

Potentially Serious Adverse Events at CT Colonography in Symptomatic Patients: National Survey of the United Kingdom¹

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Purpose:

To retrospectively determine the incidence of potentially serious adverse events associated with computed tomographic (CT) colonography performed in patients with symptoms of colorectal cancer.

Materials and Methods:

Ethical approval and informed consent were waived, since the study was deemed a clinical audit and patients would not be approached. With a national survey in the United Kingdom, all departments offering CT colonography in everyday practice were identified. The lead gastrointestinal radiologist from all responding departments was interviewed, and the frequency of potentially serious adverse events associated with CT colonography performed in patients with symptoms of colorectal cancer, the total number of examinations performed, and technical factors possibly related to perforation were determined. Where a potentially serious adverse event was encountered, it was explored in detail. Responses were collated, and raw frequencies were determined. Fisher exact test was used to determine differences in event rates between groups.

Results:

At 50 centers, 17 067 CT colonographic examinations (mean number per center, 359; range, 10–3000) were performed. No deaths were reported. Thirteen patients (one [0.08%] of 1313) had had a potentially serious adverse event related to the procedure. There were nine perforations: Four (44%) were asymptomatic and five (56%) were symptomatic, and perforation had an attributable cause, with a symptomatic perforation rate of 0.03% (one in 3413 patients). One patient required laparotomy. An inflated rectal balloon was used to perform 9378 examinations. There was no significant difference between the proportion of perforations associated with rectal balloon inflation ($n = 6$) and the proportion of those that were not ($n = 2$) ($P = .3$).

Conclusion:

Potentially serious adverse events related to CT colonography occurred in 0.08% of symptomatic patients.

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Computed tomographic (CT) colonography (virtual colonoscopy) is an increasingly used technology with which to examine the large bowel in both symptomatic patients (1) and patients undergoing screening for colorectal cancer (2). CT colonography has attracted considerable media and medical attention as a possible screening test for colorectal cancer because it may be as accurate as colonoscopy for detection of colonic adenomas (2) and patients generally prefer it instead of barium enema examination and colonoscopy (3–5). It has also been claimed widely that CT colonography is much safer than colonoscopy and, as such, is more suitable for implementation in a screening program (6). For example, in preparation for a national screening program in the United Kingdom, it has been estimated that 12 patients per annum would die as a consequence of colonoscopy-related adverse events (7).

Isolated case reports, however, are starting to emerge that suggest that CT colonography also is associated with potentially serious adverse events, particularly luminal perforation (8,9). The true incidence of serious complications associated with CT colonography currently is unknown. Although Sosna and co-workers (10) found nine perforations in 24 365 examinations, suggesting a rate of 0.04%, these abstracted data were obtained by questioning in-

ternationally visible experienced radiologists and may be subject to selection and spectrum bias. For example, there is evidence that colonoscopy-associated adverse events are more frequent in nonspecialist and/or nonacademic centers (11). The same scenario may well apply to CT colonography.

The aim of our study was to retrospectively determine the incidence of potentially serious adverse events associated with CT colonography performed in patients with symptoms of colorectal cancer.

Materials and Methods

Several authors (D.B., S.H., and S.A.T.) are remunerated consultants for Medic-sight, London, England, a computer-aided diagnosis software development company. One author (S.A.T.) holds a research agreement with E-Z-Em, London, England.

Collection of Data

Radiology departments offering CT colonography in routine day-to-day clinical practice were identified by interrogating the database produced with a prior postal questionnaire survey of all radiology departments in the United Kingdom. This postal survey aimed to determine the total number of departments that offered CT colonography in everyday clinical practice and details of their service and experience (12). In brief, all 216 United Kingdom National Health Service hospitals that offered radiology service for adults were identified through the database held by the Royal College of Radiologists.

A questionnaire was posted to the clinical director of each department in February 2003, and in the questionnaire, each respondent was asked for details of any CT colonographic service. We asked that the questionnaire be completed by the clinical director or the lead radiologist with a subspecialty interest in gastrointestinal radiology, if the latter was believed to be more appropriate. We received a response from 138 (64%) of 216 departments, which is an acceptable response rate for surveys of this type (13). Of these departments,

50 (36%) provided CT colonography as part of everyday clinical practice, and details of this information have been published previously (12).

All the patients in this survey underwent CT colonography for symptoms that might have been attributable to colorectal cancer. For example, these symptoms included a change in bowel habits, rectal bleeding, and weight loss. There were no patients who were undergoing screening, which was not offered at that time by the United Kingdom National Health Service. Ethical approval and informed consent were waived for this survey because the review board considered it a clinical audit rather than a research study; patients would not be approached, nor would their normal care be altered. The review board stipulated, however, that no details of patients' ages or sex be revealed.

For the purpose of the present survey, we attempted to contact by telephone the lead gastrointestinal radiologist from each of the previously identified 50 centers at which CT colonography was practiced. The lead gastrointestinal radiologist from each center was questioned in February 2005 by one of two radiologists (D.B. contacted 30 centers and A.S. contacted 20 centers) who both had extensive experience in performing CT colonography (200 and 100 cases, respectively) and interpreting the findings (600 and 150 endoscopically validated cases, respectively). The radiologists asked a series

Advances in Knowledge

- The incidence of potentially serious adverse events for CT colonography in patients with symptoms of colorectal cancer was 0.08%.
- The incidence of symptomatic colonic perforation associated with CT colonography was 0.03% (overall perforation rate, 0.05%).
- The occurrence of symptomatic luminal perforation associated with CT colonography performed in day-to-day clinical practice in patients with symptoms of colorectal cancer is more than four times lower than is that published for colonoscopy.

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Guarantor of integrity of entire study, S.H.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, D.B., S.H., S.A.T.; clinical studies, D.B., M.J.N.; statistical analysis, S.H.; and manuscript editing, D.B., S.H., S.A.T.

See Materials and Methods for pertinent disclosures.

See also the article by Sosna et al and the editorials by Pickhardt and Dachman in this issue.

of six questions that were read from a study sheet (Table 1). In particular, the radiologists asked how many serious adverse events (including the number of deaths), if any, the respondents had experienced in their department and the total number of examinations performed at the time of the present survey. This procedure was followed so that we had both the numerator and the denominator to determine the potentially serious adverse event complication rate associated with CT colonography.

We also asked additional questions related to those aspects of the technique that could possibly influence perforation rates, namely, whether a rectal balloon was inflated *in situ* and whether an automated insufflation device was used (Table 1). We were particularly interested in luminal perforation (rectal and colonic) but asked for details of any potentially serious adverse event. We defined a potentially serious adverse event as either luminal perforation, where gas was observed beyond the bowel wall, or any other complication that required a period of observation before the patient was thought to be able to leave the department safely.

If a serious adverse event had been identified, the lead gastrointestinal radiologist from the respective center was contacted again (D.B.), and further questions related to the adverse event were asked in detail. In particular, we asked questions about characteristics related to the adverse event in question as follows: diagnosis, clinical severity, treatment, and ultimate clinical outcome of the patient. We also asked for details about the anatomic distribution of gas in those patients with luminal perforation (specifically whether this distribution was retroperitoneal, intraperitoneal, or both) so that we could determine the theoretical risk of fecal peritonitis.

Statistical Analysis

Responses were collated and tabulated, and raw frequencies were determined. The Fisher exact test was used to determine differences in the proportion of cases of perforation encountered

among centers at which an inflated rectal balloon catheter was used and those at which one was not used and the differences between research ($n = 3$) and nonresearch ($n = 47$) centers. Research centers were defined as those at which investigators had published peer-reviewed indexed articles relating to CT colonography and were identified by performing a Medline search of articles about CT colonography published over the past 10 years. All other centers were categorized as nonresearch centers. Statistical significance was assigned to a probability value of 5% or less, and analysis was performed by using software (Stats Direct, version 2.4.4.; Stats Direct, Sale, Cheshire, England).

Results

Contacts and Response Rate

The lead gastrointestinal radiologist at all 50 centers who responded to the initial survey and offered CT colonography in day-to-day practice, as noted previously, was contacted successfully; the response rate was 100% for the present survey. Of these, 47 centers still offered CT colonography in routine clinical practice; at the remaining three, this service was no longer offered, but re-

spondents could not recall any serious adverse events related to CT colonography.

Examinations Performed

In total, 17 067 CT colonographic examinations had been performed at the 50 centers (mean number per center, 359; range, 10–3000); at 36 (72%) centers, a total of 100 examinations or more had been performed. At the time of our telephone survey, on average, at five (10%) centers, more than one examination per day were performed; at 21 (42%), one examination per day was performed; at 14 (28%), one examination per week was performed; at seven (14%), one examination per month was performed; and at three (6%), CT colonography was no longer performed.

Potentially Serious Adverse Events

No deaths were reported. Thirteen (one [0.08%] in 1313) patients had experienced potentially serious adverse events believed to be related to CT colonography. Of these, there were three self-limiting vasovagal episodes and one attack of cardiac angina, which was successfully treated with sublingual glyceryl trinitrate spray. All patients were discharged to their homes after a period of observation and were apparently well. There were nine luminal perforations,

Table 1

Telephone Questionnaire for a Study of Complications Associated with CT Colonography

Question	Possible Responses
Approximately how many CT colonographic studies does your department perform on average at the moment?	More than one per day, one per day, one per week, or one per month
Approximately how many CT colonographic studies has your department performed in total?	Total given
How frequently does your department use inflated rectal balloon catheters for CT colonography?	Never, occasionally (please give an approximate percentage), or always
Does your department use an automated colonic insufflation device?	Yes or no
To the best of your knowledge, has bowel perforation related to CT colonography occurred?	Yes (please give number) or no
To the best of your knowledge, has there been any other serious adverse event associated with CT colonography? For example, have there been reactions to intravenous contrast or spasmolytic agents	Yes (please give number) or no

with a perforation rate of 0.05% (one in 1896 patients). Nine perforations occurred at six centers. At all six centers, a total of 100 or more examinations had been performed, and, collectively, these centers contributed 6500 (38%) examinations to the total number of CT colonographic examinations performed. The individual circumstances for nine patients with perforation are summarized in Table 2. In five (56%) of nine patients, perforation had an attributable cause as follows:

1. A radiologist resident, believing he was examining the distal limb of a loop colostomy (surgical details were not communicated on the request form), actually

inflated a rectal stump. Perforation occurred at the suture line at the apex of the rectal stump (patient 1).

2. A rectal catheter was forcibly inserted through apparently normal rectal wall by a radiographic technician, and, thus, perforation was caused (patient 6).

3. Transverse colonic perforation occurred in a patient who underwent CT colonography and who had previously undiagnosed ulcerative colitis (patient 7).

4. An obstructive sigmoid colonic carcinoma was believed to be the underlying cause of a sigmoid colonic perforation (patient 8).

5. Perforation was discovered on a

plain radiograph in a 72-year-old woman (patient 9) with multiple comorbidities, including known diverticular disease and rheumatoid arthritis treated with nonsteroidal antiinflammatory drugs. She did not feel well, and abdominal radiography performed before CT colonography revealed intraperitoneal gas. Perforation was deemed to be precipitated by bowel preparation. This patient did not therefore undergo CT colonography.

Eight perforations were discovered during or after the CT procedure (with one exception [patient 9]). Four (44%) patients with perforation were entirely asymptomatic (patients 2–5). In these

Table 2

Details of Nine Patients With Luminal Perforation Related to CT Colonography

Patient No.	Center No.	Catheter	Gas	Insufflation Method	Operator	Site of Perforation	Distribution of Gas	Attributed Cause of Perforation	Associated Symptoms	Treatment
1	1	28-F Foley, balloon inflated	Air	Manual	Radiologist resident	Rectum	Retroperitoneal	CT colonography inadvertently performed on a rectal stump	Abdominal pain	Conservative treatment as inpatient
2	2	Plastic enema tip	Air	Manual	Radiologist	Ascending and transverse colon	Intraperitoneal	No obvious cause	Asymptomatic	Conservative treatment at home
3	2	Plastic enema tip	Air	Manual	Radiologist	Descending colon	Retroperitoneal	No obvious cause	Asymptomatic	Conservative treatment at home
4	3	Retention balloon catheter	CO ₂	Automated	Radiographic technician	Cecum	Intraperitoneal	No obvious cause	Asymptomatic	Conservative treatment at home
5	3	Retention balloon catheter	CO ₂	Automated	Radiographic technician	Cecum	Intraperitoneal	No obvious cause	Asymptomatic	Conservative treatment at home
6	4	Retention balloon catheter	Air	Manual	Radiographic technician	Rectum	Retroperitoneal	Rectal catheter forcibly inserted through normal rectal wall	Rectal pain	Conservative treatment as inpatient
7	4	Retention balloon catheter	Air	Manual	Radiographic technician	Transverse colon	Intraperitoneal	Active ulcerative colitis	Abdominal pain with peritonitis	Conservative treatment as inpatient
8	5	Retention balloon catheter	Air	Manual	Radiologist	Sigmoid colon	Intraperitoneal and extraperitoneal	Obstructive sigmoid colon cancer	Abdominal pain with peritonitis	Laparotomy
9	6	Nil	Nil	Nil	Nil	Unknown	Intraperitoneal	Bowel preparation	Abdominal pain	Conservative treatment as inpatient

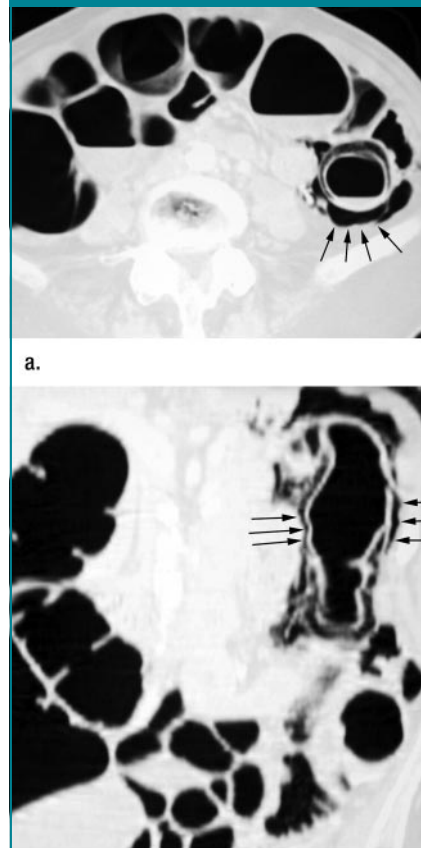
four patients, extraluminal gas was discovered incidentally by the reporting radiologist between 6 hours and 4 days after the procedure. All four patients, feeling well, had returned home and were subsequently contacted and treated at home conservatively. Thus, the symptomatic perforation rate was 0.03% (one in 3413 patients). Because of the lack of an attributable cause in these four patients, it was difficult to establish the exact site of perforation. Extraluminal gas was located intraperitoneally surrounding the cecum in two patients, it was located intraperitoneally surrounding the ascending and transverse colon in one patient, and it was located retroperitoneally in the descending colon in one patient (Fig 1).

One patient with carcinoma of the sigmoid colon that had been diagnosed at CT colonography (patient 8) underwent laparotomy because of peritonitis, fear of tumor perforation, and the knowledge that surgery would be required to treat the underlying tumor, in any event (Fig 2). Eight (89%) patients with perforation were thus treated conservatively as either inpatients or outpatients (Table 2). To the respondents' knowledge, all patients with perforation were alive and well at the time of our survey.

Use of Rectal Balloon Catheter

At 29 (58%) centers, an inflated balloon catheter was never used; at seven (14%) centers, one occasionally was used (on average, for 14% of the examinations at these centers when anal incontinence was encountered; range, 1%–50%); and at 14 (28%) centers, one was always used. At these 14 centers, the balloon catheter used at nine centers was a rectal retention catheter, and that used at five centers was an inflated Foley catheter. Overall, 9378 CT colonographic examinations were performed by using an inflated balloon in the rectum, and among these, there were six perforations. Further, 7689 CT colonographic examinations were performed without an inflated balloon, and among these, there were two perforations. One patient in our survey (patient 9) did not have a rectal catheter in-

Figure 1



b.

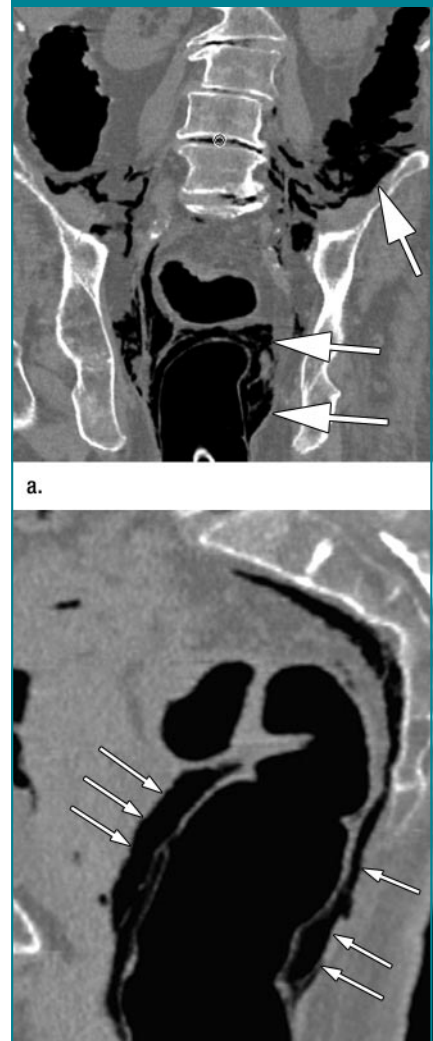
Figure 1: Patient 3. (a) Transverse and (b) coronal CT colonographic images (supine acquisition) in female patient with retroperitoneal perforation. Arrows outline extraluminal retroperitoneal air surrounding descending colon. The patient was entirely asymptomatic and required no treatment. No obvious cause for perforation was indicated.

serted, since CT colonography was abandoned because of perforation attributed to bowel preparation. There was no significant difference in the proportion of perforations associated with and without rectal balloon inflation ($P = .3$). Overall, at six (12%) centers, an automated insufflation device was used. Two perforations were associated with CT colonography performed with automated insufflation (patients 4 and 5).

Research and Nonresearch Centers

Investigators at three (6%) of 50 centers had published peer-reviewed in-

Figure 2



b.

Figure 2: Patient 8. (a) Sagittal and (b) coronal CT colonographic images (prone acquisition) in female patient with intra- and retroperitoneal perforation. Arrows outline retroperitoneal air seen surrounding the rectum and extending around both ascending and descending colon in a and around only the rectum in b. This was attributed to a sigmoid colonic carcinoma (not shown); the patient underwent laparotomy, at which the primary tumor was removed.

dexed articles that were related to CT colonography, and at one of these centers, two perforations occurred (Table 2, center 3). These three centers contributed 4350 patients to the total of 17067. There was no significant difference in the proportion of perforations

originating from research and nonresearch centers ($P = .82$).

Discussion

There have been previous attempts to establish the frequency of adverse events associated with colonography. For example, minor complications in 12 (3.5%) of 343 asymptomatic patients were reported at one center (6). Although CT colonography was initially believed to be free from serious adverse events because of its relatively noninvasive nature, the publication of two case reports that detailed colonic perforation associated with CT colonography (8,9) raised the possibility that potentially serious adverse events could occur. Sosna and co-workers (14) obtained data from three centers and suggested that CT colonography was associated with a perforation rate of 0.04% (one of 2393 examinations). These authors extended their work to include 21 centers, identified by international visibility, across seven countries and found nine perforations in 24 365 examinations (perforation rate, 0.04% [one in 2707 patients]): Five of these perforations required laparotomy (10).

Surveys directed toward specialist units, however, are inevitably subject to considerable selection and spectrum bias, and although they reflect the complication rate in these centers, they do not necessarily reflect the true incidence of potentially serious adverse events. As a case in point, in a survey of 3196 colonoscopic examinations performed as part of a research study to investigate procedural success and complications, total intubation was reported to have been achieved in 97.2%, with no perforations or deaths (15). In contrast, a United Kingdom audit of day-to-day clinical practice in 68 predominantly nonspecialist units (11) revealed total intubation rates of approximately 50% and 12 perforations in 9223 examinations (one [0.13%] of 769 examinations). In fact, colonoscopy was implicated as a possible factor in six (0.07%) deaths that occurred within 30 days of the procedure (11). To circumvent selection bias, we surveyed 50 centers

that were known to be practicing of CT colonography. Investigators at only three (6%) of these centers had ever published data in peer-reviewed journals and so would have been identifiable as practitioners through a literature search. Seven (78%) of nine perforations that we identified originated from other centers.

We concentrated our efforts on potentially serious adverse events in patients with symptoms of colorectal cancer and found that these were uncommon and occurred in 0.08% of patients examined. Of these serious adverse events, the majority were luminal perforations and occurred in 0.05% of studies performed; five (0.03%) perforations were symptomatic. These findings compare favorably with results of routine day-to-day colonoscopic practice performed in the same or similar hospitals, where the symptomatic perforation rate appears to be more than four times greater (ie, 0.13%) (11). A United Kingdom survey of the practice of day-to-day double-contrast barium enema examinations revealed that there were 30 perforations in 738 216 studies (one [0.004%] per 24 607) (16), but the consequences of barium-related peritonitis are likely to be more devastating than are those of a perforation that occurs during CT colonography; 10% of patients with barium-related peritonitis died (16). The symptomatic perforation rate that was associated with CT colonography was 0.03%; four perforations were entirely asymptomatic.

It should be borne in mind that CT colonography is exquisitely sensitive for extraluminal gas. Colonoscopy cannot depict extraluminal gas and so cannot depict an asymptomatic perforation, and a barium enema examination will inevitably also be less sensitive than is CT. As a result, lack of depiction at colonoscopy and, to a lesser extent, at barium enema examination will lead to an underestimation of the true perforation rate, because asymptomatic perforations generally will be undetected. Moreover, half of the colonoscopy-related perforations in the audit discussed previously were not recognized at the time of colonoscopy, perhaps because

the patients' symptoms were masked by intravenously administered sedatives. For this reason, the most relevant comparison between perforation rates for CT colonography and those for colonoscopy may actually be 0.03% versus 0.13%; that is, the symptomatic perforation rate seems to be 4.3 times lower for CT colonography. It should be noted that our survey and the colonoscopic comparator (11) were performed in the same and similar hospitals.

With respect to the occurrence of perforation during double-contrast barium enema examination, it has been estimated that the frequency is increased by a factor of 2.5 when retention balloon catheters are used (17), possibly because of their diameter (20 mm), radial force when expanded, and relatively stiff construction. In our survey, one such catheter was forcibly inserted through the rectal wall, and a balloon retention catheter was employed in 56% of the perforations that we encountered. It has been suggested that, if they are to be used, these wide-bore stiff plastic catheters should be inserted carefully by an experienced radiologist by using fluoroscopic guidance and then only after rectal examination (17). Given that these catheters do not substantially benefit CT colonography (18), their routine use should probably be discouraged. Although we were unable to demonstrate a marked association between balloon inflation and perforation, it should be noted that the event rate (ie, perforation rate) was low, and we likely lacked the statistical power to confidently exclude an association.

Some workers recommend automated insufflation devices to improve colonic distention and reduce postprocedural abdominal pain, since these devices utilize carbon dioxide rather than room air (19–21). These devices also allow rectal pressure to be monitored, and they cease insufflation if rectal pressure increases to more than 25 mm Hg. We encountered two perforations with use of these devices, and both were cecal; the cecum is the colonic segment most prone to perforation. Further research for quantification of the intraluminal pressures generated by auto-

ated insufflation devices in different colonic segments should be undertaken.

A number of the perforations that we encountered could potentially have been avoided. For example, one perforation occurred because the postsurgical anatomy was not fully appreciated; thus, we emphasize that it is important to have relevant information available. A relatively inexperienced technician forcibly perforated the rectum, an occurrence that leads us to emphasize that rectal insertion is potentially dangerous, and practitioners need to be aware of this possibility and need to be appropriately supervised where necessary. Intuitively, one might have anticipated an increased number of perforations at centers where experience with CT colonography is limited. All the cases of perforation, however, occurred at six centers at which, collectively, 38% of the total number of examinations had been performed. One possible explanation is that at centers at which large numbers of CT colonographic examinations were performed, the task of colonic distention was more likely to have been delegated to less experienced members of the team who may have been less careful when they inserted the rectal catheter, inflated the balloon, or distended the colon.

Among five perforations discovered during or after CT colonography, perforation occurred during two examinations performed by radiographic technicians and perforation occurred during one examination performed by a radiology resident. Perforation was caused by underlying disease, ulcerative colitis and a sigmoid colon carcinoma, in two patients. It would have been difficult to prevent these complications in advance because the underlying disease was unknown. We must emphasize that images obtained at the initial acquisition, whether performed with the patient in a prone or supine position, should be scrutinized for disease, and care should be taken when disease is discovered. There has been a previous case report of perforation that was associated with inflammatory bowel disease (9). This association, coupled with the fact that many patients with inflammatory bowel

disease are young, and the considerable difficulties that are inherent in distinguishing dysplasia from regenerative epithelium, suggest that CT colonography is best avoided in this clinical scenario. Overall, in the four cases of symptomatic perforation discovered during CT colonography (Table 2), perforation was potentially preventable in three (75%).

Although we attempted to circumvent selection bias, there were limitations to our study. Most notably, such retrospective surveys, valuable as they are, are based on self-reported practice and are, therefore, subject to recall bias. For this reason, we chose to focus on serious complications associated with CT colonography, not only because it is most important that these complications are reported in the peer-reviewed literature but also because they are more likely to be recalled accurately than are minor complications. For example, we found that the radiologists who reported potentially serious adverse events were very clear about the details of each case. It is also important to emphasize that this survey relates to a symptomatic population, in which the proportion of elderly and frail patients is overrepresented; for example, cardiac angina, as we encountered, is unlikely to be present in younger patients. It is possible that potentially serious adverse events would be reduced substantially in a younger asymptomatic screening population, in which the prevalence of any abnormality is decreased. With a prospective design, we would have been able to control recall bias and potential confounders, such as the size of the catheter and the balloon used, the experience of the individual who performs the insufflation, and the use of spasmolytic agents.

In summary, we found potentially serious adverse events that were associated with CT colonography in 0.08% of patients when it was used to investigate patients with symptoms of colorectal cancer. The rate of occurrence of symptomatic luminal perforation, however, was more than four times lower than were equivalent rates published for colonoscopy. Some complications of

CT colonography are potentially avoidable. When potentially serious adverse events occurred, they were treated conservatively, with a successful outcome in most cases.

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