

Quality monitoring in colonoscopy: Time to act

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Abstract

Colonoscopy is the gold standard test for colorectal cancer screening. The primary advantage of colonoscopy as opposed to other screening modalities is the ability to provide therapy by removal of precancerous lesions at the time of detection. However, colonoscopy may miss clinically important neoplastic polyps. The value of colonoscopy in reducing incidence of colorectal cancer is dependent on many factors including, the patient, provider, and facility level. A high quality examination includes adequate bowel preparation, optimal colonoscopy technique, meticulous inspection during withdrawal, identification of subtle flat lesions, and

complete polypectomy. Considerable variation among institutions and endoscopists has been reported in the literature. In attempt to diminish this disparity, various approaches have been advocated to improve the quality of colonoscopy. The overall impact of these interventions is not yet well defined. Implementing optimal education and training and subsequently analyzing the impact of these endeavors in improvement of quality will be essential to augment the utility of colonoscopy for the prevention of colorectal cancer.

Key words: Colonoscopy; Quality improvement; Cecal intubation rate; Adenoma detection rate

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Core tip: Quality is a measure of actual performance compared to the defined standard as outlined by the medical community. Important quality measures in colonoscopy include informed consent, adequate bowel preparation, cecal intubation, withdrawal time, adenoma detection rate, appropriate screening and surveillance follow-up recommendations, and adverse events. The above quality measures could affect patient outcomes and therefore should be implemented and monitored regularly.

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INTRODUCTION

In 1998, the Institute of Medicine identified significant variations in practice, safety, and lack of accountability in healthcare, thereby highlighting the necessity of quality assurance^[1]. Endoscopy is an important

modality in the diagnosis and management of digestive diseases. High quality endoscopy ensures that a patient receives an appropriately indicated procedure that is properly and effectively delivered with minimal risk. This satisfies the three parameters of quality outlined by the institute of medicine: safety, practice consistent with medical knowledge, and customization^[2].

More than 14 million colonoscopies were performed in the United States in 2002, making it one of the most common procedures performed^[3]. Colonoscopy is largely safe, effective, and well tolerated by patients with a major indication for colonoscopy of colorectal cancer screening and surveillance^[4]. Colonoscopy is the only cancer-screening test that can both provide diagnosis and therapy as the adenoma-carcinoma sequence renders most colorectal cancer preventable by the identification and removal of adenomatous polyps^[5].

The outcomes of health care are intimately linked to its quality. Many studies have shown that the quality of colonoscopy is directly linked to interval cancer, likely the result of missed lesions^[6-8]. A high quality colonoscopy requires involvement of three different factors in order for the exam to be adequate: the patient (bowel preparation), the structure (facility, equipment), and the provider (competence). Each component is critically important to ensure that a malignancy or adenoma is detected. The efficacy to reduce colon cancer requires adequate visualization of the entire colon, diligence in examining the mucosa, and patient compliance. Based on the available literature and expert consensus, a joint task force of the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) has proposed several quality measures to establish competence^[9].

MEASURES OF QUALITY IN COLONOSCOPY

Pre-procedure

Prior to examination, potential risk factors that may increase complications should be identified. This includes use of antithrombotic therapy or significant medical comorbidities (heart disease, lung disease, renal failure). The American Society of Anesthesiology (ASA) classification is the most commonly employed system to identify patients at higher risk of developing endoscopy (and sedation) related complications. Those with a higher ASA class (III or above) should be performed in a hospital as opposed to outpatient setting with consideration for anesthesia support.

Informed consent with discussion of risks, benefits, and alternatives should be discussed and documented. The risk of missed lesions may also be addressed, as no examination in medicine is infallible^[10]. Tandem colonoscopy has demonstrated miss rates up to 27% for lesions \leq 5 mm. Even for adenomas \geq 1 cm, the

miss rate has been calculated to be as high as 6%^[11].

Quality of bowel preparation

Complete examination of the colon is feasible only with an adequate bowel preparation^[12]. Inadequate bowel cleansing is associated with increased healthcare expenditure between 12% to 22% given altered recommendations for earlier follow-up^[13]. Education on the importance of sufficient bowel cleansing should be addressed^[14,15]. Patients with a lower socioeconomic status (and decreased health literacy)^[16], history of constipation^[17], diabetes^[18], those on chronic narcotics, or prior history of inadequate bowel preparation have an increased probability for poor bowel preparation and should be recognized early. These patients should have modifications to their regimen such as following a low residue diet^[19], and/or extended (two day) bowel preparation. Split-dose preparation yields improvement in bowel quality and should be universally applied to all patients^[20].

Documentation of the bowel preparation is fundamental to the overall quality of the procedure^[10]. The effectiveness of the bowel cleansing can be described with qualitative terms ranging from poor to excellent. An adequate preparation is defined by the ability to detect lesions \geq 5 mm^[21]. However, this format is not validated and subject to operator bias. Integration of a validated scale such as the Boston Bowel Preparation Scale^[22] may reduce bias and aid in consistent and objective documentation.

Cecal intubation rate

Depth of maximal insertion should be documented in the text with support of endoscopic photographs. Cecal intubation with complete inspection of the cecal caput is imperative given the fact that many interval cancers occur in the proximal colon^[23,24]. Two major landmarks confirm visualization of the cecum: the appendiceal orifice and ileocecal valve. A careful inspection of the cecal floor behind the ileocecal valve is very important. Current guidelines expect cecal intubation in \geq 90% of cases overall and in \geq 95% of screening colonoscopies^[9]. In a large population based study, colonoscopy performed at an office or private setting in contrast to a hospital or academic institution was the strongest predictor for an incomplete examination^[25].

Adenoma detection rate

Adenoma detection rate (ADR) is perhaps the most important quality metric of colonoscopy. It is defined as the percentage of colonoscopies in which at least one adenoma was identified and removed per colonoscopy. The prevalence of adenomas varies by age and gender. According to current recommended guidelines on quality indicators, among healthy asymptomatic patients undergoing screening colonoscopy, adenomas should be detected in \geq 25% of men and \geq 15% of women^[9,26,27]. A landmark study by Kaminski *et al*^[6]

Table 1 Colonoscopy screening and surveillance guidelines

Finding	Advised interval
No polyps/adenomas	10 yr
Single first degree relative with cancer (or adenomas) \geq 60 yr	10 yr (begin age 40)
Two or more first degree relatives with cancer (or adenomas) or one first degree relative diagnosed \leq 60 yr	5 yr (begin age 40)
Few (1-2), small tubular adenomas (< 1 cm)	5 yr
Advanced adenomatous lesions (> 1 cm or villous histology or high grade dysplasia) or > 3 adenomas	3 yr
Numerous (> 10) adenomas	Individualized approximately < 3 yr
HNPCC	1-2 yr (begin age 20-25)
Sessile adenomas > 2 cm, removed piecemeal	2-6 mo
Post cancer resection surveillance	Clear colon, then 1 yr, then 3 yr, then 5 yr

Joint guidelines from the American Cancer Society, the United States Multi-Society Task Force on Colorectal Cancer, and the American College of radiology. HNPCC: Hereditary nonpolyposis colorectal cancer.

validated that ADR is an independent predictor of the risk of interval cancer if ADR is less than 20%. Missed lesions have been hypothesized to be a principal contributor for interval cancer after colonoscopy^[7], again highlighting the necessity of monitoring the ADR among individuals and the institutions.

The current benchmarks for ADR may be setting the standard too low. Multiple studies have shown much higher rates of adenoma detection^[28-30] with significant variation among individual endoscopists. The endoscopist performing the procedure may have a stronger correlation with ADR more than previously identified traits such as a patient's age or gender^[31].

Unfortunately, despite the obvious strengths of this metric, it has some limitations. It is time intensive to calculate this measure because it requires manual integration of the endoscopy and pathology reports. ADR cannot be calculated in real-time as pathology findings are not available at the time of endoscopy. Hence, PDR has been advocated in some studies to be a surrogate for ADR^[30,32]. The proposed benchmarks for PDR are 40% for men and 30% for women^[33]. This method is certainly more convenient; however given high prevalence of hyperplastic polyps in the recto-sigmoid area and non-neoplastic polypectomy, there is risk for gaming the system by falsely inflating one's PDR.

The primary goal of screening and surveillance colonoscopy is detection and removal of all neoplastic colon polyps. However, ADR fails to distinguish endoscopists who identify more than one adenoma. Because every adenoma has risk of malignancy, endoscopists who are able to identify more adenomas per colonoscopy may be providing greater protection for colorectal cancer. Hence, novel scoring systems such as ADR-Plus^[34] or mean adenoma per procedure (MAP)^[35] have been proposed to provide greater discriminating ability among endoscopists. These models do provide more detail compared to ADR, however they carry the same burden of calculation, without clear benefit on outcomes.

Withdrawal time

Withdrawal time is the time at which the cecum is

reached to when the colonoscope is withdrawn from the anus. The majority of detailed inspection of the colonic mucosa occurs during this phase. A landmark study by Barclay has demonstrated that there is increased detection of significant neoplastic lesions if the withdrawal time exceeds six minutes^[36]. As a result, the United States Multi-Society Task Force on colorectal cancer recommends that withdrawal, excluding time for biopsy and polypectomy, should average between six to ten minutes^[9]. Although this quality measure has been validated in some respects, it has significant limitations. For instance, an inefficient endoscopist may spend much longer than 6 min on withdrawal without complete visualization of the mucosa missing critical area between the haustral folds. A comprehensive examination includes careful examination of mucosa proximal to folds and flexures, better colonic distension, and washing of debris from the colon^[37]. Ideally, rather than a quantitative requirement, focus should instead be on clear and effective visualization.

Screening and surveillance intervals

Screening and surveillance interval guidelines after colonoscopy have been published by the United States Multi-Society Task Force and are summarized in Table 1^[38]. Compliance (with documentation) with these guidelines is an important quality measure. Adherence to guidelines is emphasized to decrease overuse of colonoscopy, which leads to increased exposure to potential procedural harm and drains resources that could be more effectively used. The efficiency and cost-effectiveness of colorectal cancer screening by colonoscopy is dependent upon the ability of the endoscopist to confidently follow established guidelines. For reasons unclear, studies have shown that postpolypectomy surveillance colonoscopy is frequently performed at shorter intervals^[39]. Nonetheless, there are instances when repeat colonoscopy recommendations require an individualized approach based on clinical judgment that may differ than conventional guidelines; procedures performed at shorter or longer intervals than advised should be supported by written documentation. The variation discussed above underscores the need for

Table 2 Healthcare quality improvement projects^[46]

<p>Plan-Do-Study-Act (P-D-S-A)</p> <p>Employs cycles of planning (P), small scale pilot testing (D), analysis of test results and lessons learned (S), followed by incorporation and maintenance of new processes into practice (A)</p> <p>Useful when resources and time are limited and rapid stepwise improvement is desired</p> <p>Lean method</p> <p>Seeks to increase efficiency and reduce waste by excluding all processes, steps, or inputs that fail to contribute value to the end product</p> <p>Useful when existing practices are deemed to be inefficient and cumbersome, with bottlenecks and excessive rework</p> <p>Employs collaborative team input and process revision through value stream mapping</p> <p>Six Sigma method</p> <p>Intensively data driven approach to minimizing variation and thereby reducing defects or errors to improve quality</p> <p>Use a cyclic approach referred to as the Define-Measure-Analyze-Improve-Control method</p> <p>Employs more rigorous analytical tools and process control charting under the guidance of local experts</p> <p>Especially appropriate for repetitive high frequency processes</p>

quality monitoring of this aspect of colonoscopy.

Adverse events

Risk of complication is inherent to any procedure but endoscopists should be competent and proficient in their skills in order to maximize benefit while minimizing potential harm. Once a complication occurs however, it is important to document and monitor trends to ensure quality control. If rates exceed the established guidelines for an endoscopist or institution, investigation should be pursued to assess patient risk factors and procedure complexity to amend this situation.

Postpolypectomy bleeding is the common complication of a colonoscopy^[40]. Typically, the risk of bleeding increases with increasing size of polyps, especially those located in the proximal colon. While the overall risk for postpolypectomy bleeding is around 1%^[41,42], for polyps larger than 2 cm, bleeding rates are as high as 10%^[40]. Bleeding can occur immediately or within 14 d of the procedure. Most bleeding stops spontaneously, however some patients require endoscopic evaluation. Therapy includes injection, cautery, or clipping. Data thus far is conflicting regarding the role of use of clips prophylactically^[43,44].

Perforation is the most serious complication. The incidence of perforation due to colonoscopy is variable in the literature ranging between 1 in 500 to less than 1 in 1000^[45]; about 5% of colonoscopic perforations are fatal^[41,42]. During a diagnostic procedure, perforation can occur due to mechanical rupture with insertion primarily though the sigmoid colon, or may be secondary to barotrauma causing a rent in the cecum. Perforation can also occur with attempts to traverse a stricture. The greatest risk of perforation occurs with large polypectomies in the proximal colon where the walls are thinner.

THE PROCESS OF QUALITY IMPROVEMENT

Quality improvement refers to monitoring the performance, making continuous refinements, and then

further assessing the outcomes of the interventions taken. As mentioned previously, there is marked variation in quality in colonoscopy. As a result, continuous quality improvement is essential to the success of colonoscopy.

Continuous tracking of performance for high volume procedures can be challenging. Monitoring quality metrics is time intensive and costly because it often requires data collection from multiple sources. Automated data collection *via* modern electronic endoscopic databases assist with this process, yet some deficiencies still exist. This includes integration of pathology findings to determine ADR, an important quality metric. Infrequent and delayed occurrences such as adverse events are also difficult to capture. Episodic audits of sequential procedures on a monthly, quarterly, or annual basis are one option to accruing representative data samples^[46].

Methods used in quality improvement projects are outlined in Table 2. The essential elements include collecting information about standards, assembling data about current practices, identifying gaps in performance, executing a performance strategy, followed by reassessment, and further testing.

FUTURE AREAS FOR IMPROVEMENT

There are several patient-related, procedural-related, and endoscopist performance-related factors that account for inconsistency. In an editorial by Douglas Rex, he tabulated multiple questions to improve detection during colonoscopy^[47]. Review of this editorial provides important hypotheses that warrant further investigation to improve quality.

Patient related improvements include health literacy on the benefits of colorectal cancer screening. Increasing awareness leads to increased attendance for screening examinations^[48]. Better compliance with bowel cleansing will have innumerable benefits as poor bowel preparation prolongs procedure time, reduces detection of polyps, and increases likelihood of an incomplete procedure^[14,49]. Education on quality markers will encourage patients to seek high quality

endoscopists.

One procedural related method that may improve the quality of colonoscopy includes the use of the water method. Rather than the use of air insufflation, which causes sharp angulations, water infusion results in the straightening of the sigmoid colon and other angulations easing insertion. Studies have shown aid with technically difficult colonoscopies^[50], decreased pain, and lower requirements for sedation^[51]. Future prospective studies are needed to assess the true value of water immersion. Another technique proposed is use of a cap-fitted colonoscopy. A cap may ease insertion by creating a distance between the instrument tip and colonic mucosa, thus facilitating navigation through angulation^[52]. Data has shown shorter intubation times as well as avoidance of a failed or incomplete procedure with use of this method^[53]. Cap-fitted colonoscopy may also assist with detection of lesions between the haustral folds though studies have had conflicting results in regards to overall adenoma detection^[54-56].

Technology to aid with adenoma detection includes chromoendoscopy and the Third Eye Retroscope (Avantis Medical, Sunnyvale, California, United States). Chromoendoscopy has been advocated for use in order to identify subtle flat lesions^[57]. Chromoendoscopy includes use of a colored dye that is sprayed into the colon or electronic light variation such as narrow band imaging (Olympus America, Center Valley, Pennsylvania, United States). Studies thus far have shown marginal benefit with only an improvement in the detection of diminutive lesions^[58-60]. The Third Eye Retroscope is passed down the colonoscope channel and provides a continuous retrospective view on a second monitor^[61]. A randomized control trial showed improved adenoma detection however with a longer withdrawal time^[62]. This technology also requires accessing the accessory (and suction) channel making it a bit tedious in practice. One recent development is known as the full spectrum endoscopy (FUSE; EndoChoice, GA, United States). While a standard forward viewing colonoscope visualizes 170° of the colon, the FUSE instead has a more comprehensive view with the capability to capture 330° of the mucosa. This is accomplished by the addition of imagers on the sides of the tip of the scope to provide three images on adjacent monitors. The result is a lower miss rate of adenomas (7% vs 41%; $P < 0.00001$)^[63]. Thus far, these technologies are not yet supported for incorporation into routine care. They may however, have a role for patients with increased risk for malignancy and/or endoscopists with low adenoma detection rates.

The quality of the examination by the proficient endoscopist is a significant predictor of adenoma detection therefore should be the focus of quality improvement efforts^[64]. Internal audits are necessary to identify weaknesses in the practice. For instance, several studies have found that physician fatigue has an impact on adenoma detection with less

adenomas found during afternoon procedures^[65]. This phenomenon improves if endoscopists work in shorter shifts such as half-day blocks^[66]. Direct observation and feedback has had variable results on outcomes^[67]. In a study by Imperiali *et al*^[68], less experienced endoscopists had more time dedicated to endoscopy with intermittent supervision, and their skills were regularly audited. Completion rates improved, variability between endoscopist polyp detection decreased, but no change in overall adenoma detection was observed^[68].

A controversial issue is the endoscopic training of nongastroenterologists. The suggested threshold number for competence in colonoscopy is 200 procedures^[69]. However, this quota may be misleading, as most trainees require many more procedures than dictated to achieve competence. Studies have shown an increase in interval cancer among nongastroenterologists^[70]. This issue should be resolved through a collaboration of gastroenterology and nongastroenterology training programs to define uniformity to grant involvement in endoscopy.

In accordance with the changing paradigm of healthcare, rather than the fee-for-service model which rewards volume, a pay-for-performance reimbursement method will become the primary financial incentive with a focus more on value^[71]. Within this model, satisfying national quality metrics may have a role in compensation as well. Several national endoscopic benchmarking programs are now in effect around the world. For instance, the GI Quality Improvement Consortium is a non-profit collaboration between the ASGE and ACG. This program facilitates data submission to various institutions, including the Physicians Consortium for Performance Improvement^[46].

CONCLUSION

Quality measurement and improvement are essential components of a colonoscopy program. Quality is a multifactorial and dynamic process that requires regular monitoring to ensure adherence to national standards. Although several challenges exist, development and implementation of educational tools and improved endoscopic technology are imperative to enhance the benefits of colonoscopy, thereby reducing the incidence and mortality attributed to colon cancer.

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