 30 months after.

Results: At completion of the study, 72,202 patients were eligible for screening. The overall rate of eligible patients screened for colorectal cancer did not change (80.9% vs 81.3%; $P = 0.287$). There was a significant increase in the percent of patients screened with multitarget stool DNA (1.6% to 15.6%; $P = .001$) and a significant decrease in the percent of patients screened using CTC (3.8 % to 1.5%; $P = .004$), FIT (9.3% to 4.9%; $P = .003$), and sigmoidoscopy (2.4% to 1.5%, $P = .024$). There was a nonsignificant decrease in the percent use of screening colonoscopy, from 82.9 % to 76.5% ($P = .313$).

Conclusion: While the overall colorectal cancer screening rate did not increase after the USPSTF update with additional recommended screening tests, practice patterns did change with a shift in the type of screening test used.

INTRODUCTION

Colorectal cancer (CRC) is the second-leading cause of cancer-related deaths in the United States. Although the incidence is declining, it is estimated that there were approximately 135,000 new cases of CRC diagnosed in 2017.[1] Several CRC screening modalities have been shown to decrease disease mortality.[2-8] Despite this, many Americans are not up-to-date with recommended CRC screening guidelines. In 2016, 67% of US patients between the ages of 50 and 74 years were up-to-date with colon cancer screening.[9] In an effort to increase patient compliance, there has been growing interest to develop alternative screening tests.

In June 2016, the US Preventive Services Task Force (USPSTF) included multitarget stool DNA and computed tomography colonography (CTC) as accepted CRC screening modalities for average risk patients to the already recommended tests: colonoscopy, fecal occult blood test (FOBT), fecal immunochemical test (FIT), or flexible sigmoidoscopy.[10,11] The updated guidelines recognize the different sensitivities, specificities, strengths, and weaknesses of each screening test but report that no single modality is more effective than the others.[10] Given the current lack of screening for approximately 30% of eligible US adults, the goal of the update was to increase the use of CRC screening by offering several screening options.[12,13] The theory is that more screening options will result in more patients being screened, and offering less invasive options will result in patients screened who otherwise might not agree to testing. The USPSTF added a multitarget stool DNA test, which consists of a FIT test in combination with an assessment for DNA biomarkers shed into stool, and CTC to the recent guideline update. The multitarget stool DNA is more sensitive but less specific than FIT alone.[14] CTC using software technology creates a 2-dimensional and 3-dimensional image of the colon to detect polyps with the aid of a bowel prep but without the need for sedation.[15]

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The goal of this study was to determine the effect of the USPSTF expansion of acceptable CRC screening tests on overall CRC screening rates and on existing CRC screening modalities within a unified academic primary care network. We wished to examine primarily if CRC screening rates would increase with more screening tests recommended as equal options. Additionally, though stool DNA and CTC have been available to some degree, we wanted to examine whether moving these tests to first tier tests recommended equally to existing modalities would result in an increase in stool DNA and CTC use and whether it would it affect already existing screening modalities.

METHODS

Data from the Wisconsin Collaborative for Healthcare Quality (WCHQ) on overall colorectal cancer screening rates and type of screening modality used were prospectively collected on a monthly basis on individuals 50 to 75 years old. WCHQ is a voluntary, statewide partnership of health care organizations that has tracked CRC screening rates across multiple health systems in Wisconsin since 2005.[16,17] The University of Wisconsin health system (UW Health) has been a member of WCHQ since 2005. We prospectively collect data on overall screening rates and the type of method used at our institution each month. We present overall screening rates to WHCQ on a quarterly basis, and they are published annually to the public.

Adults aged 50 to 75 years are included as eligible for screening if they are "currently managed" by the University of Wisconsin physician group. Patients are considered "currently managed" if they had at least 2 primary care office visits in an outpatient, nonurgent care setting within the previous 36 months, with at least 1 of those visits in the prior 24 months. This group is the ongoing cohort of patients who can and should be screened for CRC.

Completion of CRC screening is defined as having completed 1 of the 5 recommended tests by the USPSTF within the correct screening interval. A patient is considered screened if FOBT/FIT has been completed in the prior 12 months, if multitarget stool DNA has been performed within the previous 3 years, flexible sigmoidoscopy or CTC in the past 5 years, or colonoscopy in the prior 10 years. Both screening and diagnostic colonoscopy, if complete, satisfied screening requirements. If a patient underwent a positive test (FIT, stool DNA, sigmoidoscopy, or CTC) and then subsequent colonoscopy, the initial screening modality was the test recorded for that patient. Tests were identified using current procedural terminology (CPT); logical observation identifiers, names, and codes (LOINC); and healthcare common procedure coding system (HCPCS) codes for the above-mentioned CRC screening tests based on codes designated by the Healthcare Effectiveness Data Information Set (HEDIS) to calculate CRC screening metrics. Within the primary care network, all primary care providers have open access to order the various screening modalities, which are all covered by local third-party payers.[18] The decision on the type of screening modality used was made by the primary care providers.

We evaluated the screening practices for eligible average risk patients within UW Health. We compared the monthly overall CRC screening rate and overall number of patients screened from 6 months prior to the updated USPSTF to 30 months after. We calculated mean monthly total numbers and relative percentage of multitarget stool DNA, colonoscopy, flexible sigmoidoscopy, CTC, and FOBT/FIT for eligible 50- to 75-year-old patients from January 2016—6 months prior to the USPSTF update—through December 2018.

Statistical Analysis

The analysis was focused on comparisons between the colorectal cancer screening rates and numbers 6 months prior to the June 2016 USPSTF update compared to the subsequent 30 months. Comparisons were made using the Student *t* test for continuous outcomes and a chi-square analysis for categorical outcomes. Statistical significance was considered at a 2-tailed P value < 0.05.

The Institutional Review Board at the University of Wisconsin granted the study an exemption as a project of quality control and program evaluation.

RESULTS

In our primary care network, 65,327 patients were eligible for colorectal cancer screening at the initiation of this study, and 72,202 patients were eligible for CRC screening during the last month of the study, providing the study cohort.

There was a significant increase in the number of eligible screening patients within our primary care network during the study period, from 65,327 to 72,202 ($P < .001$). There was also a significant increase in the absolute number of patients screened for CRC (52,906 to 60,100; $P < .001$) during the course of the study, before and after the 2016 USPSTF screening guidelines. However, the overall percent of eligible patients screened within the primary care network did not change significantly during the study period (80.9% vs 81.3%; $P = 0.287$).

There was a significant increase in the percent of eligible patients screened with multitarget stool DNA, from 1.6% (mean 3.9%, SD ± 1.37) to 15.6% (mean 7.9%, SD ± 2.65) ($P = .001$), as well as a significant increase in the absolute number of stool DNA tests completed per month, from 48/month (SD ± 18) to 117/month (SD ± 48) ($P = .002$). There was also a significant increase in the absolute number of colonoscopies completed, from 970/month (SD ± 116) to 1152/month (SD ± 140) ($P = .005$), but a nonsignificant decrease in the percent use of screening colonoscopy as a percentage of all screening tests employed—from 82.9% (mean 80.5%, SD ± 1.54) to 76.5% (mean 79.7%, SD ± 1.95) ($P = .313$).

There was a significant decrease in the percent of patients screened using CTC, from 3.8% (mean 3.3%, SD ± .31) to 1.5% (mean 2.5%, SD ± .58) ($P = .004$) and a decrease in the absolute number of screening CTC exams completed, from 40/month (SD ± 3) to 37/month (SD ± 7) ($P = .35$). There was a significant decrease in the percent of patients screened using FIT, from 9.3%

(mean 9.6%, SD ± .98) to 4.9% (mean 7.6%, SD ± 1.49) (P = .003) and a decrease in the absolute number of tests completed, from 114/month (SD ± 16) to 109/month (SD ± 14) (P = 0.52). The smallest percent of eligible patients were screened using flexible sigmoidoscopy; however, there was also a significant decrease in the percent screened using flexible sigmoidoscopy—from 2.4% (mean 2.5%, SD ± .50) to 1.5% (mean 2.0%, SD ± .38) (P = .024)—but no significant change in the absolute number of tests completed (n = 29/month, SD ± 6) and (n = 29/month, SD ± 5) (P = 0.96).

DISCUSSION

In June 2016, the USPSTF reported that multiple screening modalities could be used for patients 50 to 75 years old to detect early-stage colorectal cancer and adenomatous polyps. The previous USPSTF guidelines, from 2008, recommended screening with colonoscopy, annual FOBT/FIT, or flexible sigmoidoscopy plus FOBT/FIT.[19] Thus, the aim of our study was to determine the effect of the updated USPSTF guidelines expansion of acceptable CRC screening tests on overall CRC screening rates and existing screening modalities.

In our cohort, since the 2016 USPSTF update, there was an increase in the overall number of patients screened for CRC within our network but no increase in the overall rate of CRC screening. The screening rate within our health care system is one of the highest in the nation,[20] approaching or above 80% for the past 5 years. This may explain why the overall screening rate did not increase with the additional CRC tests recommended. To have shown a statistical improvement in overall screening rate at our institution, we would have had to see an increase of 2.0% rather than the 0.4 % we witnessed. This means we would have needed to have screened approximately 1,300 more patients than the already added 8,000 patients who received CRC screening during the study period. Further, as screening rates for colorectal cancer or any cancer get closer to 100%, there may be a subset of patients who will never get screened or will be more challenging to get screened. However, for health care systems with lower than average screening rates, it is possible that the increased number of CRC screening modalities would lead to a significant percentage increase in eligible patients screened. In addition, our health care system has a long history of a colonoscopy-dominated screening practice, with >80% of patients screened by colonoscopy. It is also possible that at health care systems with lower screening rates and less resources to provide colonoscopy, the addition of more screening tests may further increase screening rates.

Of the CRC screening modalities studied, the utilization of stool DNA increased the most within our health care network. The reason for the increase in adoption is likely multifactorial, with contributions from its lack of invasiveness compared to an endoscopic exam, increased perceived patient privacy, increased sensitivity compared to alternate stool based tests, local and national media attention, lack of pretest preparation, ease of use, and the fact it is a new or novel screening modality. The multitarget stool DNA test Cologuard also uses direct-to-consumer advertising and sales representatives, which may affect patient choice and primary care ordering practices. Exact Science, producer of the multitarget DNA stool test (Cologuard) is also based in the same city as our institution, likely further influencing local provider practices and ordering patterns. Primary care providers are the ultimate decision-makers as to which type of screening modality is used and, thus, were likely influenced by all of these factors, resulting in an increase in screening with stool DNA.

Previous studies have shown a gradual increase and stability in the use of CTC once a program has been established.[21,22] CTC has a sensitivity and specificity to detect adenomas ≥ 10 mm that ranges from 67% to 94% and 86% to 98%, respectively.[23-25] Of all CRC screening tests, CTC's detection of polyps and cancer is closest to endoscopic colonoscopy. Interestingly, since the USPSTF update, there was a gradual decrease in the use of CTC within our health care system. Reasons for this are not completely clear, as we assumed that just as fecal DNA testing increased after the USPSTF 2016 recommendations, that the use and ordering of CTC would have increased with CTC being considered a relatively equivalent screening test compared to other modalities. It is possible that this decrease is secondary to the impact and increased adoption of multitarget stool DNA as a less invasive means to screen for colon cancer at our institution. To patients and ordering providers, while stool DNA is an at-home study, CTC still requires a full bowel prep and requires a visit to a clinic or hospital to be performed. In addition, CTC is not a new screening test at our institution and has been covered by third-party payors for greater than 10 years. This may explain why CTC did not receive the same "bump" in its relative ordering for CRC screening by our primary care providers as compared to multitarget stool DNA.

Colonoscopy continues to be the most commonly used test to screen for CRC nationally and at our institution. During the study period, the absolute number of colonoscopies increased significantly. However, although nonsignificant, there was a decrease in the percent of screening colonoscopy within our health care system, from 82.9% to 76.5%. Further screening colonoscopy was the only screening test that had a wait time during the study, which may further explain the ascent of stool DNA as a screening test compared to colonoscopy. Still, colonoscopy remains the dominant screening modality at our institution, as it does nationally. It is unknown but possible this decrease in colonoscopy use as a screening test will continue as the use of multitarget stool DNA increases.

Some limitations of our study include possible lack of generalizability to different health care systems. The Midwest and the state of Wisconsin have one of the highest colon cancer screening rates in the nation.[20] Within Wisconsin, our institution has one of the higher screening rates—over 80% at the initiation of our study. This actually may have blunted the effects of the additional screening tests being recommended, while at other institutions with lower rates of CRC screening the changes in the 2016

in USPSTF guidelines may lead to an even greater increase in screening rates. Further, our CRC screening program was one of the first to adopt and implement a CTC screening program. Such results and patterns might not be applicable to health care systems with different insurer coverage and CTC availability for CRC screening. Lastly, as stated, the geographic location of Exact Sciences—the maker of Cologuard—may contribute to both patient and provider preferences in our study. However, with the national advertising and distribution of Cologuard, it is unlikely that the significant increase in multitarget stool DNA as a screening test will remain a local phenomenon.

Our study does not mean to imply that the changes in the 2016 USPSTF update were the actual cause or the only factor that affected CRC screening rates at our institution. There are other screening guidelines present for CRC screening, and we do not have data or information on which guidelines our primary care providers use and how they use them. However, what is unique about the 2016 USPSTF update is that it recommends an increased number of screening modalities, and while not indicating that all are equal per se, it states that no modality is more effective than the other and all satisfy screening requirements.

CONCLUSION

Colorectal cancer continues to lead to significant patient morbidity and mortality, and screening can decrease this burden. Focusing on the health care benefits of screening, the most recent USPSTF update recommended providing multiple screening options for patients and providers rather than prioritizing one modality over another. This change did not influence overall screening rates but did influence screening patterns within our large unified academic primary care network. The use of multitarget stool DNA testing increased significantly and will likely continue to increase based on this early data. Colonoscopy continues to be the most frequently used screening modality, but it did show a decline in the rate of use compared to other modalities. Further time out since the 2016 USPSTF guideline changes and data from other institutions with varying patient populations will help to further determine if offering more CRC screening modalities will truly help increase national CRC screening rates.

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