

The Impact of Incomplete Colonoscopy, Particularly for Women

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BACKGROUND

Guidelines establish targets for successful intubation rates of $\geq 90\%$ for all colonoscopies and $\geq 95\%$ for screening colonoscopies. Complete colonoscopy is a quality indicator that increases effectiveness in reducing CRC. No clear guidelines exist for further management after an incomplete colonoscopy (IC).

GOALS AND OBJECTIVES

Determine rates of IC and rates of follow-up exams occurring in practice. Assess clinical need for a complete colonic exam and determine if new technology could offer additional value for patients with IC.

METHODS

Literature search of peer-reviewed journals, two surveys of US GIs (n=60, n=100), and one survey of US colorectal surgeons (n=50) performing colonoscopy.

RESULTS

- Rates of IC from published literature ranged widely from 7-19%, while self-reported survey data showed mean rates of 8% and 7% among GIs and colorectal surgeons (Chart 1). Population-based studies show that women are significantly more likely than men to undergo an IC (Dataset 1). Patient compliance with follow-up exams is suboptimal at 54-82% (Chart 2).
- IC increases the risk of proximal cancer and there is a fourfold increase in the risk of interval cancers in women. Sessile serrated adenomas are a significant risk factor for CRC, and are more commonly found in women (Data set 2). Lack of complete removal of all polyps is the most important single factor for late-stage and proximal cancer (Dataset 1).
- Recent studies have shown colon capsule endoscopy (CCE) completes colon examinations in 93% of IC patients, finding additional lesions in 60% of patients, and changing the medical management in 45% (Chart 3). CCE provides a greater than twofold increase in diagnostic yield versus CT colonography in patients with IC (Chart 4).

CONCLUSIONS

Decreasing rates of IC are an important part of reducing cancer risk, particularly in women. New technologies such as CCE could improve the rates of complete colonic examination when the cecum cannot be intubated during colonoscopy.

DISCUSSION

- Compliance with CRC screening has been shown to increase when different modalities are offered, so new modalities like CCE should be offered to patients after an IC.
- Some studies have shown that women have increased rate of proximal adenomas, so a follow-up exam in women after IC is essential.

CHART 1: Reported Rates of Incomplete Colonoscopy Occurrence

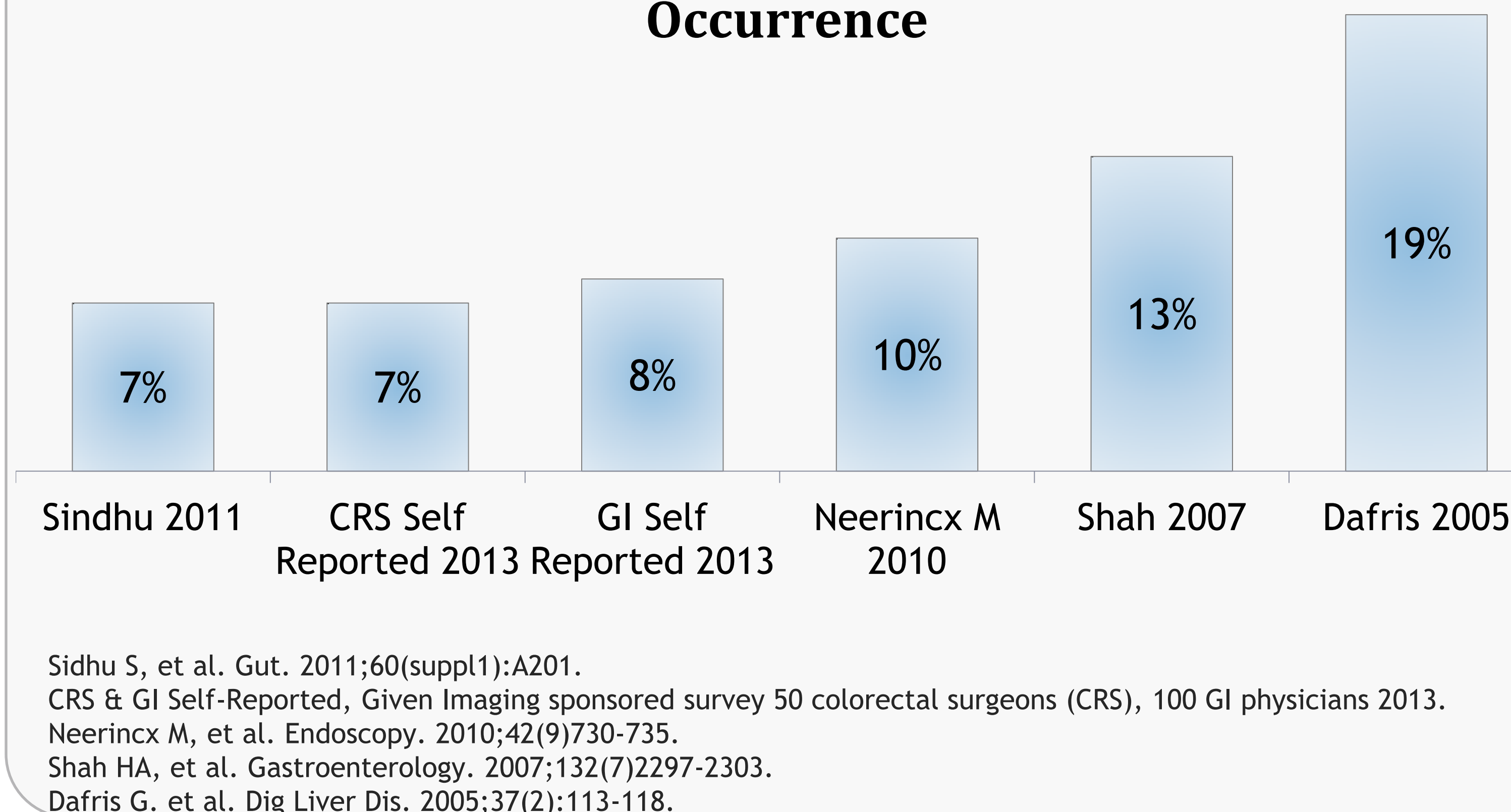
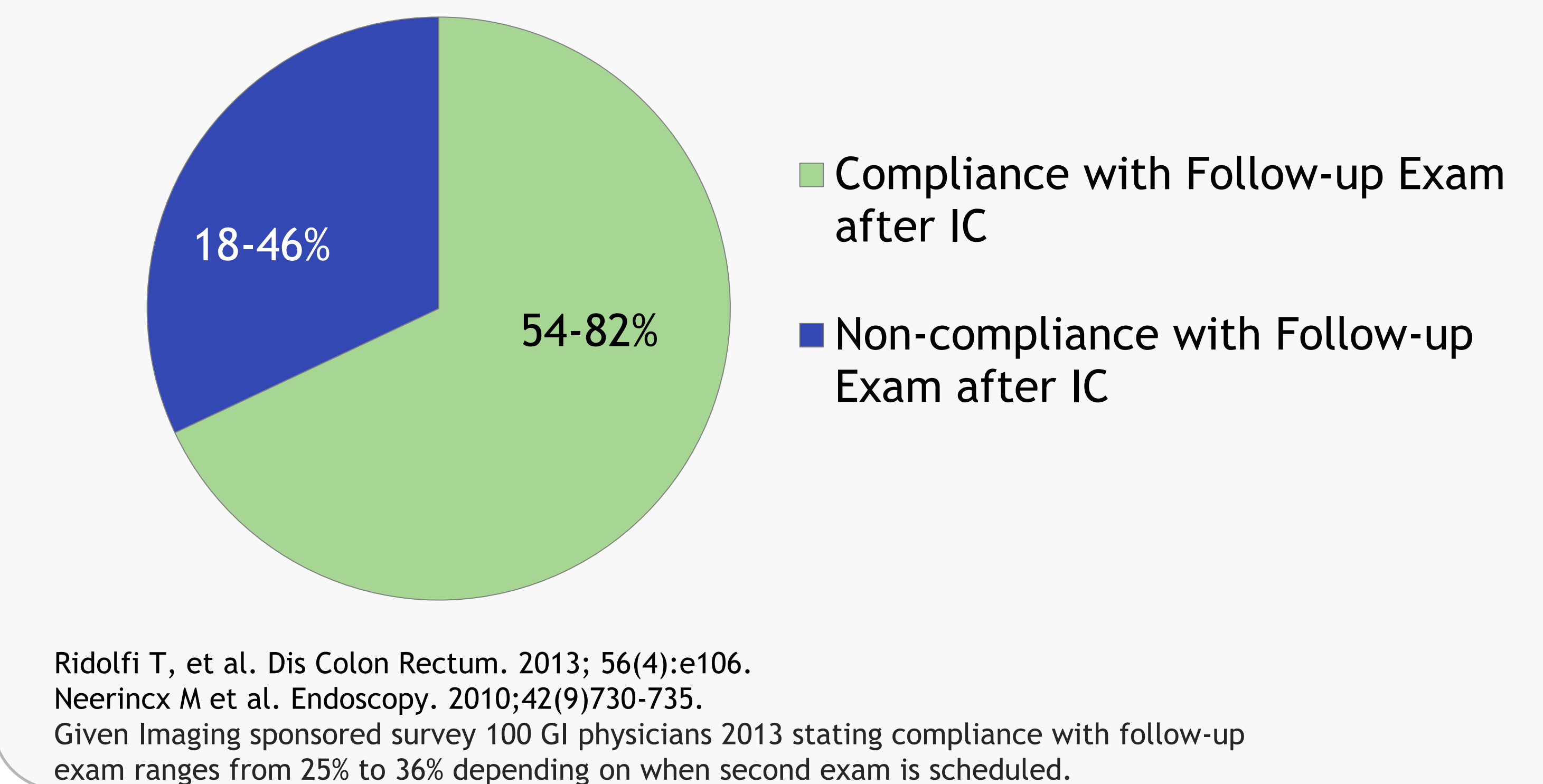


CHART 2: Patients Compliance with Follow-Up Exam After Incomplete Colonoscopy



DATASET 1: Increased Colorectal Cancer Risk Associated with IC

- Rate of successful cecal intubations is critical because interval colon cancer is often located in the proximal colon¹
 - Guidelines propose targets for successful intubation rates: $\geq 90\%$ for all colonoscopies and $\geq 95\%$ for screening colonoscopies²
- Lack of complete removal of all polyps is the most important single factor for late-stage and proximal cancer³
- The odds of developing proximal cancer is associated with incomplete colonoscopy⁴
 - The odds ratio for an incomplete colonoscopy to be associated with later development of CRC is 1.42 [CI, 0.56-3.61], not quite as high a risk of polyps not being completely removed (OR 3.73 [CI, 2.11-6.60])
 - There is a strong independent association between lack of surveillance colonoscopy within 5 years (OR 2.96 [CI, 1.70-5.16]) and later development of colorectal cancer

¹ Rex DK. Gastrointest Endosc. 2008;67(6):938-944. ³ Brenner H, et al. Ann Intern Med. 2012;157(4):225-232.
² Rex DK, et al. Am J Gastroenterol. 2006;101(4):873-885. ⁴ Brenner H, et al. Gut. 2012;61(11):1576-1582.

DATASET 2: Female Increased Risk of IC and Colorectal Cancer

- Population-based studies have shown that women are more likely to undergo an incomplete colonoscopy, especially those with previous hysterectomy¹⁻³
 - 61.5% of incomplete colonoscopies were performed in women¹
 - Lower completion rates in women 77% versus men 85%²
 - Patients with an IC were more likely to be female (OR 1.35 [CI: 1.30-1.39])³
- Sessile serrated adenomas are a significant risk factor for CRC, and are more commonly found in women⁴⁻⁵
- Only 35.2% of women with advanced neoplasia had lesions identified with flexible sigmoidoscopy alone, versus 66.3% of matched men (p < 0.001)⁶
- IC with negative findings is independently associated with a greater than fourfold increase in the risk of interval cancers in women⁷
- The rate of IC in women is associated with subsequent development of colorectal cancer⁸

¹ Rizek R, et al. Med Care. 2009; 47(1):48-52. ⁵ Imperiale TF, et al. N Engl J Med 2000; 343:169-174.
² Dafnis G, et al. Dig Liver Dis. 2005;37(2):113-118. ⁶ Schoenfeld P, et al. N Engl J Med 2005;352:2061-8.
³ Shah HA, et al. Gastroenterology. 2007 Jun;132(7):2297-303. ⁷ Brenner H, et al. Gut. 2012;61(11):1576-1582.
⁴ Hiraoka S, et al. Gastroenterology. 2010 Nov;139(5):1444-7. ⁸ Baxter, N et al. Gastroenterology. 2011;140(1):65-72.

CHART 3: Colon Capsule Endoscopy Performance in IC Patients

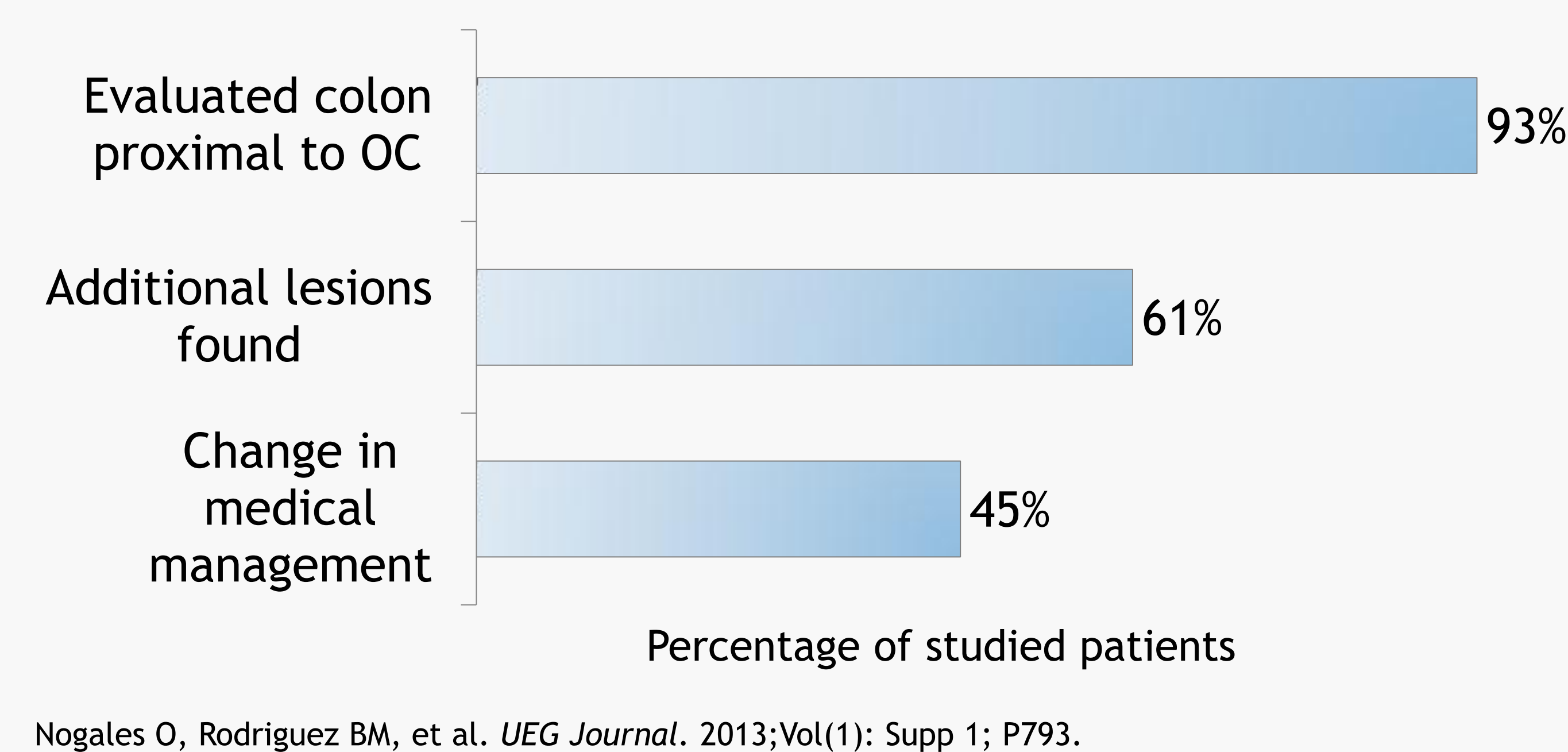
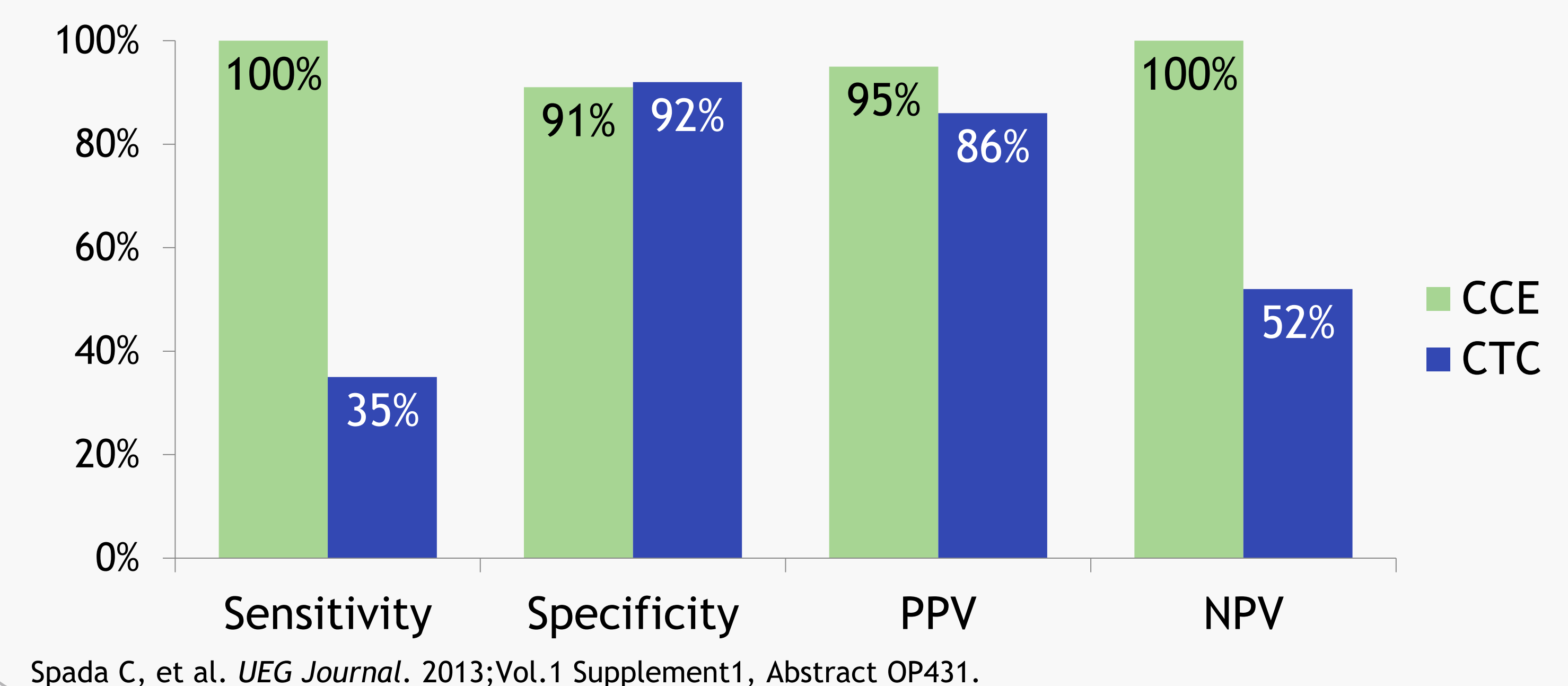


CHART 4: Colon Capsule Endoscopy Versus CT Colonography ≥ 6 mm Polyp Detection in Patients with IC



The risks of CCE include capsule retention, aspiration and skin irritation. Endoscopic placement may present additional risks. The risks associated with colon preparation include allergies or other known contraindications to any preparation agents or medications used for the CCE regimen, according to laxative medication labeling and per physician discretion. After ingesting the CCE capsule and until it is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created by an MRI device. Medical, endoscopic or surgical intervention may be necessary to address these complications, should they occur. A normal or negative CCE examination does not exclude the possibility of colon polyps or colon cancer.