Colon Examination for Patients at Higher Risk of Colonoscopy Complications

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BACKGROUND

Serious complications have historically been quoted as 0.35% according to the ACG 1976 study, but the rate of colonoscopy complications may be higher as reporting relies on gastroenterologist who likely would not see ER visits related to cardiopulmonary or neurologic events. These events could be higher for patients with risk factors or conditions such as use of blood thinning medication or comorbid conditions increasing sedation risk.

GOALS AND OBJECTIVES

Determine the prevalence of patients at higher risk for cardiopulmonary or neurologic events from colonoscopy, what these rate of these events could be, and how these patients are managed today.

METHODS

An international survey of 303 gastroenterologists in five countries was administered as well as a comprehensive literature search for currently available clinical information was performed.

RESULTS

- 19-24% of patients presenting for colon examination have factors that increase the risk of complications from colonoscopy (Chart 1).
- Only 22% of ER visits post colonoscopy are captured by the current physician reporting today, and 1.1% of patients had unplanned events from colonoscopy using conscious sedation according to ASGE-CORI analysis (Dataset 1).
- Between 24-69% of patients on blood thinning medication, with sedation risk, or previous incomplete colonoscopy are receiving non-colonoscopy colon examinations currently; over 4% of these patients do not receive any colon exam (Chart 3).
- Gastroenterologists state that availability of colon capsule endoscopy may allow more than half of these 4% of patients to receive a colon exam, thereby increasing the quality of care (Chart 5).

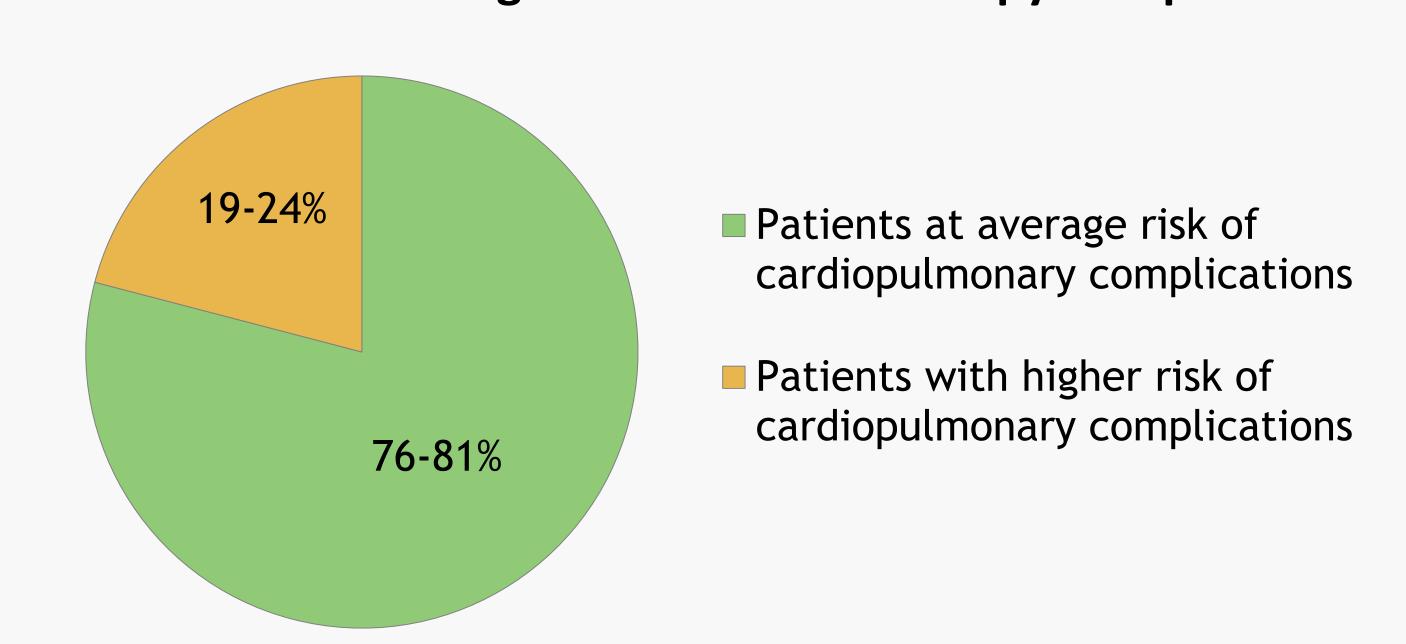
CONCLUSIONS

Patients and physicians could benefit from additional non-invasive colon examination modalities that provide accurate results such as colon capsule endoscopy (CCE) to provide safer options for patients at higher risk of complications.

DISCUSSION

- A number of small, diverse studies have shown increased risk of cardiopulmonary and neurologic complications within 30 days of colonoscopy. More research is needed to better understand which comorbidities and medications are correlated with higher rates of adverse events after a colonoscopy with a specific focus on antithrombotic medications. This information can help physicians to better target which patients should have a primary diagnostic only colon exam such as colon capsule endoscopy and thereby reduce adverse events with patients only needing intervention directed to colonoscopy.
- This analysis suggests that the availability of colon capsule endoscopy could provide a benefit for managing medically complex patients having a colon exam. More than two-thirds of gastroenterologists have performed colonoscopies with an unfavorable risk/benefit ratio possibly due to limited options of high accuracy, minimally invasive exams. Colon capsule endoscopy, a non-invasive colon exam with direct visualization of the colon mucosa, could potentially help reduce post-colonoscopy adverse events, increase the number of higher complication risk patients receiving a colon exam with direct visualization, and increase the number of patients able to have a colon exam.

CHART 1: Patients at Higher Risk of Colonoscopy Complications



Rutter C. Adverse events after screening and follow-up colonoscopy. Cancer Causes Control (2012) 23:289-296. Campbell E. Automated before-procedure electronic health record screening to assess appropriateness for GI endoscopy and sedation. Gastrointestinal Endoscopy 2012: In Press.

Given Imaging sponsored, multi-national survey of 303 GI physicians who estimated the percentage of large bowel examinations with patients having high bleed risk or high sedation risk.

DATASET 1: Literature References Regarding Colonoscopy Complications and Clinical Indications for Increased Risk Rate

- Only 22% of ER visits post colonoscopy are captured by the current physician reporting today¹
- The risk of cardiovascular complications in 65+ aged patients is:
 - 245% higher if the patient had previous congestive heart failure¹
 - 170% higher if the patient had previous atrial fibrillation¹
 - 81% higher if the patient has chronic obstructive pulmonary disease¹
- In the general population, sedation-related unplanned cardiopulmonary events (including death) complicate approximately 3.3 in 1000 colonoscopies, and account for approximately half of serious adverse events during colonoscopy²
- Patient ASA classification was a significant independent predictor of cardiopulmonary unplanned events among those with an ASA III or greater³

Warren J. et al. Adverse Events After Outpatient Colonoscopy in the Medicare Population. Annal of Internal Medicine Vol 150, No 12: 2012.
 Waye, J., Rex D., Williams C. Colonoscopy Principles and Practice Second Edition. Chichester: Blackwell Publishing, 2009.
 Sharma, A national study of cardiopulmonary unplanned events after GI endoscopy. Gastrointestional Endoscopy. Volume 66, No. 1: 2007.

CHART 3: Current Colon Exam Use in High Complication Risk Patients (n=303 Gastroenterologists) Colonoscopy Diagnostic Test No Testing 100% 8% 24% 32% 60% 60% 66% 69% 20% 34% 33% 29%

Given Imaging sponsored, multi-national survey of 303 GI physicians who estimated the percentage of large bowel examination modalities used with patients on antithrombotic medications, high sedation risk, and incomplete colonoscopy.

Australia

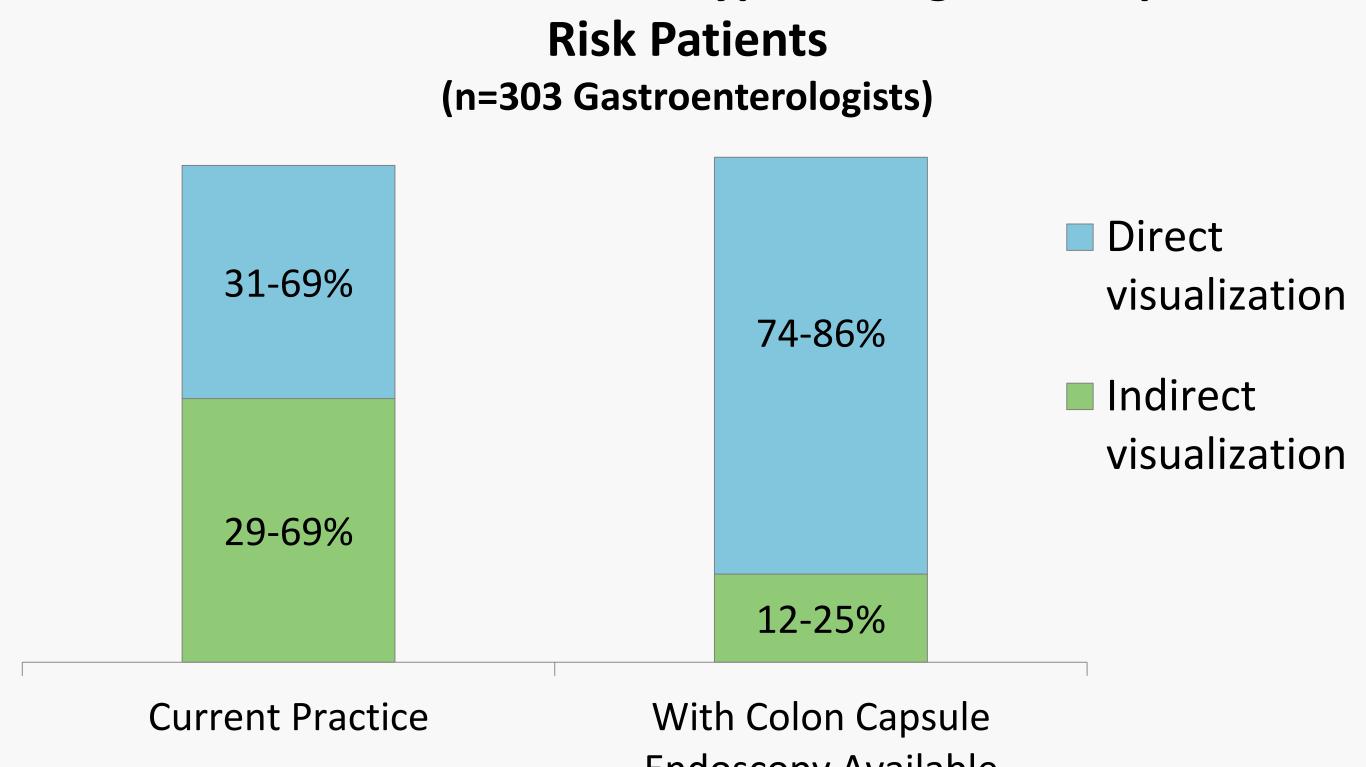
CHART 4: Exam Visualization Type for Higher Complication

Japan

France

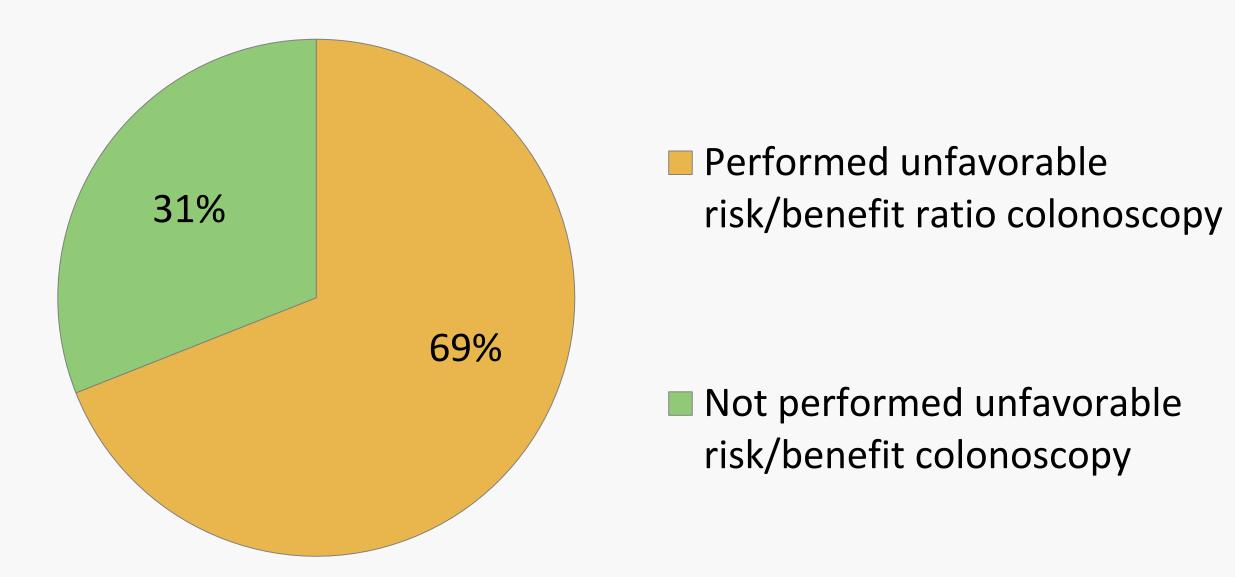
Italy

ate



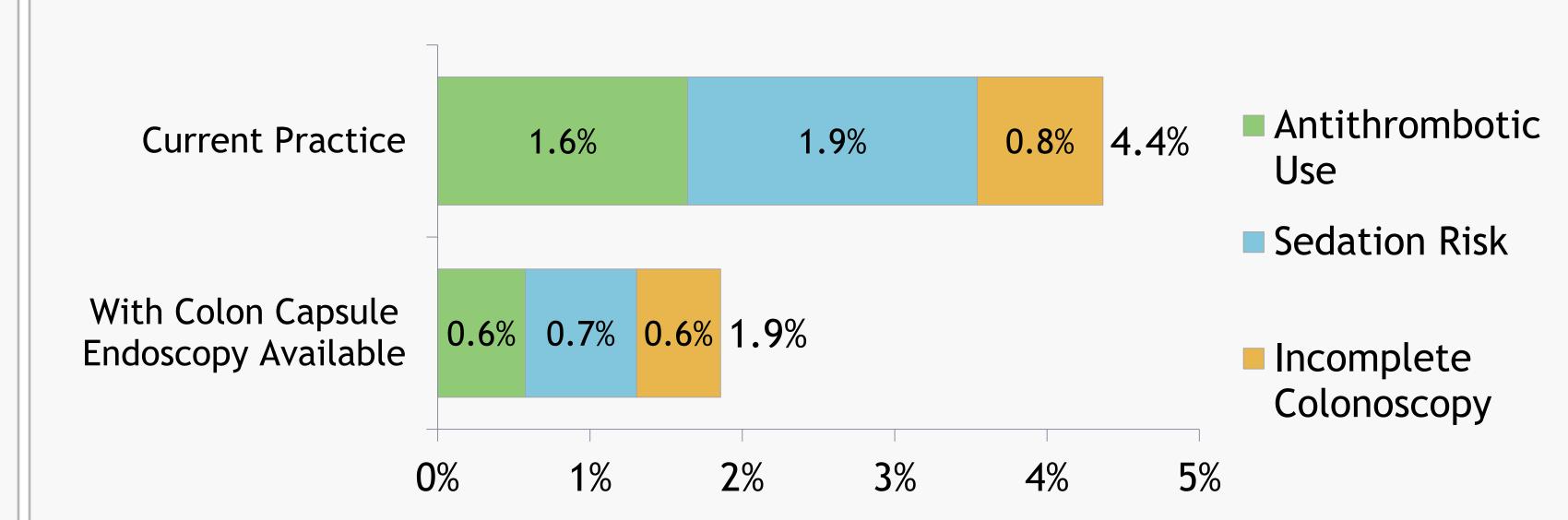
Endoscopy Available
Given Imaging sponsored, multi-national survey of 303 GI physicians who estimated the percentage of large bowel examination modalities used with patients on antithrombotic medications, high sedation risk, and incomplete colonoscopy.

CHART 2: Percent of Doctors Performing Unfavorable Risk/Benefit Ratio Colonoscopy



Mount Sinai sponsored 40-question survey of 1,073 ASGE members working in the US published in the March 2012 issue of Gastrointestinal Endoscopy.

CHART 5: Higher Complication Risk Patient Recommended a Colon Exam



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