

PRACTICE OF MEDICINE

Advice Regarding Reduction of Malpractice Risk in Colonoscopy

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Introduction

Whether or not a medical malpractice lawsuit is filed often has more to do with the outcome of a procedure, the physician's relationship with the patient, and the patient's attitude than it does with whether a procedure was performed in a negligent manner. Therefore, this article contains advice about how to best put yourself in a position that can be defended well should you be sued regarding the performance of a colonoscopy, rather than advice about how to keep from being sued for the performance of colonoscopy. The following advice is also good medical care and is in the best interests of patients.

These recommendations are anecdotal in nature, and are based primarily on my experience as an expert witness in malpractice cases involving the performance of colonoscopy. The recommendations are also based on my own experience as a colonoscopist, and what I and others have written regarding quality in the technical performance of colonoscopy.¹

The two areas which, in my experience, have created the most medicolegal difficulties for colonoscopy are perforation and missed lesions. The recommendations that follow highlight measures that address the most frequent areas where colonoscopists are alleged to be at fault in malpractice actions. Postpolypectomy bleeding—which seldom results in a serious outcome—and sedation reactions are rare causes of malpractice action, and therefore are not included in this discussion.

Although some of these elements of advice may be considered to represent defensive medicine, I also believe them to represent good medicine.

Recommended Measures

Obtain Informed Consent for Missing Cancer and Adenomas

By now, most gastroenterologists must be aware that colonoscopy and sigmoidoscopy have imperfect sensitivity.²⁻⁶ Tandem colonoscopies reveal that the miss rate for small adenomas is on the order of 25% and for large adenomas, 0–6%.^{2,3} However, recent studies using computed tomography (CT) colonography and so-called segmental unblinding as the gold standard demonstrate miss rates of 12–17% for large adenomas using conventional colonoscopy.^{4,5} Optimal colonoscopic withdrawal technique has been discussed elsewhere.⁶ Miss rates for cancers are lower: in a large study, the overall miss rate of colonoscopy was 5%, but only 3% among gastroenterologists.⁷ While there was variation among gastroenterologists, the majority had a miss rate for cancer of 1% or lower. The negative predictive value for cancer with colonoscopy is almost certainly very high.

Despite these low miss rates, there is increasing evidence that a significant number of patients will present with an incident cancer within a few years after a colonoscopy that had apparently cleared the colon of adenomas.⁸⁻¹⁰ In these studies, the endoscopists appeared to be well-trained experts. Such findings point to the fact that colonoscopy is not perfectly protective against the development of colorectal cancer, even when it is performed by experts. Thus it is appropriate that patients share the risk associated with an imperfect technology.

How this situation is handled in the informed consent process is up to the individual endoscopist. At Indiana University, informed consent statements include the term “missed lesion.” An optional term would be “missed cancer.” In my experience with malpractice actions alleging inadequate observation during colonoscopy, I almost invariably find that the informed consent statement contained nothing written about the possibility of a missed lesion.

A second common question is what to tell the patient regarding the probability of a missed lesion. Ideally, physicians should convey the risk of a specific poor outcome according to their own experience; however, many physicians may not have enough accumulated experience to

know their chance of a missed cancer, or may have never had a missed cancer in clinical practice. In the absence of a quote of the probability based on one's own experience, one can quote the published 1% chance of a gastroenterologist using careful colonoscopy technique missing a cancer (if one is present), or the more general number of 5% as the overall risk,⁷ the latter of which includes the risk of cancers not detected because the cecum (and the cancer) was not reached during insertion. Rather than quoting numbers to patients with regard to the risk of missing a cancer, I tell patients: "This test is the best test available for examining the colon but it is not perfect. Rarely, it can miss something important."

It goes without saying that if the cecum has not been reached in a patient who is either symptomatic or in whom the test has been performed for a non-screening indication, the colonoscopy must either be repeated or a radiographic test to complete evaluation of the colon must be ordered.

Document the Extent and Quality of the Examination

Specific quality indicators for colonoscopy have been recommended by the US Multi-Society Task Force on Colorectal Cancer and the American Society for Gastrointestinal Endoscopy.¹ The cecum should be documented both by observed landmarks and by photography.¹¹ The specific landmarks that should be named are the appendiceal orifice and ileocecal valve as a minimum, and it is also useful to mention that the cecal strap fold has been seen, and the terminal ileum intubated if that was done (the standard of medical care does not require intubation of the terminal ileum during routine colonoscopy). It is unwise to say only that "the cecum was intubated" or the equivalent of that. Rather, the specific cecal landmarks should be noted in the report.

A competent colonoscopist can recognize the cecum with 100% certainty. However, that certainty relies fundamentally on identification of the landmarks. There is no other part of the gastrointestinal tract that has the appearance of the cecum in real time.¹¹ Without exception, correct identification of the ileocecal valve, the appendiceal orifice, and the strap fold, with or without terminal ileal intubation, has perfect sensitivity and specificity for correct identification of the cecum. However, the landmarks should be specified in the report.

The wise endoscopist obtains photographs of the cecum. Several photographs could be obtained, including the terminal ileum, the appendiceal orifice, and the cecum from just distal to the valve. The two most useful photographs to obtain are the appendiceal orifice and the cecum from just distal to the valve. Photographing the appendiceal orifice helps to document that the medial wall of the cecum was well visualized. The photograph



Figure 1. The appendiceal orifice and strap fold as seen during colonoscopy.

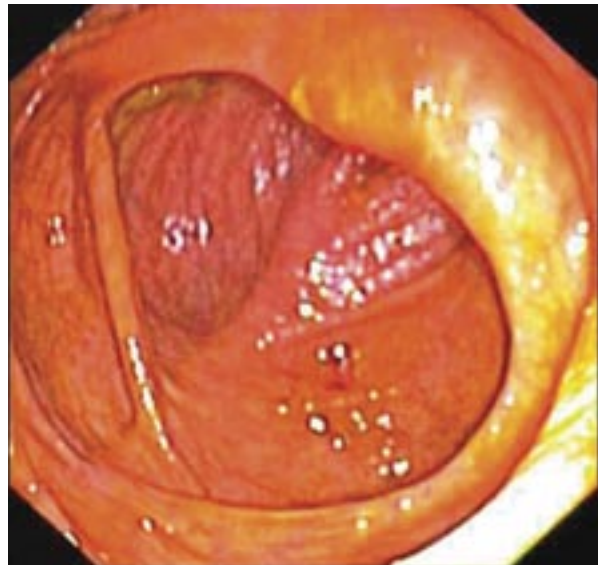


Figure 2. The cecum as seen from just distal to the ileocecal valve.

should be taken from far enough away that the appendiceal orifice does not appear to simply be a diverticulum. In general, if the strap fold or triangular folds around the appendiceal orifice can be visualized, the photograph will be of high quality (Figure 1). The second photograph from just distal to the ileocecal valve is overall the most convincing photograph (Figure 2), but a photograph of the appendiceal orifice demonstrating that the scope tip reached into the cecal caput is also useful. A photograph

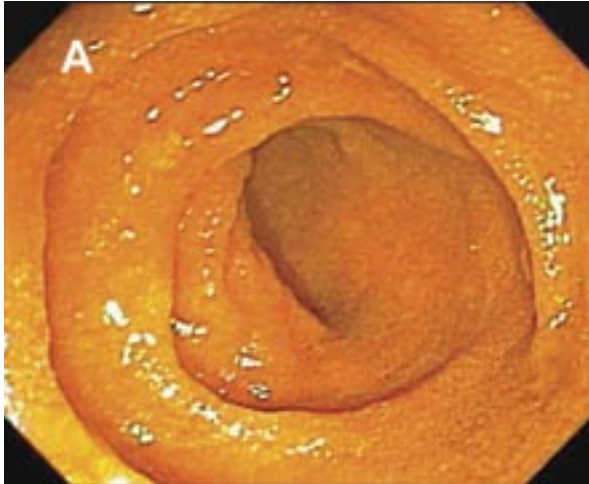


Figure 3. Terminal ileum photographs are most convincing when they demonstrate circular valvulae conniventes (A) or lymphoid hyperplasia (B).

of the terminal ileum is sometimes useful if circular valvulae conniventes (Figure 3a) are shown, or if it shows a villous pattern to the mucosa lymphoid hyperplasia (Figure 3b). However, in many cases the terminal ileum has the endoscopic appearance of the sigmoid colon, a relatively narrow tube with a colonic-appearing vascular pattern and villi that are not prominent.

If a patient presents with a tumor in the cecum or the ascending colon in a short interval after performance of a colonoscopy, then in a malpractice trial the plaintiff's expert will usually allege that the cecum was never intubated. Good documentation of cecal landmarks and cecal photography eliminates this argument.

It is also useful to document the duration of the examination and the length of withdrawal. The length of withdrawal can be used to monitor the quality of exami-

nation in the continuous quality improvement program, and it has been recommended that examination times in normal colonoscopies should average 6 minutes or more.¹ In individual cases, a careful examination can be performed in less than 6 minutes, but until better data are forthcoming the 6 minute rule serves as a general guide for careful withdrawal examination. For the examiner who uses careful technique, it is also appropriate to state in the body of the colonoscopy report that such technique was utilized. For example, the report might state: "During withdrawal, careful attention was paid to the proximal sides of folds, flexures, bends, and the rectal valves. A careful and meticulous examination was performed." Juries understand that medical technologies are imperfect. However, they expect that medical procedures will be performed with a caring approach and with high-quality technique. It is useful from a medicolegal standpoint to document that this approach was taken to colonoscopy.

I also recommend a photograph of the rectum in retroflexion. The standard of medical care does not require retroflexion in every case, since the rectum is sometimes narrow and retroflexion with a standard instrument may be difficult. In such cases, it may be appropriate to take a forward view of the rectum from the dentate line, particularly a view that shows that the rectal walls can be seen sloping away from the scope tip circumferentially.

It is also reasonable to obtain photographs of one or more polyps. If large polyps are removed by electrocautery, it can be useful to take a photograph of the polyp site before and after polypectomy. A reasonable looking polypectomy site after removal of a polyp can help to defend any subsequent polypectomy-related perforation. There is no requirement that every polyp or every polypectomy site needs to be photographed.

Never Release a Patient From the Recovery Room Postcolonoscopy in Severe Pain

Most pain after colonoscopy is due to air distention. However, it is quite possible for a perforation to manifest itself as pain either during the procedure or as the patient wakes up. Pain related to perforation will generally not improve, whereas pain related to gas distention will typically improve as the patient passes flatus.

The recovery room nurses must understand that they should not release a patient who complains of severe pain. The patient should be examined by a physician and if he or she appears to be distended, it is reasonable first to have the patient change positions in bed, walk around with the assistance of a nurse or family members, or sit on the toilet and attempt to pass gas. Some endoscopists place a rectal tube in this situation. Once the patient appears to be relieved, it is safe and reasonable to discharge them. The

patient who is unable to pass gas and who is distended on examination should be taken back to the procedure room and deflated colonoscopically. The use of carbon dioxide, of course, will generally obviate the need for the occasional decompression of air postcolonoscopy.¹²⁻¹⁴

If the patient persists in having pain after decompression or after passing considerable flatus, something is likely to be wrong. Plain abdominal x-rays can be taken or the patient can proceed directly to CT scanning. If plain abdominal x-rays are negative and the pain persists, the patient should undergo a CT scan. Likewise, a patient with persistent severe pain postcolonoscopy should be admitted for observation if a diagnosis cannot be made, particularly in the case of a patient who has undergone polypectomy using electrocautery.

Treat Persistent Postprocedure Pain as an Emergency

Instructing patients with persistent pain after a colonoscopy to go to the emergency room should be the general guideline for you, your partners, your nurses who take postprocedure phone calls, and, in an academic program, your gastroenterology fellows who take postprocedure phone calls. It is a mistake to attribute pain that persists for many hours after colonoscopy to retained gas, even though in fact that may be the cause. Perforation should be assumed until proven otherwise. Likewise, it is inappropriate to give a patient enemas for persistent postprocedure pain. Sometimes the lack of a bowel movement after colonoscopy suggests that enemas may help to produce relief; however, it is generally expected that patients may not have a bowel movement for 2–3 or even more days postcolonoscopy because there is little or no stool in the colon. Furthermore, lack of a bowel movement could reflect ileus related to perforation. Enemas are not going to help a perforation.

Once the patient goes to the emergency room, be sure that the emergency room physician knows to call you and be certain to obtain at that time all of the necessary information regarding the patient. This information should include the level of the patient's pain, whether the pain has remained steady, improved, or worsened as the result of the physical examination, the complete blood count with differential, and the results of any x-rays that are obtained. Remember that this is your patient and be very suspicious of any emergency room physician who believes that a patient with persistent pain postcolonoscopy should be released from the hospital. The general rule is that if a patient has persistent pain and the plain films are negative, an abdominopelvic CT scan should be obtained. Plain films are far from being perfectly sensitive for perforation, particularly localized perforation.

The CT scan is much more sensitive, but even this technology has imperfect sensitivity. It is possible for a

localized perforation into the leaves of the mesentery to be associated with virtually no free air. The key factor in determining a course of action is whether the patient has persistent significant discomfort. If so, the patient should be admitted for observation. The total white blood cell count and differential are useful pieces of adjunctive information, particularly if abnormal. Normal values should not deter you from observation of a patient with persistent pain. During observation, patients should ingest nothing by mouth, intravenous antibiotics should be given if there is suspicion of postpolypectomy syndrome, serial history should be taken, and a physical examination and laboratory tests should be done, and if needed, repeat abdominopelvic CT scan.

In summary, for a patient in the emergency room with severe and persistent pain postprocedure, evaluation and treatment must be aggressive. For patients with presumed postpolypectomy syndrome or in whom there is evidence of localized perforation but a trial of conservative therapy is to be attempted, CT scan, surgical evaluation, and close observation are the mainstays of proper management.

It is very difficult for a plaintiff to win a case of perforation based only on the fact that a perforation occurred. There is widespread acknowledgement that perforation can occur during or following a colonoscopy that was performed competently. Further, there is almost never sufficient documentation in the chart to indicate that a polypectomy or an insertion to the cecum was performed in a negligent or incompetent fashion. However, it is quite possible for a plaintiff to win a case of mismanagement of a perforation. A physician who mismanaged a phone call in the middle of the night from a patient who has persistent pain after a mismanaged colonoscopy can be at greater risk than the physician who performed the colonoscopy that resulted in perforation.

Concluding Remarks

As you perform colonoscopy, remember that your greatest risks are associated with complications that result in the worst outcomes for patients. In general, these complications comprise perforation and missing cancer. Being an attentive and caring physician who listens carefully to patients' complaints and performs colonoscopy in a technically competent fashion, and who takes postprocedure complaints seriously and evaluates them aggressively, can greatly reduce your risk of being sued. However, if a patient has a poor outcome, the physician may still be sued. At that point, your success in defending yourself will depend on the quality of examination documented in the colonoscopy report in the case of missed lesions and the aggressiveness of management of severe or persistent postprocedure pain in the case of perforation.

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