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Quality in Colonoscopy

Ashish Malhotra

Aasma Shaukat

INTRODUCTION

The use of screening colonoscopy to identify early cancer and remove pre-malignant polyps has become the keystone in reducing deaths from colon cancer. A population-based screening test must be effective, safe, cost-efficient and widely available; colonoscopy, on the contrary, is invasive, expensive and potentially dangerous. Most will agree that colonoscopy is an effective prevention modality for colorectal cancer (CRC) as evidenced by declining incidence and mortality rates of CRC in the United States (US) over the past two decades,[1,2] but it may fail to detect clinically important lesions. Prior studies have reported rates of post-colonoscopy cancers, also referred to as interval cancers, of 2% to 7%,[3-5] and miss-rates for adenomas by tandem colonoscopy of 2% to 26%.[6] The initial cost-effectiveness analysis by Sonnenberg assumed a 75% reduction in CRC risk with a colonoscopy pre-procedure cost of $681 for screening exam and $1000 for an exam including polypectomy.[7] Studies have shown that actual risk reduction from colonoscopy is approximately 65% [8] and costs are much higher than previously estimated. Hence, for colonoscopy to survive as an effective screening modality, we must strive to maximize its health value. This can be achieved by providing high-quality exams and mitigating unnecessary costs.

In this review, we discuss important quality indicators suggested by professional societies, which help in optimizing general performance of colonoscopy.[9] These indicators are process indicators as opposed to true outcome measures. We will present scientific evidence supporting the utility of these measures, possible interventions to improve these measures as well as potential caveats that still need to be addressed.

Quality Improvement

The scientific study of quality improvement requires the identification of individual steps involved in the delivery of care, an analysis termed "process literacy".[10] Figure 1 shows a simple process map for a patient undergoing colonoscopy at an open access unit, a model applicable to any practice. The map identifies three distinct areas, pre-procedural, intra-procedural and post-procedural, to discuss quality issues.

Pre-procedural Quality Bowel Preparation

The diagnostic accuracy of colonoscopy depends upon the quality of bowel preparation. Inadequate bowel cleansing results in lower diagnostic yield[11] with an adenoma miss rate as high as 47.9%.[12] Similarly, another study on inadequate cleansing showed that of all adenomas detected, 42% were discovered only

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Ashish Malhotra, MD, Aasma Shaukat, MD, MPH Section of Gastroenterology, Department of Medicine, Minneapolis VA Medical Center and University of Minnesota, Minneapolis, MN

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during repeat colonoscopy. The miss rate for advanced adenomas was 27%, a relatively large percentage. It is important to note that authors defined early repeat colonoscopy as an exam performed within one year of the index exam, suggesting a true miss rate as opposed to subsequent neoplasia. Meta-analysis determined that adenoma detection rate (ADR) and advanced ADR were significantly higher with adequate vs. inadequate preparation: OR=1.30 (1.19-1.42) and 1.30 (1.02-1.67).[13] Such studies highlight the fact that inadequate bowel preparation substantially compromises colonoscopy effectiveness as a screening tool. Additionally, patients with fair bowel preparation undergo repeat colonoscopies usually at a shorter interval. For example, patients with normal colonoscopy results and a fair prep were recommended to undergo a screening colonoscopy within 5 years in 57.4% and only 23.1% received a 10-year recommendation.[14] When an adenoma was detected, 77.9% of patients received a recommendation for follow-up colonoscopy within 5 years of the index colonoscopy. The 2012 multi-society guidelines now specifically recommend repeat colonoscopy in ≤ 1 year if bowel preparation is graded as poor or inadequat.[15] Inadequate bowel preparation thus increases the cost of colonoscopy as a screening tool and decreases its overall health value. In an era when bundled payments for colonoscopy are likely, overage resulting from repeat colonoscopies would place the providers and practices at financial risk.

Epidemiology and Risk Factors for Inadequate Bowel Preparation

Inadequate bowel preparation ranges from 9% to 67%.[16-21] The variability in the percentage of procedures with an inadequate preparation depends upon the study's definition of inadequacy, the type of preparation used, pre-procedural instructions given to the patients, patient inclusion criteria and potentially the practice patterns of the gastroenterologist. Table 1. Awareness of these factors can help identify patients at higher risk of inadequate bowel preparation who might benefit from more attention to their bowel preparation regimen.

Determination of Inadequate Bowel Preparation

In order to objectively categorize and grade bowel preparation at the time of colonoscopy, several bowel prep rating scales have been formally developed and validated (Table 2). Characteristics of what constitutes a reliable scale merit attention. A scale should be valid, reliable, sensitive to change, user friendly and have acceptable range of values.[40] A recent meta-analysis[41] concluded that none of the scales have included validation with important clinical outcomes such as missed lesions in follow-up. The Boston bowel prep scale remains the most user-friendly and extensively validated scale available to date. Lastly, there is the very real problem of physician subjectivity in grading of bowel cleansing. A recent study highlighted provider variability in grading colonoscopy preparations.[42] The rate of suboptimal preparations for individual gastroenterologists in this study ranged from 3% to 40%.[42] Gastroenterolgists who judge that 40% of their patients have inadequate preps markedly increase the cost of screening colonoscopy

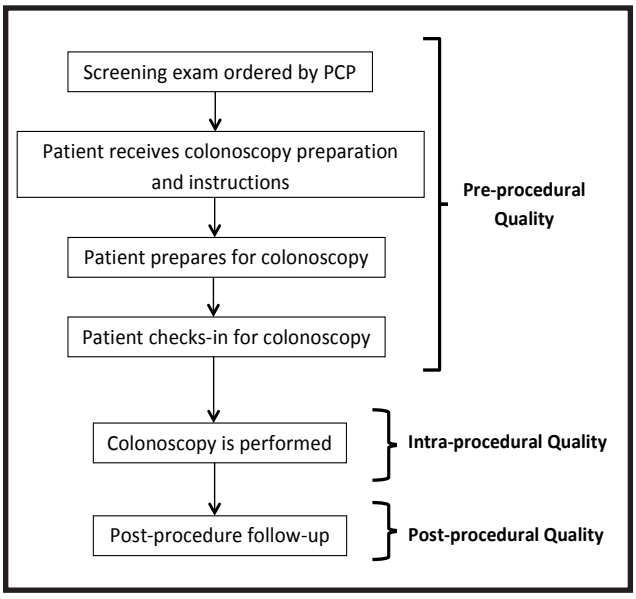

Figure 1. Generic process map for a patient undergoing outpatient colonoscopy at an open access unit

Strategies to Improve Bowel Preparation

The quality of bowel preparation depends upon the type and timing of the preparation agent, medical factors affecting preparation quality and socio-demographic factors affecting compliance with the pre-procedural preparation instructions.

Type and Timing of Preparation

Split dosing of preparation (administration of the last dose of the agent on the morning of the procedure) has improved overall preparation rates[43-48] and is now the

Table 1. Predictors of Inadequate Bowel Preparation for Colonoscopy

Biological Factors	Socio-demographic Factors	Setting-related Factors
History of chronic constipation	Age ≥ 60	Type of preparation used (spilt dose, use of sennosoides)
Use of constipating medications such as tricyclic antidepressants, opioids	Male gender	Time between end of preparation and colonoscopy
Diabetes mellitus	Lower educational level	Only written disposal of preparation instruction
Obesity	Low health literacy	
History of inadequate preparation for colonoscopy	Low patient activation	
History of colonic resection	English not first language	
Bristol stool scale ≤ 2	Living alone	
ASA score ≥ 3	Medicaid insurance	
Current hospitalization	Unmarried	
Liver cirrhosis requiring active treatment		
Neurological disease (stroke, dementia, Parkinson's disease)		

standard of care. Four liters split-dose polyethylene glycol electrolyte solution (PEG-ELS) remains the gold standard for efficacy among standard bowel preparations.[49]

Medical Factors Causing Inadequate Bowel Preparation

The usual response to medical reasons of inadequate preparation is a more aggressive preparation regimen. An open label prospective trial established the efficacy of an intensive bowel regimen for repeat colonoscopy after preparation failure. Over 90% of the subjects had achieved adequate bowel preparation at the second colonoscopy.[50] Thus the goal should be to identify patients who are at risk of failing conventional regimen and triaging them to a more aggressive bowel preparation prior to the initial colonoscopy.

Improving Patient Compliance

Factors such as poor health literacy, low patient activation or motivation can affect understanding of and compliance with pre-procedural preparation instructions. Reminders and aggressive pre-procedural education by means of phone calls, videos, social media apps or navigators are some of the novel ways of improving prep quality. Table 3 lists various interventions that have been shown to improve preparation quality possibly by more aggressively delivering pre-procedural instructions.

More work is needed to simplify and establish clinically usable protocols that help in identifying at-risk patients and triage them to either more aggressive prep regimens or more aggressive educational regimens.

Intra-Procedural Quality

The majority of colon cancers progress slowly; there is often a ten year interval between the appearance of the precancerous lesion and invasive carcinoma. With such tumors, there is strong evidence that the quality of the colonoscopy measured by adequate removal of all pre-cancerous lesions is related to the rate of interval cancer.[56-59] Several quality indicators for colonoscopy have been proposed.[9] One such indicator, the adenoma detection rate, is defined as the proportion of screening colonoscopies in which at least one adenomatous polyp is detected, for a given endoscopist, in a given time period. Most recent guidelines propose an adequate ADR for asymptomatic individuals 50 years of age or older undergoing screening colonoscopy should be >30% in men and >20% in women.[9] ADR is the only current quality indicator reported to be significantly associated with the risk of interval cancers. An

ADR <20% was associated with an increased risk of interval CRC.[60] Each 1% increase in ADR is associated with 3% decrease in the risk of interval CRC and 5% decrease in the risk of fatal interval cancers.[61] Numerous studies have shown significant heterogeneity in endoscopist ADR. It remains to be determined if there is threshold for maximum benefit of ADR, where we may see no further protective benefit of a very high ADR. The answer to this question may hinge on why a low ADR is associated with a higher rate of interval cancers and whether every missed polyp, independent of size, is a potential interval cancer or if hasty, inadequate or incomplete examinations of the colon are the underlying concern.

It has been proposed that some cancers harbor genetic features that allow such rapid progression that they may be undetectable at the index colonoscopy yet present as interval cancers. These cancers arise via the sessile serrated adenoma pathway,[62,63] which is characterized by mutations in the BRAF oncogene, gene promoter hypermethylation (i.e. CpG island methylator phenotype [CIMP]). To the extent that these tumors progress from undetectable to invasive cancers during the interval period, screening colonoscopy will be ineffective at reducing the impact of these tumors. However, these lesions are flat and more prevalent in the right colon, both of which render these lesions difficult to identify at colonoscopy. Thus, the tendency of such tumors to present as interval cancers could be largely attributable to defective detection; rapid growth of such a tumor simply increases the chance that the lesion becomes clinically apparent during the interval period (3- 5 years) after the index colonoscopy. In this situation, improved colonoscopic technique could prevent interval cancers. The proportion of screening colonoscopies with at least one proximal serrated polyp is 13%, and a higher endoscopist ADR correlates strongly with proximal serrated polyp detection rates.[64]

Withdrawal time, the interval elapsing between cecal intubation and withdrawal from the anus (in the absence of polyp removal) has also been studied as a quality metric in colonoscopy. Studies have demonstrated that a withdrawal time of ≥ 6 minutes increased the detection of neoplastic lesions during colonoscopy in patients with intact colons.[9] Shaukat et al. found a statistically significant correlation between interval CRC and withdrawal times shorter than 6 minutes in a large community based study with over 76,000 colonoscopies.[65] However, there was no association between ADR and interval CRC, suggesting that for practices with optimal ADRs (i.e. >25%), withdrawal time may be a more sensitive marker of quality of colonoscopy than ADR.

Clinical studies have shown mixed results on improvements in adenoma detection with implementation of a longer withdrawal time.[66] Studies that have evaluated total withdrawal time alone versus with performance feedback failed to show statistically

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Table 2. Different Scales Available to Grade Adequacy of Bowel Preparation

Name of Scale	Reference
Aronchick scale	33
Ottawa bowel preparation quality scale	34
Boston bowel preparation scale	35
Harefield cleansing scale	36
Chicago bowel preparation scale	37
The Marden bowel preparation classification	38
B-clear	39

Table 3. Strategies to Improve Delivery of Pre-procedural Education

Findings	Reference
Use of mobile social media app increases quality of bowel preparation	51
Telephone-based re-education on the day before colonoscopy improves the quality of bowel preparation	52
Physician-delivered education consisting of a brief counseling session in addition to written instructions improves the quality of bowel preparation	53
Short message service (SMS) was the optimal education modality, and was as effective as telephone reminders for the quality of bowel preparation	54
Bowel preparation quality improves with addition of a short educational video	55

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significant improvements in adenoma detection, but some showed improvement in non-adenomatous polyp detection.[67-74] The potential to alter colonoscopy practice via multiple interventions were studied. A 1% financial penalty for endoscopists who did not achieve a ≥ 6 minute withdrawal time for > 95% of examinations resulted in no statistically significant changes in AD.[75,76] When an audible timer was used during withdrawal (implementing an 8-minute withdrawal time) in addition to enhanced inspection techniques, ADR increased by 50% compared to baseline, a statistically significant finding ($P < 0.0001$.[66,77] In summary, mandating longer withdrawal time alone is not likely to increase the rate of adenoma detection and ultimately reduce the incidence and mortality of colorectal cancer.[9]

Current standards mandate that cecal intubation, defined as reaching proximal to the ileocecal valve with complete visualization of the entire cecum, should be achieved in ≥ 90% of all colonoscopies and in ≥ 95% of cases for screening colonoscopies. Documentation of reaching this landmark should be confirmed with photography of the cecal landmarks (i.e. appendiceal orifice and ileocecal valve).[9] The importance of this quality indicator derives from the findings that a large fraction of colorectal neoplasms are located in the proximal colon, including the cecum,[9] and an even larger fraction of interval cancers are found in this location.

The quality of colonoscopy is also assessed by process measures for healthcare delivery.[24] Documentation of various measures has been proposed by the American Society of Gastrointestinal Endoscopy (ASGE) as well as the ASGE/American College of Gastroenterology (ACG) Taskforce on Quality in Endoscopy.[9,79] The Quality Assurance Task Group of the National Colorectal Cancer Roundtable (NCCRT) has developed a standardized colonoscopy reporting and data system (CO-RADS) to improve the quality of colonoscopy.[80] Procedure reports should be created by programs to allow systematic documentation of the details of the colonoscopy that would include the indication(s), anatomic extent of the examination, findings and complications, among others.

Post Procedural Quality

Complications are inherent to the practice of colonoscopy. Some of these can be potentially serious

Table 4. Summary Table For Common Colonoscopy Complications

Complication (Reference)	Rate of Occurrence	Risk Factors
Post-polypectomy bleeding (9, 81-87)	0.1%-0.6% (Rate >1% should prompt review)	Polyp-related factors: Size >1cm, polyps on the right side, polyps on a thick stalk, laterally spreading lesions and villous histology Patient-related factors: Age >65, hypertension, cardiac disease, renal disease
Colon perforation (81, 88-94)	0.7%-0.9% (with endoscopic submucosal dissection rates are 4%-10%)	Polyp-related factors: Cecal polyps, non-pedunculated polyp, laterally spreading lesions, lesions that involve deeper tissue layers such as non-invasive high-grade dysplasia Technique-related factors: Torque-related such as passing through fixed/extremely redundant sigmoid colon, retroflexion in small rectum such as after radiation therapy/proctitis, thermal injury such as use of argon plasma coagulation, barotrauma.
Post-polypectomy syndrome (95, 96)	1.0 in 1000 to 3.0 per 100,000	Lesions >1cm, non-polypoid morphology, hypertension, higher prolonged thermal energy
Modest increase risk of cardiovascular events (mainly arrhythmia) (81, 97)	10.2/1000	Patients needing polypectomy, presence of comorbidities such as stroke, atrial fibrillation, diabetes, or congestive heart failure

and life threatening while less attention is given to minor complications, these events may adversely impact patients' willingness to undergo future procedures thus diminishing the effectiveness of surveillance. Occurrence of complications raises the cost of colonoscopy thus lowering its health value. Therefore, monitoring complication rates and implementing quality improvement programs to reduce the rate of complications are essential to optimize the overall value of colonoscopy as a screening tool. Detailed discussion of various types of complications related to colonoscopy is beyond the scope of this paper.

Table 4. Adequate awareness of potential complications, their risk factors and the expected incidence can help clinicians (both primary care physicians and endoscopists) have better risk-benefit assessment and facilitate a comprehensive informed consent process. Various techniques have been suggested to lower the risk of complications. However, given overall low incidence of complications high-quality studies evaluating the efficacy of these techniques are generally absent.

We recommend an ongoing quality improvement program for individual practices to help physicians monitor complications on a regular basis. Since some of the complications can be delayed, specific efforts should be made to capture adverse events for up to 30 days after the procedure. The complications should be reviewed in a structured quality improvement forum to freely discuss and identify how care could be improved. Since complications occur infrequently, it is helpful to review multiple months of procedures to more reliably determine complication rates for the practice and/or an individual.

SUMMARY

Quality indicators in colonoscopy are available for practitioners and institutions to review and follow. The goal is to ensure that patients maximally benefit from screening colonoscopies both from the detection of early colorectal cancer and the prevention of cancer via the resection of precancerous lesion. Quality measures for colonoscopy are adopted by Centers of Medicare and Medicaid through the PQRS reporting system, with financial penalties associated for not meeting the required benchmarks. Every practice setting must implement and monitor quality metrics. Impact of these efforts on patient outcomes is an important area of future research. ■

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