Avoiding and Defending Malpractice Suits for Postcolonoscopy Cancer: Advice From an Expert Witness

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When a patient develops colorectal cancer within a few years of colonoscopy it sometimes results in a malpractice action against the colonoscopist.[1] This often results from an impression on the part of the patient, the patient's attorney, and some expert witnesses that colonoscopy is a guarantee of protection against colorectal cancer. Although it is always troubling to be sued, and some doctors are emotionally devastated by the process, malpractice suits alleging missed cancer are (in my experience) very difficult for the plaintiff to win, and a series of measures can further greatly increase the chance of a defense verdict. Colonoscopy is generally a poorly documented procedure in the absence of video recording, and no one involved in the medical-legal case can be certain that the colonoscopist performed a careful examination. Therefore, the case usually revolves around other documentation (or the absence of it) that supports a careful examination, the size of the tumor at diagnosis and the interval since the baseline colonoscopy, and the knowledge and performance of the defending doctor and the expert witnesses.

In this article I review issues commonly encountered in malpractice suits centered on this issue, make recommendations for avoiding these suits, and discuss medical evidence that can be used by the defense when a suit proceeds. These recommendations represent both my understanding of the medical literature on colonoscopy and missed cancers, my own experience in performing colonoscopy, and my experience as an expert witness.

Avoiding Malpractice Suits Alleging Missed Cancer

Informed Consent

The key risks to include in the informed consent discussion for colonoscopy are perforation and "missed cancer" or "missed lesion." Other elements such as postpolypectomy bleeding and medication reaction typically also are discussed, and consideration should be given to including aspiration pneumonia and splenic injury.[2] A doctor who knows their adenoma detection rate (ADR) might present it to the patient during the process, although my own practice is to provide it only when the patient asks. Another approach is to say the general chance of a missed cancer, but this chance will depend greatly on the patient's age, sex, presence of risk factors, and the indication for the procedure.[3] For example, the risk of a missed cancer is higher when colonoscopy is performed for the indication of a positive fecal occult blood test (FOBT)[3] because the prevalence of cancer and advanced adenomas are both higher in patients with a positive FOBT than screening patients, and therefore the opportunity for missing is greater with a positive FOBT. The miss rates of colonoscopy for polyps of various sizes have been best defined by tandem studies,[4] and computerized tomographic colonography (CTC) studies that combine good CTC performance with "segmental unblinding."[5,6] For polyps 1 cm or greater in size, the miss rates in tandem colonoscopy studies are 2% to 6%,[4] and in CTC studies are 12% to 17%.[5,6] My own approach is not quantitative with regard to missing, as in "this test is the best available to examine the colon but it is not perfect, and rarely it can miss a significant growth."

Bowel Preparation Issues

Three guidelines have now endorsed split-dosing of preparations for colonoscopy.[7–9] The evidence that split-dosing improves the efficacy of preparation is overwhelming.[10,11] A reasonable question is whether the standard of medical care requires the use of split dosing. The answer would be that split-dosing is the standard of care if we consider evidence and guideline recommendations,[7–11] but not if we consider that many practitioners still do not split dose. My own impression is that using split-dosing helps provide an impression of awareness of the state of the art by a colonoscopist, and systematically not split-dosing implies a lack of seriousness about polyp detection. However, the issue is to avoid and defend malpractice in individual cases, and therefore the key is the documentation of preparation quality[12] in individual cases in which cancer develops postcolonoscopy.

Appropriate documentation of preparation quality is essential to the physician's defense. It is acceptable to use either simple term 4 scales ranging from "excellent" to "poor," to rate the preparation as "adequate" or "inadequate," or to use validated scoring systems such as the Boston Bowel Preparation score,[13] the Ottawa score,[14] or the Aronchick scale.[15] The US Multi-society Task Force on Colorectal Cancer recommended that an "adequate" preparation is one that allows detection of polyps 6 mm and larger.[12,16] By using this definition, an inadequate preparation is not one with scattered bits of adherent mucus and feces but one in which there are pools of solid and semisolid debris that cannot be removed and cannot be moved out of the way by patient rotation. One issue that warrants clarification is whether to use the scales noted earlier to describe the contents of the colon on insertion or before the inspection begins, or to describe the preparation after the colon has been prepared for inspection by washing and suctioning. In many

Abbreviations used in this paper: ADR, adenoma detection rate; CTC, computerized tomographic colonography; FOBT, fecal occult blood test; ICV, ileocecal valve.

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clinical trials reporting the results of bowel preparation regimens the scales describe residual fluid and solid material that can be washed off the mucosa and suctioned. To a certain extent this approach lacks meaning in everyday practice because the only issue of relevance to the patient is the appearance of the colon after suctioning and washing. Many, if not most, "good" and many "fair" preparations according to these scales can be made "excellent" and "good," respectively, for the purposes of the examination. Any preparation that cannot be cleaned to be above a grade of "fair" should be followed by a recommendation to repeat the examination at an interval shorter than would otherwise be appropriate for the findings. In some cases very specific language might be used to describe an area with less than ideal preparation such as "the ascending colon preparation was such that polyps less than 1 cm could not be ruled out." Such language removes the risk of the plaintiff's expert deciding what the colonoscopist meant by "fair" preparation, and more effectively could support an intermediate postpolypectomy interval. To summarize, the optimal defense requires a description of the preparation as "excellent" or "good" throughout the colon.

Photography can be very useful in supporting the adequacy of the preparation.[17,18] Standard photographs should be taken of the cecum and the rectum (see later) and they should be taken after suctioning and washing off mucus and bubbles. I have seen plaintiffs' experts argue that the preparation was not good enough because a photograph of the cecal base showed a small area of adherent mucus. In addition, capturing photographs of several segments of the colon showing excellent preparation provides support for the endoscopist's claim of an adequate preparation.

Rectal Examination

It is important to document the results of a rectal examination performed before a colonoscope insertion. A surprising number of postcolonoscopy cancers are diagnosed in the distal rectum. Sometimes the defendant's doctor will testify that they always perform a rectal examination and the endoscopy room nurses will support the claim. This is good, however, documentation is better. The rectal examination should be a full finger insertion and circumferential sweep of the distal rectal mucosa, and not just lubricating of the anal canal.

Landmark Documentation

Cecal intubation should be documented by notation of landmarks and photography.[12,16,17] If photography is lacking, the plaintiff's expert may claim that the cecum was not intubated. A key photograph is the appendiceal orifice, optimally taken with the colonoscope tip far enough away to see the cecal strap fold around the appendiceal orifice but still proximal to the ileocecal valve (ICV). A second key photograph is of the cecum from just distal to the ICV, and showing both the ICV and the lateral wall of the cecal pouch. If the terminal ileum is intubated, it should be photographed. These photographs provide powerful proof that the cecum was fully intubated.[18] Because the majority of interval cancers occur in the proximal colon, these photographs assume even greater importance. I frequently examine the right colon twice, especially if a careful first examination from the cecal caput to the hepatic flexure has shown 1 or more polyps. This examination can be performed either in the forward view or in retroflexion,[19] and if retroflexion is chosen, I invariably take a photograph of the right colon in retroflexion. Finally, if retroflexion is performed in the rectum, as it should be unless the rectum appears narrow, that photograph also is taken.[20,21] If retroflexion is not performed, a forward-viewing photograph can be taken from the dentate line.

Withdrawal Time

The first quality recommendations regarding mucosal inspection during colonoscopy came in 2002 from the US Multisociety Task Force on Colorectal Cancer,[16] and these were updated by a joint task force of the American Society for Gastrointestinal Endoscopy/American College of Gastroenterology in 2006.[17] Both documents recommended that the ADR should be the primary measure of mucosal inspection and that secondarily the average withdrawal time in colons in which no biopsies or polypectomies were performed should be at least 6 minutes. Both documents recommended that the withdrawal time not be applied to individual cases because colonic length and fold anatomy is quite variable, and some colons can be effectively and carefully examined much faster than others. Subsequently, the withdrawal time began to assume more importance than it deserves after a landmark study showed that withdrawal times longer than 6 minutes were associated strongly with a better ADR as well as better detection of large adenomas.[22] This finding was interpreted incorrectly by many as evidence that simply lengthening withdrawal to more than 6 minutes would fix detection problems. Although withdrawal time is associated very strongly with ADR in retrospective studies,[22–26] insisting on longer withdrawal times will not necessarily increase the ADR,[27] probably because the longer times are not used to effectively examine the colon. On the other hand, colonoscopist education on lesion recognition combined with training in technique of examination has produced systematic increases in ADR.[28]

Despite these caveats regarding the limitations of the withdrawal time as a quality indicator, there is no doubt that procedure times are reviewed and discussed in every malpractice suit involving missed cancer. Further, the 6-minute recommendation has, despite the attempts to avoid it, become a sort of medical-legal standard. Several years ago I defended a doctor in a missed cancer case involving a colonoscopy performed in 1998 (4 years before the first recommendations regarding withdrawal times) in which the doctor had photographed the cecum and then the rectum in retroflexion. The 2 photographs were both timed and the interval between the 2 photographs was exactly 4 minutes. The plaintiff's experts argued successfully that this could not have been enough time to carefully inspect the colon. Based on experiences of this type, I inspect for at least 6 minutes in almost all cases with intact colons. Parenthetically, I find that it almost always takes at least 6 minutes to carefully examine an intact colon, so this policy has little effect on my examination technique. In defense of a malpractice suit, having the withdrawal time documented and having it exceed 6 minutes has multiple advantages. First, documentation of the withdrawal time creates the impression that the colonoscopist is up to date on and takes current quality recommendations seriously. Second, documenting the withdrawal time prevents the plaintiff's expert from speculating on how long the withdrawal lasted. This is particularly important when the total procedure