Potential Screening Benefit of a Colorectal Imaging Capsule That Does Not Require Bowel Preparation

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Introduction: Check-Cap is a capsule device that images the colon using low-dose radiation (total dose equivalent to a plain abdominal radiograph) and does not require bowel preparation. Check-Cap is in development for colorectal cancer imaging.

Aim: To survey patients in a primary care setting for their preferences for Check-Cap versus fecal occult blood testing (FOBT), including among patients who decline colonoscopy.

Methods: Patients aged 50 and older presenting to the general medicine and family practice clinics of Indiana University Health sites within a 3-month period were approached during clinic visits. A total of 502 patients who agreed to participate were given the opportunity to complete an anonymous survey (Supplementary Appendix 1, http://links.lww.com/JCG/A71) regarding their preferences for colon cancer screening. The survey presented procedure descriptions and projected accuracies for colonoscopy, FOBT, and Check-Cap. For Check-Cap, projected sensitivity was 80% for cancer and 50% for large polyps.

Results: The mean age of the subjects was 61.6 years, 39% were males, 44% white, 62% of patients had prior colonoscopy, and 26% had prior polypectomy. We defined 3 groups of patients—those that had never had a colonoscopy (NC)—38%, those who had a colonoscopy but no polypectomy (CNP)—36%, and those who had a colonoscopy and polypectomy (CP)—26%. Overall, 284 patients (57%) were willing to undergo a future colonoscopy. Patients with prior colonoscopy and polypectomy were more willing to get another colonoscopy than the other 2 groups (CP:CNP:NC = 78%:64%:38%; $P < 0.0001$). Willingness to undergo colonoscopy decreased with age in all the 3 groups. Among those not willing to undergo colonoscopy, 30% were willing to undergo Check-Cap, 20% were willing for FOBT), 25% were willing to do both, and 24% were not willing for either test. Among those who declined future colonoscopy, 40% reported Check-Cap as their preferred screening test versus 22% for FOBT; $P = 0.0002$.

Conclusion: Our survey suggests that an imaging capsule like Check-Cap could contribute to screening adherence among patients who decline colonoscopy, provided that it can achieve projected sensitivities of 80% for cancer and 50% for large polyps.

Key Words: colonoscopy, fecal occult blood test, capsule, screening

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Colorectal cancer (CRC) is the second leading cause of death from cancer in the United States, with 143,460 new cases and 51,690 deaths estimated in 2012.[1] Findings from the National Health Interview Survey, which is administered by Centers for Disease Control, indicate that in 2010, only 59% of US adults aged 50 or older had undergone a sigmoidoscopy or colonoscopy within the previous 10 years or had used a fecal occult blood test (FOBT) home test kit within the preceding year.[2] Although colonoscopy is considered the gold standard investigation for screening and diagnosis of CRC, there are barriers to colonoscopy adherence,[3,4] including the need for bowel preparation, procedural discomfort, patient anxiety, and embarrassment about testing, and test cost.[5] Many other tests are available for CRC screening including FOBT, sigmoidoscopy, computed tomography colonography, double-contrast barium enema, and in some countries capsule colonoscopy (Pill Cam), but each of these tests has barriers to adherence and none is used as extensively as colonoscopy in the United States.

Check-Cap (Check-Cap, Mount Carmel, Israel) is a new technology in development for CRC imaging.[6] Check-Cap is a capsule device that images the colon using low-dose radiation (total dose equivalent to a single plain abdominal radiograph) and creates a 3-dimensional reconstructed image of the colon surface (Fig. 1). The imaging capsule is swallowed by the patient and moves passively through the gastrointestinal tract. The capsule employs x-rays and patients drink an oral contrast solution to label fecal material, but do not take any laxative preparation. Data from the Check-Cap is captured on a hand-worn data receiver, which is reviewed later by a gastroenterologist. Patients continue their daily routines after Check-Cap ingestion. The clinical performance of Check-Cap device is under investigation.

We hypothesized that a test like Check-Cap capsule may be acceptable to patients and may result in higher rates of adherence to CRC screening. We conducted a survey of potential screening subjects attending our primary care clinics to compare their preferences of CRC screening using Check-Cap versus the traditional FOBT, and to determine the potential impact of Check-Cap on CRC screening adherence.

Our aim was to survey patients in a primary care setting for their preferences for Check-Cap versus FOBT, particularly among patients who decline colonoscopy.

METHODS

The study was approved by the Institutional Review Board at Indiana University. Consecutive patients aged 50 and older presenting to the general medicine and family

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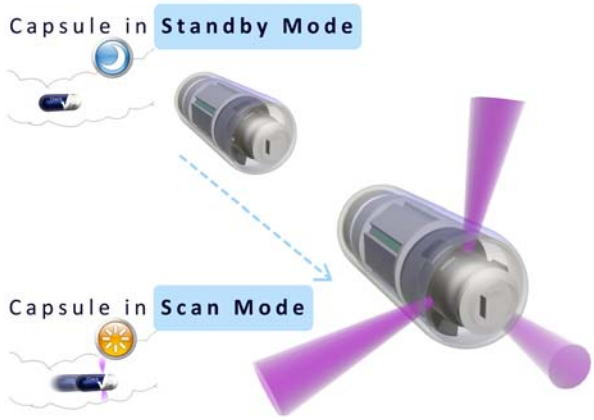

FIGURE 1. Schematic of Check-Cap function. The patient ingests a contrast agent that mixes with feces and allows differentiation of feces from the colon wall. No laxatives are required. The capsule is sensitive to motion and does not scan when stationary (Standby Mode). When the capsule moves, it emits low-dose radiation (Scan Mode). The reflected energy is used to create images of the colon surface.

practice clinics of Indiana University Health sites over a 3-month period were approached by the first author during clinic visits. Patients were given the opportunity to complete an anonymous survey (Supplementary Appendix 1, http://links.lww.com/JCG/A71). They were not paid to complete the survey. A total of 502 patients agreed to complete the questionnaire and approximately 100 patients refused. Most refusers indicated that they were too busy to complete the survey. Demographic information was collected and patients were asked if they had a previous colonoscopy and whether it included polypectomy. Patients were given information about colonoscopy and asked if they would undergo the test for CRC screening. Those who declined colonoscopy were asked to consider FOBT and Check-Cap. The survey presented procedure descriptions and projected accuracies for FOBT and Check-Cap. The survey indicated that FOBT finds about 70% of colon cancers and 35% of large polyps every time it is performed. We estimated that Check-Cap would detect about 80% of colon cancers and 50% of large polyps. Patients were told that both tests require colonoscopy when positive. No patient identifiers were collected.

Questionnaire data were analyzed using SPSS version 14.0 statistical software (SPSS). Comparisons between groups were made using the t test for continuous variables and the χ^2 test for categorical variables. A P value of < 0.05 was considered statistically significant.

RESULTS

Table 1 shows the demographic profile of the 502 survey participants. Their mean age was 61.6 years, 39% were male and 44% white. Five percent of patients had a self or sibling history of CRC. A total of 62% of patients had prior colonoscopy and 26% had polypectomy. We defined 3 groups of patients: those that had never had a colonoscopy (NC)—38%, those who had a colonoscopy but no polypectomy (CNP)—36%, and those who had a colonoscopy and polypectomy (CP)—26%.

Overall, 284 patients (57%) were willing to undergo a future colonoscopy for CRC screening (Table 2).

TABLE 1. Demographics of Study Population

	All [n = 502 (%)]
Sex	
Female	306 (61)
Race	
Asian	3 (1)
Black	267 (53)
Hispanic	10 (2)
White	222 (44)
Self or sibling history of CRC	26 (5)
Never had a colonoscopy before (NC)	189 (38)
Had prior colonoscopy but no polyps removed (CNP)	183 (36)
Had prior colonoscopy and polyps removed (CP)	129 (26)

CNP indicates prior colonoscopy without previous polypectomy group; CP, prior colonoscopy with polypectomy group; CRC, colorectal cancer; NC, no previous colonoscopy group.

Of patients who were not willing to undergo colonoscopy (n = 218), 167 patients were willing to undergo alternate screening tests. Among these 167 patients, 50 (30%) were willing to undergo Check-Cap screening, 33 (20%) were willing for FOBT, 42 (25%) were willing to do either test, and 42 (25%) were willing to do neither. The total group unwilling to have colonoscopy but willing to do Check-Cap (n = 92) approached being larger than the group unwilling to have colonoscopy but willing to do FOBT (n = 75) ($P = 0.08$). When asked which test they preferred, 87 patients (40%) reported Check-Cap as their preferred screening test versus 48 (22%) patients who preferred FOBT; $P = 0.0002$).

Group comparisons are shown in Table 3. Age, sex, race were similar among the 3 groups with different prior colonoscopy experience. Personal or sibling history of CRC was highest among patients with prior colonoscopy and polypectomy (CP > CNP > NC; $P < 0.03$). Patients with prior colonoscopy and polypectomy were more willing to get another colonoscopy than the other 2 groups (CP > CNP > NC = 78%:64%:38%; $P < 0.0001$). Willingness to undergo colonoscopy decreased with age in all the 3 groups. Willingness for alternative CRC screening (with FOBT and/or Check-Cap) was higher among the group with colonoscopy with polypectomy than others but this was not statistically significant.

TABLE 2. CRC Screening Test Preferences

		P
Patients willing to undergo colonoscopy	284 (57%)	
Patients not willing for a colonoscopy	218 (43%)	
Not willing for colonoscopy, but agreeable for alternative methods of screening	167 (77%)	
Willing to undergo Check-Cap vs. FOBT*	92 (42%) vs. 75 (34%)	0.08
Preferred test: Check-Cap vs. FOBT*	87 (40%) vs. 48 (22%)	0.0002

*Among the 218 patients not willing to undergo colonoscopy.
CRC indicates colorectal cancer; FOBT, fecal occult blood test.

TABLE 3. Group Comparisons

		P
Self or sibling history of CRC	CP (9%) > CNP (5%) > NC (1%)	0.04*
Willing to undergo colonoscopy	CP (78%) > CNP (64%) > NC (38%)	0.001*
Willingness for colonoscopy decreases with age in all 3 groups	CP = CNP = NC	
Willing for Check-Cap	CP (34%): NC (29%): CNP (24%)	0.60
Willing for FOBT	CP (26%): CNP (24%): NC (17%)	0.65
Check-Cap was preferred test	CP (47%): NC (46%): CNP (41%)	0.75
FOBT was preferred test	CP (28%): CNP (24%): NC (20%)	0.71

CNP indicates colonoscopy without previous polypectomy group; CP, colonoscopy with polypectomy group; CRC, colorectal cancer; FOBT, fecal occult blood test; NC, no previous colonoscopy group.

DISCUSSION

Check-Cap is in development for CRC imaging. This is the first study to assess patient preferences regarding Check-Cap. Our study shows that almost half of the primary care patients we surveyed, were not willing to get a future colonoscopy for CRC screening, despite information regarding its benefits. This is consistent with various reports of adherence to CRC screening in the general population.[2] Adherence rates have been lower among racial and ethnic minorities.[7,8] However, we did not find differences in willingness for colonoscopy or other screening modalities among different racial groups.

History of previous colonoscopy with or without polypectomy increased the willingness of our study subjects to undergo another colonoscopy. This may reduce anxiety once the test has been experienced. Also, this group of patients had a significantly higher personal and family history of CRC.

It is widely acknowledged that regular screening reduces mortality related to CRC.[9] Our study confirms that significant numbers of primary care patients say they would decline screening colonoscopy. However, 76% of our study subjects who declined colonoscopy were willing to undergo alternate forms of screening, although half of these patients were unwilling to complete FOBT. Hence, development of additional screening tests that are accurate, safe, and acceptable to the public could potentially increase adherence to CRC screening. Our study showed that patients who declined colonoscopy previously were more likely to prefer capsule examination to conventional FOBT as a screening test. Ease of administration of Check-Cap and better sensitivity than FOBT may have been likely reasons for this observation.

A strength of our study is that we involved a large population of primary care patients at the right age for screening. Further, >80% of invited subjects completed the survey, probably because the invitation was made in person. The study showed that the new Check-Cap could potentially result in an overall increase in adherence of CRC screening, especially among patients who had declined colonoscopy.

Limitations of our study include features common to any survey-based study. Thus, recall bias and generalization of questions to make them appropriate for all respondents could affect the results. Second, we do not have demographic information or experience with prior screening among the refusers. Fortunately, the overall response rate to the survey was very high so the results should approximate the responses of the overall primary care patient population in this clinic. Third, soliciting information in the survey regarding which feature of Check-Cap was most appealing to them might have been useful. Fourth, we could not provide responders with cost and insurance information of Check-Cap as the capsule is still in development. Finally, and most important, we fully acknowledge that the major issue with these data is we cannot verify at this time that Check-Cap can achieve or exceed the performance characteristics we indicated in the survey. We chose estimated performance characteristics that Check-Cap engineers have indicated should be achievable and which we considered were minimally acceptable for an imaging device that does not require bowel preparation.

More data are needed to establish the safety and efficacy of the Check-Cap System before its implementation as a CRC screening modality. However, our survey suggests that Check-Cap or a device with similar characteristics and performance, could contribute significantly to screening adherence among patients who decline colonoscopy.

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