The Case for Universal Screening Colonoscopy

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The mortality related to colorectal malignancy each year remains significant. Although improvements in chemotherapy and surgical management may allow for some improvement, any profound impact must come through the implementation of appropriate screening. Several strategies for screening are available and widely practiced, but this review focuses on the concept of universal screening colonoscopy for the average-risk patient and addresses whether this is the appropriate recommendation in terms of safety, medicolegal, reimbursement and manpower issues, effectiveness and cost-effectiveness, patient acceptance, and appropriate intervals.

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Colorectal cancer (CRC) remains one of the most prevalent malignancies in the United States. In 2002, an estimated 148,300 new cases and 56,600 deaths will be related to CRC (1), making it the third most common cause of new cancer cases and deaths are expected for both men and women. In Louisiana alone, 2600 new cases and 1000 deaths are expected in 2002 (1). Discouragingly, these numbers are almost identical to those observed 15 years ago. Thus, despite the availability of several strategies of screening designed for early detection and prevention, one cannot show improvement in the most important statistics. In 2000, both the American Gastroenterology Association (AGA) and American College of Gastroenterology (ACG) published position papers on the status of screening recommendations for CRC (2,3). The ACG advocates that for average risk persons (defined as older than 50 years with no other risk factors) the preferred screening strategy is colonoscopy every 10 years (2). Burt, in his comprehensive review of colon cancer screening published in Gastroenterology in 2000, also states that colonoscopy may be the most effective screening tool, but he also acknowledges that a variety of factors may have deterred the widespread use to date (3).

Is universal colonoscopy a practical strategy? Past reviews of CRC screening have suggested that offering this to the entire population is not practical and it should be targeted only to groups with a higher than average risk (4). However, the available data provide a strong case for universal screening.

Past Recommendations For Colorectal Cancer Screening

Various screening strategies for colorectal cancer have been promoted in the past 20 years. Numerous agencies and organizations have promulgated guidelines. Current Medicare guidelines, as published in the Federal Register, suggest four options for screening including (but specifically not recommending any option over the other): annual fecal occult blood testing (FOBT), flexible sigmoidoscopy every 4 years, air-contrast barium enema every 4 years, or colonoscopy every 10 years. The US Preventive Services Task Force (USPSTF) published their review and guidelines in 1996 (5). This group promoted annual FOBT and periodic sigmoidoscopy, but concluded there was insufficient evidence for or against barium enema or colonoscopy. In 1997, guidelines published by a multidisciplinary expert panel working on behalf of the Agency for Healthcare Policy and Research also advocated annual FOBT or flexible sigmoidoscopy every 5 years; this was considered to be based on solid clinical evidence (6). The combination of these two techniques has strong theoretical support, and the use of colonoscopy (or air contrast barium enema) every 5-10 years was believed to have strong rationale but no direct evidence of efficacy. Nonetheless, the guidelines did recommend that practioners offer either ACBE or colonoscopy every 10 years.

FOBT has been the most widely used screening technique in the past 20 years. It offers many of the ideal traits of a good

screening test: widespread availability, it is relatively inexpensive, and it does not require special training or use in interpretation of results. Mandel et al initially showed a reduction in colorectal cancer mortality and later,with a longer term follow-up, were able to show a reduction in overall incidence of colorectal cancer in a large cohort of patients divided into three groups: annual FOBT, biennial FOBT, and a control group without screening (7). Any positive FOBT led to full colonic evaluation, which usually was colonoscopy. Annual FOBT screening in this study resulted in a statistically significant reduction in the number of cancer cases, from 507 events in the control population to 417 in the screened group. This impressive long-term study recruited over 46,000 participants. An optimist would look at these data and be pleased with the lower incidence, but conversely, the data also show that most cases of colorectal cancer have a negative FOBT. Moreover, despite the simplicity and noninvasive nature of this screening method, a problem exists with patient compliance. Only about 50% of patients were compliant with all offered screenings. This and other studies have shown that it is important to not have a false sense of reassurance after a negative FOBT. Rex et al specifically designed a study doing colonoscopy on patients with negative FOBT (8). In a group of 620 asymptomatic patients, 3 cancers were found and the prevalence of adenomatous polyps was 27%. Thus, one may conclude that FOBT screening alone is an inadequate way of screening for colorectal malignancy.

The other strategy recommended by the USPHTF is flexible sigmoidoscopy, and most other guidelines recommend an interval of 4-5 years between examinations. This represents a more invasive and expensive method for screening and is somewhat less available than FOBT. There is a very small but real risk of complications from sigmoidoscopy. It is offered in a wide variety of settings and is considered an integral part of training for both internal medicine and family practice residents. In some locales, physician extenders such as nurse practitioners perform the test. Flexible sigmoidoscopy has been shown to directly decrease mortality from CRC in observational studies, but no randomized trials have demonstrated this result. Selby et al initially showed this reduction in mortality related to patients in the Kaiser Permanente Medical Care Program who had rigid sigmoidoscopy (9). Winawer et al used a combination of annual FOBT and sigmoidoscopy and found reduced cancer mortality when compared with controls (10). However, an examination of the incidence data demonstrates that only 28 of 144 cancer cases were found in the screening process. Although the combination of sigmoidoscopy and FOBT is likely to be more beneficial than either strategy alone, many cases of cancer will still not be detected in an early stage.

A large study by Imperiale et al looked at screening colonoscopy with particular emphasis on findings in the distal colon and its relation to colonoscopic findings in the more proximal colon (11). This has direct implications to the theoretical yield and inefficiencies of a sigmoidoscopy strategy. In this study of 1994 adults, the relative risk of proximal neoplasia was significantly greater (4.0, confidence interval 1.9 to 8.3) when adenomas were found in the distal colon. Although this would be favorable for sigmoidoscopic screenings, this study showed that only about half of the cases of advanced proximal neoplasia would be detected by a strategy that relied on findings in the distal colon, equivalent to the yield achieved with flexible sigmoidoscopy.

The important point to be learned from such studies is that any screening strategy that does not study the entire colon will miss lesions. The issue then becomes whether the incidence of missed lesions is acceptable, and who determines what is acceptable: the public, economic policy or expert-based guidelines.

Universal Screening Colonoscopy

With the inherent and proven inefficiencies of screening for colorectal cancer by FOBT, sigmoidoscopy, or the combination of the two, what proof is available that periodic colonoscopy offers a better solution? The concept of screening colonoscopy is not new. Rex et al first advocated it in 1991 on the basis of a study of 210 asymptomatic average-risk patients in which 53 patients (25%) were shown to have adenomas and 2 were found to have cancer (12). All of the patients had negative FOBT and only half of the lesions were distal enough to have been detected by sigmoidoscopy.

More recently, Lieberman et al published the results from a large multicenter study, enrolling 3121 patients from 13 Veterans Administration medical centers (13). Patients were excluded if they had a history of colonic disease or any colonic examination within the previous 10 years. Neoplastic lesions, comprising both adenomatous polyps and cancer, were found in 37.5% of patients. Their results were very similar to those of the small initial study by Rex et al in that about 1% of those undergoing colonoscopy were found to have cancer and about half of all lesions found in the proximal colon were without distal lesions, implying that they would have been missed with sigmoidoscopy. While the above studies are noteworthy, they lacked a control group and sufficiently long follow-up to determine whether colonoscopy saved lives. In order to bear on these issues, any such study would be an incredibly large undertaking and likely be deterred by ethical concerns. Intuitively, however, it seems clear that any approach that is more sensitive for the detection of adenomatous polyps and cancer, particularly when the latter is found at an early stage, should improve survival. Based upon the results of a 6-year cohort study by the National Polyp Study Workgroup, it has been shown that patients who have adenomatous polyps removed and then undergo surveillance colonoscopy have a significantly lower risk for cancer (14). Even though cancer was not totally prevented in this large

study (1418 patients and 8400 person-years), the five cancers that were detected on follow-up were all early-stage. This validates the concept that if adenomas are found by any technique, removal of the adenoma and subsequent surveillance are appropriate. However it does not answer the question of when follow-up examinations should be performed. The cancers in this study were found at 3 years and beyond; therefore, a repeat colonoscopy at 3 years seems to be a reasonable interval after removal of simple adenomas.

Safety Issues

Whether screening colonoscopy will be the preferred strategy offered to asymptomatic individuals 50 years and older involves a number of issues. Much has been written about the importance of colonoscopy screenings in the lay press, and patients are asking for this procedure. There are concerns, however, about safety when applied as a universal strategy. One of the attractive aspects of FOBT is the absolute safety. Clearly the safety of colonoscopy must be considered before advocating this for an entire population. The two most significant complications of the procedure are perforation and hemorrhage. Both complications are more often seen after polypectomy and are exceedingly rare after diagnostic procedures. Dafnis et al recently published data from 6066 colonoscopies done in a single county of Sweden from 1975 to 1995 (15). Bleeding occurred in 0.2% and perforation in 0.1% of procedures. These were procedures done for a variety of reasons, so it may not be applicable to a screening paradigm, but the numbers are so large that they do provide important safety data. If one looks specifically at the diagnostic colonoscopy (for example, procedures in which polypectomy was not involved), perforation occurred in 5 of nearly 4700 procedures, and bleeding did not occur at all. All of the cases in which perforation occurred involved the use of an overtube, a technique that is not commonly employed today.

Ochsner Clinic Foundation has recently reported colonoscopy safety data (16). In this retrospective review, 31 perforations occurred in 34,620 colonoscopies over 30 years, yielding an incidence of .09%. Again, most of the perforations occurred during therapeutic procedures. In discussions with patients, it is important that this small risk is clearly understood. Taken from the available recent literature, the risk of perforation from a screening diagnostic colonoscopy is probably less than 1 in 1000, and the risk of significant bleeding would be low as well, since most instances occur after polyp removal. There is a very small risk of complications from moderate anesthesia, including both cardiac and respiratory events.

Even a low risk of serious complications raises concerns when dealing with a universally applied screening method. The otherwise healthy asymptomatic patient who has a complication from a screening procedure now has a potentially serious problem. This is a unique aspect of colorectal cancer screening when compared with other well-accepted screening techniques. Mammography, Pap smears, digital rectal examinations, and prostate-specific antigen tests might entail some degree of discomfort but do not have any significant risk.

Medicolegal Issues

Unfortunately, medicolegal issues pertain to every aspect of medical decision-making, and colonoscopy is no different. The issues with regard to CRC screening neither favor nor condemn a particular method. A complication occurring during colonoscopy, the procedure with the highest risk for the patient, might prompt legal action, but a valid informed consent prior to the procedure should safeguard the endoscopist. Also to be considered is the fact that the most common reason that primary care doctors have malpractice claims filed against them is for "failure to diagnose," and it is certainly possible that a patient over 50 who is not offered colonoscopy and who subsequently is found to have a colon cancer might file a claim. Even more problematic would be the patient who receives one of the non-colonoscopy screening strategies currently recommended by Medicare, for example flexible sigmoidoscopy or air-contrast barium enema, and is subsequently found to have a right-sided colonic malignancy. Furthermore, it should be understood that even colonoscopy will not detect every lesion. Careful explanation of all strategies to the patient, along with the relative risks and sensitivities for detection, is well advised.

Manpower Issues

If hundreds of thousands or even millions of eligible Americans decide to undergo screening colonoscopy, does our current health care system have the capacity to perform all these procedures? Surgeons and gastroenterologists are specifically trained to perform colonoscopy and polypectomy. Many internists and family practitioners perform the procedure as well. I am not aware of current manpower studies to address the capacity of the American health care system, but it is likely that physician shortages will become evident as universal screening is applied. Although Maule demonstrated that nurse practitioners can safely and effectively perform flexible sigmoidoscopies (17), I do not personally believe that physician extenders will have a significant role in screening colonoscopy because the American public, aware of the small risk of serious harm, will probably demand that physicians perform the procedure. Most likely any increase in overall procedures will be absorbed into a system that is slightly growing in number and will rely on increased efficiencies within that system. Clearly the increased demand for colonoscopy will mandate increased system efficiencies.

Cost-Effectiveness

The discussion so far has shown that colonoscopy is a more accurate procedure than other screening strategies. In addition to the risk, however, it also carries a much higher price tag than other strategies. Several reports have addressed the cost-effectiveness of universal screening colonoscopy (18-20). Using a statistical model, Lieberman compared the cost benefit ratios of colonoscopy and other strategies and demonstrated a predictable trade-off (18). The inexpensive FOBT, assuming 100% compliance, had the greatest cost-effectiveness, as determined by cost per death prevented. Yet far fewer theoretical deaths were prevented when compared with colonoscopy, which also had a higher cost per death prevented ($274,000 for colonoscopy versus $225,000 for FOBT). In contrast, Sonnenburg, et al determined that screening colonoscopy every 10 years after age 50 was the superior cost-effective strategy (19). The initial cost was offset by the subsequent costs of medical care for cancers missed by annual FOBT and sigmoidoscopy. Frasier and associates found that the most cost effective strategy was annual rehydrated FOBT in addition to flexible sigmoidoscopy every 5 years (20). Importantly they found that, in general, colorectal cancer screening compares favorably in terms of cost-effectiveness to other accepted cancer-screening strategies. In their models, colonoscopy, as a one time screening procedure, had an incremental cost-effectiveness ratio of $22,400 per life-year saved, compared with $99,000 for annual Pap smears and $132,000 for annual mammography in women aged 55 to 64 years. One limitation of modeling studies, however, is that they make many assumptions regarding theoretical issues like compliance. It is difficult to imagine a randomized study with an adequate number of patients able to provide definitive data with regard to the relative cost-effectiveness or general effectiveness of screening colonoscopy versus another strategy. Therefore, despite their limitations, studies based on statistical models are likely to be those upon which decisions will be based. While more expensive, colonoscopy clearly seems to detect more cancers and falls within the normally accepted bounds of cost-effectiveness.

Patient Acceptance

Very few studies have specifically analyzed the importance of patient preference among the various screening strategies. Schoen et al interviewed 1221 patients after a flexible sigmoidoscopy (21). Approximately 70% of the patients were satisfied and found the procedure more comfortable than expected. An impressive 93% said they would be willing to have the procedure again. Of note, at this study center, the majority of the procedures were performed by nurse practitioners. A recent study from San Francisco compared virtual colonoscopy (CT colonography or VC) to traditional colonoscopy, again by questionnaires filled out by patients after undergoing both procedures on the same day (22). Patients generally tolerated both well, but they did report more pain and less respect when undergoing VC, as compared with standard colonoscopy.

The importance of this study lies in the fact that compliance is vital to the success of any screening strategy, and one can presume that compliance with colonoscopy will be directly linked to patient acceptance.

Insurance and Reimbursement

As described in the Balanced Budget Act and publication in the Federal Register, Medicare beneficiaries are currently insured for colorectal cancer screening with any of the approved methods, including colonoscopy every 10 years. Initially many physicians around the country claimed Medicare was not reimbursing them despite appropriate use of the GO105 Code. The initial problems seem to have been corrected. At the time of this writing there is variability among private insurers with regard to coverage for screening colonoscopy. (Ochsner Health Plan was one of the first private plans to cover screening colonoscopy.)

Alternative Prospects

Studies are underway to explore other methods of colorectal cancer screening, with an emphasis on noninvasive testing. Although FOBT is known to miss many cases of cancer, investigators at Mayo have recently reported on the testing of stool for a variety of genetic markers (23). This panel of assay targets included point mutations of K-ras, P53 and APC genes, and a microsatellite instability marker known as Bat-26. The stool specimens were taken from known cancer patients and also patients with adenomatous polyps and colons free of neoplasia. All stools yielded analyzable human DNA, and the assay had an impressive sensitivity for cancer detection (91%), interpreting in a blind fashion 20 of 22 cases of cancer. Of possibly more importance was the excellent sensitivity (82%) for the detection of large (> 1cm) adenomatous polyps. All of these patients had been previously negative for occult blood. Optimal sensitivity did require a full panel of DNA markers, as no one marker had sufficient yield. The authors acknowledge that the current assay and protocol is labor intensive and that the technique will need to be streamlined and subjected to larger clinical investigations.

Currently, patients undergoing VC, or CT colonography receive a bowel preparation similar to colonoscopy. They have a rectal tube placed to allow colonic insufflation and then rapid thin-section helical CT images are obtained. The subsequent image processing yields a series of images remarkably similar to those obtained at colonoscopy (Figure 1). Yee and colleagues have recently reported their findings at the University of California at San Francisco (24).

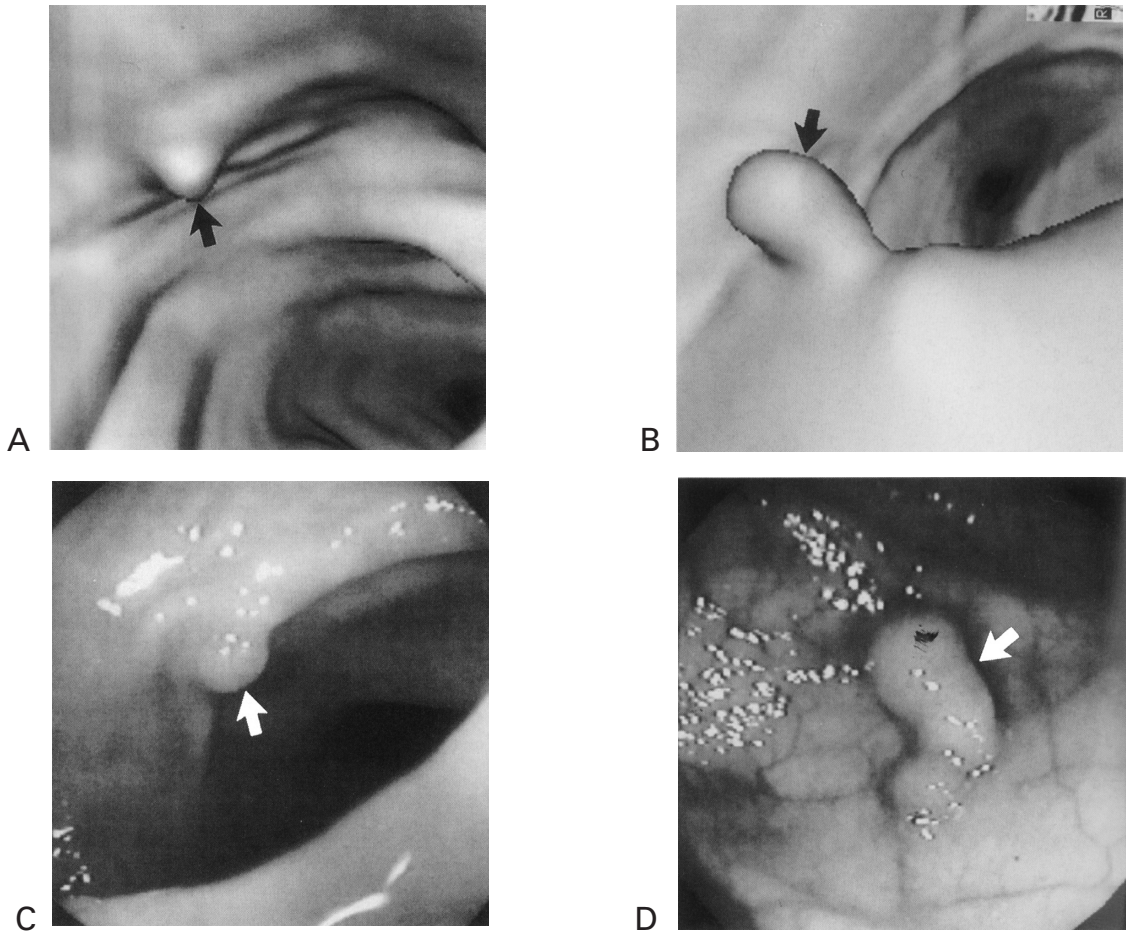

Figure 1. Findings from computed tomography (CT) virtual colonoscopy images (A, C) compared with corresponding colonoscopic photographs (B, D). Adapted with permission from the Radiological Society of North America (24), (Radiology 2001; 219:685-692).

Of the 300 patients who underwent scanning prior to colonoscopy, polyps were detected in 174 and 8 were found to have cancer. Of note, most of these patients were actually symptomatic; only 96 were there for screening purposes. CT colonography detected all of the cancers and 90% (74 of 82) of the polyps that were greater than or equal to 10 mm in diameter. The success rate was less for smaller polyps, although clearly the larger polyps are more important. Another benefit of this methodology lies in its ability to detect lesions outside the colon, clearly a feat unaccomplished by colonoscopy. In one study of 100 patients undergoing VC in Perth, Australia, 15% of patients were found to have extracolonic abnormalities, including clinically important ones such as abdominal aneurysms and renal tumors (25). It should be kept in mind that there are also several limitations to CT colonography. In the study by Yee, many false positive polyps were also detected (185 in 113 patients), which were mostly related to poorly distended or poorly prepared colons. Also, this technique yields many images and is labor intensive for the radiologist (averaging about 30 minutes for interpretation), a fact that may limit its application. Finally, as compliance remains an important issue for any screening method, the need for full colonic preparation (which most patients say is the worst part of colonoscopy), and the discomfort associated with insufflation, will continue to be problematic. Notwithstanding these areas of concern, we will likely see more clinical studies and ultimate application to patient screening. Undoubtedly there will be modifications and improvement in technique and software. Already the same group of investigators has reported on a technique that uses a contrast material that obviates the need for an intense colonic preparation (26). This technique was successful but required a 48-hour lead-time for multiple doses of the oral contrast.

Conclusion

The use of screening colonoscopy for average-risk individuals 50 years or more has arrived. It is unlike any other cancer screening method in that it is expensive, labor intensive, would be painful without the use of moderate anesthesia, and even involves a small but defined risk of serious complications. On the other hand, it is also a novel screening tool in that it not only has great accuracy for

detecting even small neoplasms but also has the real and proven ability to prevent cancer. It has been definitely shown that patients who have polyps detected and removed will rarely have cancer detected on subsequent surveillance examinations. The Gastroenterology section and Colon and Rectal Surgery Department at Ochsner Clinic Foundation have witnessed a dramatic increase in the number of procedures done purely for screening purposes. In 2000, for example, only 104 out of nearly 1500 colonoscopies were entered into the Gastroenterology Section's database as indicated for screening purposes. Last year this figure increased to 358 out of approximately 1900 examinations. Of note, in these 358 screening procedures, 90 (25%) had adenomatous polyps and none had cancer.

I believe the next several years will witness the increasing acceptance of screening colonoscopy by patients and primary care physicians, and I do not believe that virtual colonoscopy will have a great impact. However, research into detecting altered DNA markers in stool holds particular promise and may be used in a widespread fashion someday. This could ultimately allow screening colonoscopy to be used selectively in patients who are targeted as being at high risk for adenomatous polyps and cancer. Recently, the Ochsner Clinic Foundation has been enrolled as a study site for a multicenter study of the multitarget assay panel for stool specimens.

Currently, many issues are unresolved with respect to colonoscopic screening. For example, what is the appropriate interval between examinations? Guidelines from the Practice Parameters Committee of the American College of Gastroenterology suggest that patients at high risk for developing future polyps should have a follow-up procedure in 3 years (27). This would include patients with multiple adenomas, large lesions, adenomas with villous histology or significant dysplasia, and those patients with a positive family history of colorectal cancer. A follow-up examination of 5 years has been recommended for low-risk patients who did not meet the criteria above. But totally unsettled is the appropriate interval after a negative screening colonoscopy. Medicare guidelines advocate a 10-year interval, but other than modeling cost-effectiveness studies, I am not aware of other data to support this long an interval. I suspect the appropriate interval is indeed somewhere between 5 and 10 years and, hopefully, future studies will help clarify the optimal frequency.

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