Quality in Colonoscopy

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Financial Disclosures

- Partner, Rapid City Medical Center, LLP
- Shareholder, The Endoscopy Center, LLC
- Shareholder, Dark Canyon Laboratories, LLC
The barrier to reducing the number of deaths from colorectal cancer is not a lack of scientific data but a lack of organizational, financial, and societal commitment.

Daniel K. Podolsky, MD (NEJM 7/20/00)
Outline

• Rationale for screening and surveillance colonoscopy
• Limitations of colonoscopy
• Interval cancer rate
• Adenoma Detection Rate as a quality indicator
• Performing high quality colonoscopy
• Supporting high quality colonoscopy
Normal to Adenoma to Carcinoma

Human colon carcinogenesis progresses by the dysplasia/adenoma to carcinoma pathway
Genetic Model of Colorectal Cancer

- **Bat-26 (HNPCC)**
- **Bat-26 (Sporadic)**

**Mutation**
- **APC**
- **K-ras**
- **p53**

**Normal Epithelium** → **Adenoma** → **Late Adenoma** → **Early Cancer** → **Late Cancer**

**Dwell Time:**
- Many decades
- 2-5 years
- 2-5 years

**Optimum phase for early detection**

Courtesy of Barry M. Berger, MD, FCAP  EXACT Sciences
Benefits of Screening

- Cancer Prevention
  - Removal of pre-cancerous polyps prevent cancer (unique aspect of colon cancer screening)

- Improved survival
  - Early detection markedly improves chances of long term survival
Colonoscopy is Not 100% Protective

- In Canada, two studies demonstrate a lack of benefit in preventing CRC in the proximal colon.
- In Germany, colonoscopy reduces CRC risk overall by 77%, but only by approximately 50% in the right colon.
- In the US, both the National Polyp Study and the Nurses’ Health Study show colonoscopy is associated with a >50% reduction of death from CRC.
- Current studies in the US show a protective effect of 75%.
Reduced Effectiveness of CRC Screening

- Non-compliance at any step
- Screening tests with less than 100% sensitivity
- Errors in interpreting screening tests
- Errors in follow-up
- Errors in performance of screening tests
- Errors in therapy
Colonoscopy has a Measureable Miss Rate

<table>
<thead>
<tr>
<th></th>
<th>1st Exam</th>
<th>2nd Exam</th>
<th>Miss Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total adenomas</td>
<td>289</td>
<td>89</td>
<td>24%</td>
</tr>
<tr>
<td>Adenomas &lt;5 mm</td>
<td>217</td>
<td>81</td>
<td>27%</td>
</tr>
<tr>
<td>Adenomas 6-9 mm</td>
<td>42</td>
<td>6</td>
<td>13%</td>
</tr>
<tr>
<td>Adenomas &gt;10 mm</td>
<td>30</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Masses</td>
<td>9</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

Rex et al, Gastro 1997
### CTC vs. Optical Colonoscopy: Sensitivities for All Polyps

<table>
<thead>
<tr>
<th>Polyp Size</th>
<th>CTC</th>
<th>Colonoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;10mm</td>
<td>92.2%</td>
<td>88.2%</td>
</tr>
<tr>
<td>&gt;8mm</td>
<td>92.6%</td>
<td>89.5%</td>
</tr>
<tr>
<td>&gt;6mm</td>
<td>85.7%</td>
<td>90.0%</td>
</tr>
</tbody>
</table>

*Pickhardt et al, NEJM 2003*
Interval Colorectal Cancer

- World Endoscopy Organization defines an interval CRC as a "colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam".

- US studies define interval CRC as CRC occurring within 6-60 months of colonoscopy
  - 6% of colon cancers
  - Tend to be more proximal
  - Positive family history more common
  - Higher survival
Adenoma Detection Rate (ADR)

- Defined as the frequency of finding at least one adenoma in a patient at average risk at their first colonoscopy
- Wide variation (7% to over 50%) among endoscopists in this measure
- Reflects the degree of thoroughness of the colonoscopic exam
- Inverse relationship between ADR and Interval CRC Rate
- Now considered the primary quality measure in the performance of screening colonoscopy
ADR and CRC Risk

Kaminski et al, NEJM 2010

No. at Risk

<table>
<thead>
<tr>
<th>ADR</th>
<th>0</th>
<th>12</th>
<th>24</th>
<th>36</th>
<th>48</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR &lt;11.0%</td>
<td>15,883</td>
<td>15,805</td>
<td>15,744</td>
<td>15,669</td>
<td>9355</td>
<td>4717</td>
</tr>
<tr>
<td>ADR 11.0–14.9%</td>
<td>13,281</td>
<td>13,223</td>
<td>13,182</td>
<td>13,120</td>
<td>7571</td>
<td>4003</td>
</tr>
<tr>
<td>ADR 15.0–19.9%</td>
<td>6,607</td>
<td>6,582</td>
<td>6,562</td>
<td>6,539</td>
<td>4022</td>
<td>2529</td>
</tr>
<tr>
<td>ADR ≥20.0%</td>
<td>9,255</td>
<td>9,235</td>
<td>9,202</td>
<td>9,166</td>
<td>7155</td>
<td>5548</td>
</tr>
</tbody>
</table>
Interval CRC Risk Falls with Increasing ADR

Corley et al, NEJM 2014
Adenoma Detection Rate

Current guidelines:

- ADR in Men should be >30%
- ADR in Women should be >20%
- ADR overall >25%

All Endoscopists should measure their ADR

For every 1% improvement in ADR, the risk of developing an interval CRC decreases by 3%
Flat Lesions

Background

- Described in Japanese patients since 1980’s. Thought to be uncommon in the U.S.

- Study published in March 2008 detected flat lesions at much higher rate than any previous U.S. reports

- Colonoscopies in over 1800 veterans found:
  - Polyps in 37%
  - “Flat lesions” in 9.35%

Soetikno, JAMA 2008
Flat Lesions

- Most lesions not truly flat
- Many are Sessile Serrated Polyps
- Many occur in the right colon

New Sources of Risk

Colorectal cancer prevention largely focuses on finding polyps, but flatter, less visible lesions that are not polyps are also cancer risks.

The New York Times: Illustrations by JAMA

Soetikno, JAMA 2008
Sessile Serrated Polyps

Rex, Healio Gastroenterology 2016
Sessile Serrated Polyps

Burgess et al, GIE 2015
Sessile Serrated Polyps/Flat Polyps

- May be more common in the U.S. than previously believed
- Account for 10-20% of polyps in the colon
- May account for 30% of CRC
- More frequent in the right colon
- More difficult to see, and more difficult to remove
The Importance of Prep

A higher quality colonoscopy prep will:

- Improve ADR
- Improve detection of sessile lesions
- Improve detection of advanced neoplasia
- Decrease failed preps/Inadequate preps
- Decrease your colonoscopy time
- Improve your quality numbers
The Importance of Prep

- Split Dosing of the Colonoscopy Prep for all exams
- Split Dose 4 liter PEG-ELS (GoLYTELY, Colyte, etc.) is the Gold Standard for efficacy and safety
- Document the quality of the prep on each exam
- Consider use of the Boston Bowel Prep Scale
- The prep quality should be “Excellent” or “Good” in >85% of your exams. If not, fix your prep regimen
Boston Bowel Prep Scale (BBPS)

Lai et al, GIE 2009
The Beneficial Effect of Intraprocedural Cleansing

Insertion
Withdrawal

Change in Ottawa Score After Intraprocedural Cleaning

Ottawa Scale Score

Right
Middle
RectoSig
Overall

MacPhail et al, GIE 2015
High Quality Colonoscopy

- Split dosing of prep
- Document cecal intubation
- Regular review of adenoma detection rates
- Withdrawal time of at least 6 minutes
- Cold snaring (if possible) of all polyps greater than 5 mm in size
- Close follow-up of larger sessile lesions
- If above measures are followed, then tight adherence to recommended surveillance intervals
Closing the Loop in Surveillance

- Polypectomy
- Polyp Pathology Review
- Colonoscopy
- Report to Patient
- Recommend Timing of Next Colonoscopy
### Surveillance Interval Guidelines

<table>
<thead>
<tr>
<th>Screening Colonoscopy Findings in Average Risk Patients</th>
<th>Surveillance Interval (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No polyps</td>
<td>10</td>
</tr>
<tr>
<td>Small hyperplastic polyps distal colon</td>
<td>10</td>
</tr>
<tr>
<td>1-2 tubular adenomas &lt; 10 mm</td>
<td>5-10</td>
</tr>
<tr>
<td>3 or more tubular adenomas</td>
<td>3</td>
</tr>
<tr>
<td>Tubular adenoma &gt; 10 mm</td>
<td>3</td>
</tr>
<tr>
<td>Villous component</td>
<td>3</td>
</tr>
<tr>
<td>High grade dysplasia</td>
<td>3</td>
</tr>
<tr>
<td>Serrated polyp &gt; 10 mm</td>
<td>3</td>
</tr>
<tr>
<td>Serrated polyp &lt; 10 mm</td>
<td>5</td>
</tr>
</tbody>
</table>
Closing the Loop in Surveillance and Quality Reporting

- Colonoscopy
- Polypectomy
- Polyp Pathology Review
- Recommend Timing of Next Colonoscopy
- Report to Patient
- Report to CMS
System Support for Quality Colonoscopy

- Invest in high quality endoscopic equipment and software
- Invest in endoscopic documentation software
- Invest in quality reporting software
Endoscopy Report Writer/EHR Software

- Provation
- gMed
- CORI

Interface with pathology
Interface with general EHR
Interface with Qualified Clinical Data Registry
GIQuIC

- GI Quality Improvement Consortium
- Joint project between ASGE and ACG

Objectives:

- Establish a national GI endoscopy data repository for storage and maintenance of Endoscopy Quality Measures for GI Endoscopists who want to document and improve their endoscopy performance.

- Provide Benchmarking reports to participating physicians and facilities to support their quality improvement initiatives.

- Identify gaps in care and develop Endoscopy Quality Indicators to address gaps.

- Collect data that can be used by researchers conducting clinical outcomes studies and quality initiatives
AGA Digestive Health Outcomes Registry

Colorectal Cancer Prevention Measures

- CRC-P 1: Identification of CRC Risk
- CRC-P 2: Endoscopic Examination Interval
- CRC-P 3: Use of Anesthesia Professionals
- CRC-P 4: Procedure-Related Complications
- CRC-P 5: Colonoscopy Assessment (Procedural Adequacy)
- CRC-P 6: Adenoma Detection Rate
CMS Colonoscopy Quality Measures 2017

- Appropriate follow-up interval following normal colonoscopy in average-risk patients
- Appropriate follow-up interval for patients with a history of adenomatous polyps
- Screening colonoscopy adenoma detection rate (ADR)
System Support for Quality Colonoscopy

- Encourage appropriate credentialing and privileging
- Invest in the team:
  - Nursing staff to assist in endoscopy
  - Technical staff to maintain equipment and assist in endoscopy
- Invest in high quality endoscopic equipment and software
- Invest in endoscopic documentation software
- Invest in quality reporting software
Further Reading