Patient Understanding of Benefits, Risks, and Alternatives to Screening Colonoscopy

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BACKGROUND: While several tests and strategies are recommended for colorectal cancer (CRC) screening, studies suggest that primary care providers often recommend colonoscopy without providing information about its risks or alternatives. These observations raise concerns about the quality of informed consent for screening colonoscopy.

METHODS: We conducted a telephone survey (August 2008 to September 2009) of a convenience sample of 98 patients scheduled for a screening colonoscopy to assess their understanding of the procedure's benefits, risks, and alternatives and their sources of information.

RESULTS: Fully 90.8% of subjects described the purpose of screening colonoscopy in at least general terms. Just 48.0% described at least one risk of the procedure. Only 24.5% named at least one approved alternative test. Just 3.1% described the minimal required elements for informed consent: the benefit of colonoscopy, both of the major risks, and at least one approved alternative test. Compared to subjects with higher levels of education or income, fewer subjects with lower levels of education or income could name at least one risk of colonoscopy or one approved alternative test to colonoscopy. For benefits, risks, and alternatives, a smaller percentage of subjects responding reported obtaining information from their doctors than from other sources.

CONCLUSIONS: Patients scheduled for screening colonoscopy have limited knowledge of its risks and alternatives; subjects with lower education levels and lower income have even less understanding. For patients who do not receive additional information until they have begun the preparation for the test, the quality of informed consent may be low.

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Colorectal cancer (CRC) is the second leading cause of cancer death in the United States and the most common cause of death from cancer among nonsmokers.[1] The US Preventive Services Task Force (USPSTF), American Cancer Society (ACS), and other organizations recommend that all individuals with average risk undergo regular screening from ages 50 to 75 with an approved test and strategy such as colonoscopy every 10 years, sigmoidoscopy every 5 years, or fecal occult blood testing (FOBT) annually.[2,3] But, only 63% of eligible patients are up to date with screening, resulting in a large amount of preventable morbidity and mortality.[4]

Each of the approved tests has advantages and disadvantages, and the USPSTF and ACS recommend that patients should be provided with information about all of them to allow an informed decision.[2,3,5] While colonoscopy may be best at detecting precancerous lesions, it is also the most invasive, risky, and burdensome test.[6] FOBT and sigmoidoscopy are easier but have lower sensitivity and specificity for detecting adenomatous polyps and cancers. Although the American College of Gastroenterology guidelines explicitly state that

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colonoscopy is preferred, they also acknowledge that patients who are unwilling to undergo this procedure for screening should be offered a version of FOBT.[7] Studies suggest that patients have varying preferences for CRC screening tests,[8-11] with some studies suggesting that a majority prefer stool testing.[12-15] A review prepared for a recent NIH consensus conference concluded that, "Ideally, a recommendation for screening would be accompanied by a reasonable discussion of screening options, including both the expected benefits and the time, effort, costs, degree of discomfort, and risks associated with each recommended strategy."[16]

Studies suggest that when primary care providers discuss CRC screening, they often recommend colonoscopy, do not provide information about its risks, and discourage consideration of recommended alternatives.[17-19] One study of 91 audio-taped primary care visits where a CRC screening test was ordered found that just 26% of patients were informed about alternatives to colonoscopy, 17% were informed about the pros and cons of the test, and 17% were asked their preferences.[19] A study involving interviews with 65 primary care providers found that just 17% report discussing risks and benefits of CRC screening with their patients, and 11% report describing alternatives.[18]

These studies raise concerns about the adequacy of patient understanding and decision-making regarding screening colonoscopy and about the informed consent process for the procedure. Guidelines issued by the American Society for Gastrointestinal Endoscopy state that to give informed consent to endoscopy, patients must understand the benefits, risks, and alternatives of the procedure, especially in an elective situation such as screening.[20] Patients with inadequate understanding when they schedule their colonoscopy may receive additional information during the informed consent process, but this is often on the day of the procedure, which is clearly not optimal timing. At this point, patients have already prepared emotionally and practically for the test, including making arrangements such as taking a day off of work and arranging a ride home, and they have already undergone the demanding preparation of the colon and been exposed to the associated risks.

No studies have assessed the understanding of patients scheduled for screening colonoscopy, nor have they determined whether these patients obtain information from sources other than their health care provider. In this study, we conducted telephone interviews with patients scheduled for screening colonoscopy to assess these issues.

Methods

This telephone survey study was approved by the Institutional Review Board at Indiana University-Purdue University, Indianapolis (IUPUI).

Population

Participants were a convenience sample of English-speaking 50-to-80-year-old individuals who were scheduled for their first screening colonoscopy. Those with a previous diagnosis of colon cancer or who were unable to complete a telephone interview in English were not eligible. Potential subjects were identified from a roster of patients scheduled for colonoscopy at one of three endoscopy units in Indianapolis. Patients are generally referred for endoscopy by their primary care physician and do not meet the endoscopist until the day of the procedure.

Recruitment

Patients were contacted by telephone by a research assistant up to 1 month before their scheduled colonoscopy, were informed about the study, and, if willing, were asked questions to confirm their eligibility. Those who were eligible and willing to participate were almost always interviewed immediately, although a small number arranged to do the interview at a later point, at least 3 days before the colonoscopy. In all cases, the interview occurred when the patient was not scheduled to discuss these topics with a health care professional again until the day of the colonoscopy.

Data Collection and Measures

Subjects were asked in an open-ended manner to describe the benefits, risks, and alternatives of colonoscopy of which they were aware. Their narrative answers were transcribed by the interviewer. For these narrative answers, two members of the research team coded each answer for identifiable responses, and any disagreements were settled by discussion and consensus. Subjects were also asked whether their physician discussed benefits or risks of colonoscopy with them (yes/no question) and whether they obtained information about colonoscopy benefits and risks from sources such as television, newspaper or magazines, friends or family members, Internet, or other (multiple choice question). Subjects who said that they were aware of at least one alternative to colonoscopy were asked whether their physician described those alternatives and whether the subject had obtained information about alternatives from other sources. Demographic variables were recorded as well. All participants who completed the interview received a $10 gift card.

Analysis

Analyses consisted of the frequency of answers to survey questions including 95% exact binomial confidence intervals for key survey questions. Subjects who reported education beyond high school ("higher education") were compared to those who reported completing high school or less ("lower education") and subjects who reported a yearly household income of greater than $40,000 per year ("higher income") were compared to those who reported a household income of less than or equal to $40,000 ("lower income") with regard to knowledge and sources of information using chi-square or Fisher's Exact tests, as appropriate. The cutoffs between higher and lower education and higher and lower income were the round numbers closest to the median for participants answering these questions. For sources of information for alternatives to colonoscopy, we did not compare answers by education and income due to the small number of subjects who were asked this question.

Results

From November 2008 through September 2009, we successfully contacted 253 individuals, 64 (25.3%) of whom refused to participate (eight of whom were eventually determined to be ineligible by age regardless) and 15 (5.9%) of whom reported that the colonoscopy had already been completed, canceled, or rescheduled. Of 174 individuals who agreed to be screened for eligibility for the survey, 101 qualified, and 98 of these completed the telephone interview. The 59 individuals of appropriate age who were reached by telephone but refused to be screened for further eligibility or refused to participate once screened were no different from those who participated in mean age (58.2 versus 56.9 years, P=.25) or gender (38.6% versus 43.9% male, P=.52), which were the only variables available for comparison. For those who participated, the interview occurred a mean of 7.3 days (SD 5.2 days) before the scheduled colonoscopy.

Demographic characteristics of the sample are shown in Table 1. Slightly more than half of the subjects were female (56.1%) and Caucasian (56.1%), while one third were African American (34.7%). Nearly 50% reported some high school education or less, and 40.0% reported annual income of less than $40,000.

Knowledge (Table 2)

Regarding benefits, 89 of 98 subjects (90.8%) correctly described the purpose of screening colonoscopy. Regarding risks, 47 of 98 subjects (47.9%) named at least one risk of colonoscopy; 25 of 98 (25.5%) described one of the two major risks (perforation or hemorrhage); only five of 98 (5.1%) described both major risks. Regarding alternatives, 24 of 98 subjects (24.5%) described at least one approved alternative screening test for CRC. Only three of 98 (3.1%) subjects described the benefit of colonoscopy, both of the major risks of colonoscopy (perforation and hemorrhage), and at least one approved alternative test.

Sources of Information

Fifty of 97 (51.5%; 95% CI=41.2%–61.8%) responding subjects reported that the doctor had discussed

Table 1: Description of Study Sample

Participants (n=98)	n or Mean (% or SD)
Age, years	56.9 (6.2)
Sex	
Male	43 (43.9)
Female	55 (56.1)
Marital status	
Single	18 (18.4)
Married	42 (42.9)
Divorced	30 (30.6)
Widowed	7 (7.1)
Refuse	1 (1.0)
Race/ethnicity	
White	55 (56.1)
Black	34 (34.7)
Hispanic	2 (2.0)
Other	5 (5.1)
Refuse	2 (2.0)
Educational attainment	
Some high school or less	16 (16.3)
High school graduate	30 (30.6)
Technical/trade school or associate's degree	21 (21.4)
BA (College graduate) or professional/ graduate degree	29 (29.6)
Refuse	2 (2.0)
Annual household income (US dollars)	
≤ $20,000	24 (24.5)
$20,001–$40,000	15 (15.3)
$40,001–$60,000	10 (10.2)
$60,001–$100,000	5 (5.1)
> $100,000	20 (20.4)
Don't know or refuse	24 (24.5)

Table 2: Knowledge of Benefits, Risks, and Alternatives to Colonoscopy

	Total n=98 (%) [95% CI]
Benefits	
Able to name at least one benefit (%, 95% CI)	89 (90.8) [83.3–95.7]
Benefits described, by no. of subjects (%):	
Detect polyps, colon cancer (%)	58 (59.2)
Screening, prevention generally (%)	31 (31.6)
Risks	
Able to name at least one risk (%, 95% CI)	47 (48.0) [37.8–58.3]
Risks identified by number of subjects (%):	
Perforation/tear in the colon	21 (21.4)
Bleeding/hemorrhage	9 (9.2)
Risks of anesthesia	18 (18.4)
Risks from pretest prep	12 (12.2)
Infection	4 (4.1)
Alternatives	
Able to name at least one approved alternative to colonoscopy (%, 95% CI)	24 (24.5) [16.4–34.2]
Alternatives identified by no. of subjects (%):	
FOBT/ stool testing	17 (17.3)
Sigmoidoscopy	3 (3.1)
Virtual colonoscopy (CT)	6 (6.1)
Barium enema	1 (1.0)

CI—confidence interval

the benefits of CRC screening with them, and 66 of 96 (68.8%, CI 58.5%–77.8%) reported obtaining information about the benefits of CRC screening from other sources. Fourteen of 93 (15.1%, CI=8.5%–24.0%) subjects reported that the doctor discussed the risks of colonoscopy with them, while 44 of 88 (50.0%, CI= 39.2%–60.9%) subjects reported having obtained information about risks of colonoscopy from other sources.

Only subjects who said that they were aware of at least one alternative to colonoscopy for CRC screening (n=31, 31.6% of the respondents) were asked whether the physician described these alternatives and whether information about the alternatives was obtained from other sources. Of these subjects, 13 of 30 (43.3%, CI=25.5%–62.6%) responded that their doctor discussed alternatives to colonoscopy with them, and 24 of 31 (77.4%, CI=58.9%–90.4%) said that they gathered information from other sources.

Table 3 shows the number (%) of subjects who said they learned about benefits, risks, or alternatives from a friend or family member, television, newspaper or magazine, Internet, or other sources.

Comparisons by Education and Income

Knowledge. Compared to subjects in the lower education group (n=46), a larger percentage of subjects in the higher education group (n=50) could describe the benefit of screening colonoscopy in at least general terms (98.0% versus 84.8%, *P*=.03). There were no differences between higher income group (n=35) and lower income group (n=39) in the percent who could describe the benefits of screening colonoscopy (100% versus 89.7%, *P*=.12). Compared to subjects in the lower education group and lower income group, a larger percentage of subjects in the higher education group and higher income group could name at least one risk of colonoscopy (74.0% versus 21.7%, *P*<.001 and 74.3% versus 33.3%, *P*<.001, respectively), at least one of the two major risks of colonoscopy—perforation and hemorrhage—(44.0% versus 6.5%, *P*< .001 and 45.7%

versus 7.7%, $P< .001$, respectively), and at least one approved alternative to colonoscopy for CRC screening (34.0% versus13.0%, $P=.02$, and 42.9% versus 10.3%, $P=.001$, respectively).

Sources for Information. There were no significant differences between the higher and lower education groups or the higher and lower income groups in the percent reporting that the doctor had discussed benefits (60.0% versus 40.0%, $P=.05$, and 62.9% versus 47.4%, $P= .18$, respectively) or risks (17.0% versus 11.4%, $P= 0.44$, and 15.6% versus 21.1%, $P= 0.56$, respectively) of colonoscopy. However, compared to the lower education and lower income groups, significantly larger percentages of the higher education and higher income groups reported receiving information from other sources about benefits (84% versus 52.3%, $P=.001$, and 91.2% versus 52.6%, $P< .001$, respectively) and about risks of colonoscopy (65.2% versus 32.5%, $P= .003$, and 71.0% versus 35.3%, $P= .004$, respectively).

Discussion

In this study, patients scheduled for their first screening colonoscopy exhibited limited understanding of its risks and alternatives. Subjects with lower education and lower income levels exhibited even less understanding of risks and alternatives to colonoscopy. However, even those with higher levels of education and income had impressive knowledge deficits, raising concerns about the ability of patients of all education and income levels to make an informed choice of a CRC screening test and to give adequate informed consent to colonoscopy.

As discussed previously, standards for informed consent for an elective procedure such as colonoscopy specify that patients should understand the benefits, risks, and alternatives of the procedure,[20] and it appears that most of the patients in this study failed to meet this standard. More than half failed to describe even one risk, and three quarters failed to name a single approved alternative test. Few subjects (under 5%) could describe the benefit of the procedure, the two major risks, and at least one alternative test. Although some patients with inadequate understanding may learn more during the informed consent process, this is nearly always on the day of the procedure, which may not be the optimal time for learning.

Previous research has not assessed the understanding of patients undergoing screening colonoscopy. Some studies have shown that patients undergoing endoscopic procedures often fail to recall information provided to them during the informed consent process.[21-23] In all these studies, however, subjects were given information in some standardized way—for instance presented by an investigator[22] or by videotape[23]—and so were not typical of patients undergoing these procedures. In addition, while many studies have surveyed or interviewed patients eligible for CRC screening, these studies typically assess opinions and preferences rather than knowledge.[8,12-15,24,25]

The recent DECISIONS survey did assess understanding of CRC screening tests, as part of a telephone survey of individuals who considered at least one of nine medical decisions—including initiating prescription medications, undergoing screening tests for breast, colorectal, or prostate cancer, or having surgery—in the previous 2 years. The subjects who had considered CRC screening had limited understanding of the baseline risk of CRC, the risk reduction provided by screening, and the range of CRC screening tests available.[26-28] However, the DECISIONS study did not separately analyze subjects who chose colonoscopy for screening and did not assess understanding of the risks of colonoscopy, as we did here. In addition, since subjects in the DECISIONS survey could have considered screening at any time over the past 2 years, that study does not provide information regarding the understanding of patients before they underwent colonoscopy. The Health Information National Trends Survey (HINTS) also collected information regarding patient understanding of the range of tests available for CRC

Table 3: Number of Subjects Who Said They Learned About Benefits, Risks, or Alternatives From Other Sources and, of Those Subjects, the Number (%) Naming Each Specific Source

	Benefits	Risks	Alternatives
	n=66	n=44#	n=22
	# (%)	# (%)	# (%)
Friend or family member	39 (59.1)	15 (34.1)	1 (4.5)
Television	26 (39.4)	11 (25.0)	6 (27.3)
Newspaper or magazine	12 (18.2)	3 (6.8)	6 (27.3)
Internet	10 (15.2)	7 (15.9)	4 (18.2)
Other	10 (15.2)	14 (31.8)	12 (54.5)

screening, but the survey did not include questions regarding the risks of colonoscopy, and analyses do not separately analyze the responses of individuals who had colonoscopy.[29]

In our study, a higher percentage of subjects reported that their physician discussed the benefits of colonoscopy than the risks or alternatives, which is consistent with previous studies.[17-19,30] In addition, our study found that a high percentage of subjects reported obtaining information about colonoscopy and other CRC screening tests from sources other than their physician.

No previous studies have assessed what sources of information regarding risks, benefits, and alternatives to colonoscopy are used by patients scheduled for a screening colonoscopy. Our finding that patients relied on information from family members and traditional media more frequently than the Internet is consistent with the findings of the DECISIONS survey, where subjects who considered CRC screening rated the value of various sources of information.[26]

Although we cannot draw any firm conclusions due to the small sample size, our data suggest that patients with higher levels of understanding may often obtain key information from outside sources rather than their physician. For instance, subjects in the higher education and income groups were significantly more likely to know at least one risk of colonoscopy than were those in the lower education and income groups. And, members of the higher education and income groups were also more likely to report collecting information about risks from outside sources but were no more likely to report that their physician discussed the risks of colonoscopy with them. Further research is needed to more carefully explore the causal associations in this area.

While many studies have measured the impact of various types of interventions on uptake of CRC screening,[16] our findings suggest that research must assess patients' understanding as well, especially for those who choose colonoscopy. Research has shown that decision aids, sometimes computer based, can improve patient understanding and decision making regarding CRC screening[31,32] and may affect patient preferences.[11] Our study suggests that it may be important for such tools to also provide adequate information about colonoscopy's benefits, risks, and alternatives to help prepare patients to undergo the informed consent process. Such tools could be provided by primary care physicians for patients who have chosen colonoscopy, to prepare them for the preparation and procedure. Alternatively, endoscopy units or endoscopists could provide this information to patients when they are scheduled for colonoscopy, or at some other point before they begin the preparation for the test, perhaps as part of an informed consent process conducted in advance. Primary care physicians and endoscopists each have ethical responsibility to make sure that patients are adequately informed as they begin preparing for a screening colonoscopy.

Our study has important limitations. First, it is possible that our subjects had a better understanding of the risks and alternatives to colonoscopy at some earlier time, perhaps when choosing a form of screening, but forgot the crucial information before the telephone interview. Second, because we relied on recall by patients, it is possible that some patients were mistaken about whether their doctor did or did not discuss the benefits, risks, or alternatives to colonoscopy with them. At the same time, it is likely that information or discussions that are forgotten do not have a significant effect on decision-making. Third, it is possible that some patients who realized they would be interviewed about their views about colonoscopy could have collected information beforehand, perhaps increasing the reporting of nonphysician sources of information. However, the potential for a Hawthorne effect is limited since (1) almost all patients were interviewed immediately after being told about the study and (2) the informed consent process did not specify that there would be knowledge questions. Fourth, because our study involved a convenience sample drawn from a small number of endoscopy units in one city, the findings may not fairly represent other patients at these same clinics or elsewhere. A larger study would be necessary to draw firmer conclusions about subjects' understanding, where they obtained information, and what impact their sources of information has on their understanding and decision making.

In conclusion, our findings suggest that the level of understanding of benefits, risks, and alternatives to screening colonoscopy by patients who are scheduled to undergo this procedure does not support an optimal informed consent process. Further study is needed to determine the most favorable timing and process for informed consent, along with how best to present information about the benefits, risks, and alternatives to screening colonoscopy.

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