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Clinical validation of the European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) II criteria in an open-access unit: a prospective study

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Abstract

Background and study aims—The European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE I) criteria were recently updated (EPAGE II), but no prospective studies have used these criteria in clinical practice. The aim of the current study was to validate the EPAGE II criteria in an open-access endoscopy unit.

Patients and methods—A prospective observational study was conducted in an open-access endoscopy unit at the tertiary care referral center. Consecutive outpatients ($n = 1004$; mean age 58.9 ± 13.1 years; 45% men) were referred for diagnostic colonoscopy between September 2009 and February 2010. The appropriateness of colonoscopy was assessed based on EPAGE II criteria, and the relationship between appropriateness and both referral doctor and detection of significant lesions was examined. The effectiveness of EPAGE II criteria in assessing appropriateness was measured by means of sensitivity, specificity, and positive and negative predictive values for detecting significant lesions.

Results—Colonoscopic cecal intubation was achieved in 956 patients (95.2%). Most referral doctors were gastroenterologists (58.0%) and the most common indication was colorectal cancer (CRC) screening (35.2%). EPAGE II criteria were applicable in 968 patients (96.4%); of these patients, the indication was appropriate in 778 (80.4%), inappropriate in 102 (10.5%), and uncertain in 88 (9.1%). Patients with appropriate or uncertain indications based on EPAGE II criteria had more relevant endoscopic findings than those with inappropriate indications (38.8% vs. 24.5%; OR 1.95, 95% CI 1.22–3.13; $P < 0.005$). Sensitivity and negative predictive value of EPAGE II criteria for detecting significant lesions were 93.1% (95% CI 90%–96%) and 75.5% (95% CI 67%–84%), respectively, whereas for advanced neoplastic lesions these values were 98.0% (95% CI 95%–100%) and 98.0% (95% CI 95%–100%), respectively. Adherence to EPAGE II recommendations was an independent predictor of finding a significant lesion (OR 1.93, 95% CI 1.20–3.11; $P = 0.007$).

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The authors report no conflicts of interest.

Conclusions—EPAGE II is a simple, valid score for detecting inappropriate colonoscopies in clinical practice.

INTRODUCTION

In recent years, indications for diagnostic colonoscopy have gradually increased, and colonoscopy is now the most frequent endoscopic examination in the USA as well as in many European countries [1,2]. The main factors contributing to the increased use of colonoscopy include the following: 1) marked improvement in the comfort and quality of the procedure, mainly due to the extended use of sedation and the advent of new technologies; 2) progressive implementation of mass colorectal cancer (CRC) screening programs; and 3) the development of open-access endoscopy units, where patients are scheduled for an endoscopic procedure by non-gastroenterologist providers [3]. Open-access endoscopy facilitates access for patients but could increase inappropriate use of colonoscopy, colonoscopy waiting lists, and overall cost.

Colonoscopy is the last step in every CRC screening strategy, and limited capacity at endoscopy units is a major barrier to performing increased numbers of screening colonoscopies [4]. A study in the USA assessed colonoscopic requirements in average-risk populations according to several current strategies for CRC screening (annual fecal occult blood test [FOBT], flexible sigmoidoscopy, FOBT and sigmoidoscopy, and colonoscopy) [5]. Estimating the colonoscopy output could be more than 50%, FOBT was the only strategy with enough capacity for screening all unscreened individuals. Similar results were obtained in a recent study that estimated endoscopic requirements for screening the average-risk population in Europe [6]. As resources are limited, adherence to the appropriate indications for colonoscopy is critical. The indication for an intervention is deemed appropriate when benefits (effectiveness) are greater than expected risks (i.e. safety and side effects). The European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) I criteria were created in 1998 and have been used in scientific studies to assess the appropriateness of endoscopic indications [3,7–10]. These criteria were updated in 2008 (EPAGE II criteria) based on the best available scientific evidence in reports that summarized scientific studies evaluating colonoscopy benefits, effectiveness, safety, and side effects for different indications [11]. There are no reported prospective studies that use the updated criteria in clinical practice [11]. Thus, the aim of the present study was to validate EPAGE II criteria in an open access unit.

PATIENTS AND METHODS

Setting

This study was performed in the open-access endoscopy unit at the University Hospital of the Canary Islands. This is the endoscopic referral center for the northern area of Tenerife (Spain), which has 435,000 inhabitants. The referring physicians included gastroenterologists, general practitioners, surgeons, internists, and other specialists.

Patients

Between September 2009 and February 2010, all consecutive patients with outpatient colonoscopies either in hospital or outpatient healthcare settings were prospectively included regardless of whether the cecum was reached during colonoscopy. Patients who declined to participate or those with a “not listed” indication on EPAGE II criteria were excluded from the analysis. Referring physicians were unaware of the purpose of the study.

After giving patients an oral explanation of the study purpose, endoscopists obtained written informed consent and collected information from the request form and from a medical history. Our healthcare area uses a network computing system that allows additional data from the patient’s medical history (i.e. blood analysis data, and previous examinations results) to be consulted if necessary. The following data were collected: demographic information (age, sex), family history of CRC, previous colonoscopic examinations, physician-related information (sex, specialty, and healthcare setting), and indication. Depending on the indication, additional data were collected in order to calculate the EPAGE II score. Each patient was assigned an indication. In case of several indications, the one with the highest EPAGE II score was selected. Appropriateness of each colonoscopy was established according to the criteria developed by using the RAND Appropriateness Method by the EPAGE (www.epage.ch). In this context, the indication of colonoscopy was considered appropriate if the expected health benefits outweighed the expected negative consequences by a sufficiently wide margin, so that the procedure was worth doing. A more detailed explanation of the indications and the appropriateness ratings can be found elsewhere [11]. Briefly, members of the multidisciplinary European expert panel examined existing evidence summarized in a comprehensive literature review and rated the appropriateness of all possible indications for colonoscopy on a 9-point scale. Clinical indications included: iron deficiency anemia, hematochezia, nonspecific lower abdominal symptoms, uncomplicated chronic diarrhea, evaluation of known ulcerative colitis or Crohn’s disease (inflammatory bowel disease [IBD]), screening for CRC in healthy individuals and in those with IBD, surveillance after colonic polypectomy or after curative intent resection of CRC, and miscellaneous indications. Scores of 1–3 were considered inappropriate, 4–6 uncertain, and 7–9 appropriate. For statistical analysis, appropriate and uncertain indications were combined. A research assistant who was blinded regarding the colonoscopy results calculated the appropriateness of colonoscopy according to EPAGE II criteria.

Four experienced endoscopists (Each averaged >200 colonoscopies per year and had >2 years’ experience as endoscopists), performed the colonoscopies unless a major contraindication was present. The physicians were blinded to the EPAGE II appropriateness assessment. The quality of bowel preparation was assessed using a scale as described previously [11]. In the event of an inappropriate bowel preparation, the examination was stopped. In case of suspected lesions, multiple biopsies or polypectomy were performed. Chromoendoscopy using indigo carmine dye 0.5% was used when a flat or depressed lesion was suspected with conventional endoscopy. All lesions were recorded in the endoscopic report. The following lesions were considered significant [13]: neoplastic lesions (CRC; advanced adenoma, defined as adenoma ≥10mm in size, with villous component or high

grade dysplasia; and nonadvanced adenoma); IBD; non-malignant stenosis; and angiodysplasias. CRC and advanced adenoma were considered advanced neoplastic lesions. The study was approved by the Ethics Committee of the University Hospital of the Canary Islands.

Statistical analysis

Results for continuous variables are expressed as means and SDs. Categorical variables are expressed as frequencies and percentages. The chi-squared test was used to compare proportions. *P* values of <0.05 were considered statistically significant. Logistic regression was used for modeling the relationship between the finding of a significant lesion, sex, and EPAGE II criteria. In addition, effectiveness by means of sensitivity, specificity, positive and negative predictive values for detecting significant lesions and advanced colorectal lesions was used as an objective criterion to validate EPAGE II criteria. The Spearman correlation coefficient was applied to assess the effect of collinearity, as some of the variables analysed in the current study were also included in EPAGE II criteria. The results of the regression analyses were expressed as odds ratios (ORs) and 95% confidence intervals (CIs). Data were analyzed using the Statistical Package for Social Sciences v. 12.0.1 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

Overall, 1004 consecutive patients referred for diagnostic colonoscopy between September 2009 and February 2010 were considered for inclusion in the study. Of these, 449 (44.7%) were men and 555 (55.3%) were women. The mean age was 58.9 ± 13.1 years, with 216 patients (21.5%) younger than 50 years. The referral physicians included gastroenterologists for 582 patients (58.0%), general practitioners for 230 (22.9%), general surgeons for 82 (8.2%), oncologists for 43 (4.3%), internal medicine specialists for 27 (2.7%), and other specialties for 73 patients (7.3%). Three of the referrals did not include the specialty of the referring physician. Most colonoscopies (58.8%) were requested by in-hospital physicians.

Cecum intubation was achieved in 956 colonoscopies (95.2%). Significant lesions were found in 379 patients (37.7%), and 327 patients (32.6%) had neoplastic lesions. Most of the neoplastic lesions were non-advanced adenomas (22.2%); 10.4% and 3.7% of the entire patient population had advanced adenomas and CRC, respectively. IBD was diagnosed in 25 patients (2.5%), angiodysplastic lesions in 37 (3.7%), and benign stenosis in 5 (0.5%). EPAGE II criteria were applied in 968 cases (96.4%). The appropriateness could not be calculated for 36 applications for the following reasons: indication not included in the application form ($n = 6$), liver transplant protocol ($n = 3$), actinic proctitis surveillance ($n = 2$), liver metastasis ($n = 4$), radiological suspicion of CRC ($n = 7$), and suspicion of IBD based on arthropathy of unknown origin ($n = 4$). In addition, although the indication “surveillance for CRC in patients with known IBDs” ($n = 10$) is included in the list on the EPAGE II website, the assessment is not currently available and therefore it was not included in the calculation.

Overall, 866/96 colonoscopies (89.5%) were appropriate ($n = 778$) or uncertain ($n = 88$) according to EPAGE II criteria, and 102 (10.5%) were inappropriate, according to EPAGE

II criteria. Table 1 shows the appropriateness of colonoscopy according to the indication. The most frequent inappropriate indications following EPAGE II criteria were unsuitable surveillance intervals for neoplastic lesions after curative resection ($n = 50$) and CRC screening at inadequate intervals ($n = 21$).

Regarding the relationship between the specialty of the referring physician and appropriateness of colonoscopy, the rate of appropriate indication for colonoscopies requested by gastroenterologists was not significantly different from the rates for all other specialists (90.1% vs. 88.5%, respectively; $P < 0.4$). When gastroenterologists were compared with general practitioners or internal medicine specialists, there were no statistically significant differences ($P = 0.4$ and $P = 0.7$, respectively) (Table 2). However, appropriateness was higher for gastroenterologists compared with general surgeons (90.1% vs. 80.0%, respectively; $P = 0.009$).

Inappropriate indications based on these criteria were also analyzed according to the specialty of the referring physician, and showed that “surveillance of neoplastic lesions after curative resection at intervals other than those recommended by clinical guidelines” was the most frequent indication among gastroenterologists, general practitioners, and surgeons (40.0%, 33.3%, and 73.3%, respectively). This was followed by “CRC screening at a younger age than usually recommended” for gastroenterologists and general practitioners (27.3% and 33.3%, respectively), and by “miscellaneous indications” for surgeons (26.7%).

Appropriateness following these criteria was higher in patients who were over 50 years old compared with younger patients (92.9% vs. 76.7%; OR 3.98, 95%CI 2.60–6.09; $P < 0.001$). The most frequent inappropriate indication in participants younger than 50 years was “CRC screening at a younger age than usually recommended” (33.3%) followed by surveillance of neoplastic lesions (20.8%), nonspecific abdominal symptoms (20.8%), uncomplicated chronic diarrhea (14.6%), and IBD assessment (8.3%). Among gastroenterologists and general practitioners, CRC screening was the most frequent inappropriate indication (37% and 50%, respectively), followed by nonspecific abdominal symptoms (18.5%) and uncomplicated diarrhea (25%), respectively. The main inappropriate indication for surgeons was surveillance of a neoplastic lesion (75%). Overall, 91.2% ($n = 93$) of the inappropriate indication included at least one of the following conditions: colonoscopy requested in participants younger than 50 years, CRC screening or surveillance of neoplastic lesions.

Table 3 shows the association between appropriateness of colonoscopy according to the EPAGE II criteria and detection of lesions at colonoscopy. Significant lesions were found more frequently in colonoscopies deemed appropriate or uncertain than those assessed as inappropriate (38.8% vs. 24.5%; OR 1.95, 95%CI 1.223.13; $P < 0.005$). Advanced neoplastic lesions were also found more frequently in appropriate colonoscopies. Only 1 of 65 (1.5%) advanced adenomas and 1 of 34 (2.9%) CRC lesions were detected in patients with an inappropriate indication for colonoscopy. Sensitivity, specificity, positive and negative predictive values of EPAGE II criteria for detecting significant lesions were 93.1% (95%CI 90%–96%), 12.7% (95%CI 10%–15%), 38.8% (95%CI 36%–42%), and 75.5% (95%CI 67%–84%), respectively, whereas for advanced neoplastic lesions they were 98.0%

(95%CI 95%–100%), 11.5% (95%CI 9%–14%), 11.2% (95%CI 9%–13%), and 98% (95%CI 95%–100%), respectively (Table 4).

In the logistic regression analysis of potential variables associated with the diagnostic yield of colonoscopy, the only factors associated with finding a significant lesion were having an appropriate indication according to EPAGE II criteria and male sex (OR 1.93, 95%CI 1.20–3.11; $P = 0.007$ and OR 1.94, 95%CI 1.49–2.53; $P < 0.001$, respectively). Bivariate analysis revealed that age >50 years was significantly associated with the diagnostic yield (OR 2.35, 95%CI 1.71–3.51; $P < 0.001$). In the logistic regression analysis, age as an independent variable was associated with finding a significant lesion (OR 1.04; 95%CI 1.025–1.047; $P < 0.001$). However, age showed collinearity ($\rho = -0.164$; $P < 0.001$) with EPAGE II criteria; therefore, age and EPAGE II criteria were not included jointly in the regression analysis of prediction of a significant lesion.

DISCUSSION

The current study was designed to validate the recent EPAGE II criteria for assessing the appropriateness of colonoscopy in a clinical practice setting. In a large prospective cohort study of 1004 consecutive patients, these criteria enabled the identification of the most relevant inappropriate referrals, which could be valuable for optimizing the efficiency of open-access endoscopy units. The results showed that the majority of indications for colonoscopy were appropriate according to the EPAGE II criteria, whereas uncertain and inappropriate indications each accounted for approximately 10% of cases. These results contrast with those of some EPAGE I studies in which a high proportion of indication were uncertain [14,15]. In a recent multicenter study that assessed appropriateness of colonoscopy using EPAGE I criteria in a screening population [8], approximately 60% of the indications were uncertain (mostly related to slight risk or no risk for CRC). Evidence from recent screening guidelines has helped reduce the number of uncertain indications, especially now that colonoscopy is considered an acceptable screening strategy for average-risk populations [16]. The latter along with the launch of screening programs in Spain, contributed to the lower rate of inappropriate indications for colonoscopy found in the present study. In addition, the present study suggests that EPAGE II criteria are useful for identifying inappropriate indications. We found the most inappropriate requests for colonoscopy (91.2%) concerned the following: CRC screening, surveillance of neoplastic lesions, or requests for colonoscopy for patients younger than 50 years. Although requests for colonoscopy that involved at least one of these conditions accounted for 60%, 91% of inappropriate indications involved these conditions. The most frequent inappropriate indications involved surveillance of colonic polyps and CRC at intervals that differed from recommended intervals: for low- and high-risk adenomas, follow-up is recommended at 5 and 3 years, respectively, whereas for CRC surveillance, follow-up is recommended at 5, 3, or 1 year, if no lesion, low-risk adenoma or high-risk adenoma, respectively, was found at the last postoperative colonoscopy [17]. This is in agreement with other studies of criteria for appropriateness of colonoscopy [7,18,19]. In fact, Grassini et al. [19] applied the American Society for Gastrointestinal Endoscopy (ASGE) criteria to 1017 consecutive patients and found that 32% of the inappropriate indications corresponded to shortened intervals for the surveillance of neoplastic lesions. In Spain, this indication constituted 42%

of inappropriate referrals according to EPAGE I criteria [7]. Therefore, wide dissemination of new guidelines for surveillance of colon neoplasms is warranted to improve the efficiency of colonoscopy use. In addition, we found that colonoscopy appropriateness was markedly lower in patients younger than 50 years. Although these individuals constituted approximately 20% of the entire sample, they represented about 50% of the inappropriate endoscopies in the current study. In patients younger than 50 years, having CRC screening at a younger age is usually recommended was the most frequent inappropriate indication. In the total patient population, CRC screening was the second most common inappropriate indication, which is in accordance with previous studies [3,7,14]. Nevertheless, the applicability of EPAGE II criteria may be limited in some patients because the criteria do not include a number of colonoscopy indications, such as liver transplant protocol, actinic proctitis surveillance, looking for the primary tumor in patients with liver metastasis, radiological suspicion of CRC, or suspicion of IBD based on arthropathy of unknown origin. This fact precluded calculation of the EPAGE II score in 36 of our patients, which indicates that the criteria need further refinement.

In the current study, variables that might be associated with significant endoscopic findings were assessed. Consistent with previous EPAGE I studies [9], multivariate analysis identified appropriateness and male sex as the only variables associated with the finding of a significant lesion. Interestingly, we found significant lesions in approximately 24% of cases with inappropriate indications, although only two patients had significant neoplastic lesions. Specifically, CRC was detected in a 48-year-old man and advanced adenoma was identified in a 55-year-old woman by colonoscopies for indications of nonspecific abdominal symptoms and inappropriate surveillance interval for neoplastic lesions, respectively. In this regard, EPAGE II criteria showed a high sensitivity and negative predictive values for detecting advanced colorectal lesions, suggesting that it is an effective tool for ruling out inappropriate colonoscopies. In fact, most significant lesions and, in particular, most advanced colorectal lesions, were detected in colonoscopies considered appropriate by EPAGE II criteria. This positive association between appropriateness and the diagnostic yield of significant and neoplastic lesions was in agreement with similar studies that used EPAGE I criteria [3,7,9,14]. Although diagnostic yield is one of the parameters to consider when assessing the validity of appropriateness criteria [9,20], it is not a perfect gold standard for assessing appropriateness. In fact, colonoscopies based on appropriate indications do not always lead to the detection of significant lesions, nor do inappropriate colonoscopies always result in an absence of significant lesions. Therefore, as the association between appropriateness criteria and the detection of significant lesions is not perfect, EPAGE II criteria should be considered part of the evidence-based decision process. That is, the criteria should be used to assist the clinician in making the decision about whether to request a colonoscopy, but they should not be used as the sole criteria for the decision.

In the current study, appropriateness of colonoscopy was not significantly higher for gastroenterologists (90%) compared with the other specialists (88%). However, although appropriateness was similar for gastroenterologists and internal medicine specialists or general practitioners, it was markedly higher for gastroenterologists compared with surgeons. These results are not surprising and are consistent with other EPAGE studies that found similar appropriateness rates for general practitioners and gastroenterologists for

assessing colonoscopy or gastroscopy indications [14,21]. However, some authors have suggested the need for implementing educational programs for general practitioners and specialists to improve referral appropriateness [22,23]. In a prospective study that included 677 colonoscopies, Suriani et al. [23], found that there were significantly fewer inappropriate requests from gastroenterologists (9%) than from general practitioners (25%) or surgeons (29%). In a recent study that assessed the impact of an ASGE criteria educational program involving 133 primary care physicians [18], the percentage of appropriate indications increased from 77% to 97% among attendees of the educational course. This finding suggests that educational interventions concerning ASGE or EPAGE criteria are useful in reducing inappropriate indications for certain diagnoses and for educating referring physicians.

In conclusion, the present study shows for the first time that EPAGE II is a simple, valid score for detecting inappropriate colonoscopies in clinical practice. The main causes of inappropriate referrals were inadequate intervals for neoplastic surveillance, CRC screening at an early age, and colonoscopy before the age of 50 years. Therefore, EPAGE II criteria may be very useful in optimizing management of open-access endoscopy units at different levels. First, the criteria can help prioritize waiting lists for outpatient colonoscopy. Second, EPAGE II criteria can help identify patients referred for scheduled colonoscopy who have an inappropriate score, leading to a more suitable diagnostic test for such patients. Third, EPAGE II criteria can be used to develop educational interventions for referring physicians so that they make fewer inappropriate referrals.

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Table 1

Appropriateness of colonoscopy following criteria of the European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) II according to indication.

Indication	<i>n</i>	Appropriate or uncertain (<i>n</i> = 866) <i>n</i> (%)	Inappropriate (<i>n</i> = 102) <i>n</i> (%)
Colorectal cancer screening	353	332 (38.3)	21 (20.6)
Surveillance of neoplastic lesions	121	71 (8.2)	50 (49.0)
Hematochezia/rectal bleeding	179	179 (20.7)	0
Nonspecific abdominal symptoms	93	83 (9.6)	10 (9.8)
Iron deficiency anemia	128	128 (14.8)	0
Inflammatory bowel disease evaluation	12	7 (0.8)	5 (4.9)
Uncomplicated chronic diarrhea	51	39 (4.5)	12 (11.8)
Miscellaneous	31	27 (3.1)	4 (3.9)
Total	968	866 (89.5)	102 (10.5) *

* Percentages for row.

Table 2

Relationship between referral physician and appropriateness of colonoscopy.

Medical specialty	<i>n</i>	Appropriate or uncertain <i>n</i> (%)	Inappropriate <i>n</i> (%)
Gastroenterologists	557	502 (90.1)	55 (9.9)
General practitioners	229	211 (92.1) [*]	18 (7.9)
Surgeons	75	60 (80.0) ^{**}	15 (20)
Internal medicine	27	25 (92.6) [†]	2 (7.4)
Other specialists	77	65 (84.4) [‡]	12 (15.6)

^{*} $P = 0.4$ vs. gastroenterologists.

^{**} $P = 0.009$ vs. gastroenterologists.

[†] $P = 0.7$ vs. gastroenterologists.

[‡] $P = 0.1$ vs. gastroenterologists.

Table 3
Association between appropriateness of colonoscopy and detection of lesions at colonoscopy.

Colonoscopy findings	Appropriate or uncertain (n = 866)	Inappropriate (n = 102)	OR	95% CI	P
Significant lesions, * n (%)	336 (38.8)	25 (24.5)	1.95	1.22–3.13	0.005
Neoplastic lesions, n (%)	298 (34.4)	16 (15.7)	2.82	1.62–4.90	< 0.001
Advanced neoplastic lesions, ** n (%)	97 (11.2)	2 (2.0)	6.31	1.53–25.98	0.004
CRC, n (%)	33 (3.8)	1 (1.0)	4.00	0.54–29.57	0.248

CI, confidence interval; CRC, colorectal cancer; OR, odds ratio.
* Neoplastic lesions (CRC, advanced adenoma, or non-advanced adenoma), inflammatory bowel disease, non-malignant stenosis, or angiodysplasias.
** Advanced adenomas and CRC.

Table 4

Statistical performance of the European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) II criteria for significant lesions and advanced neoplastic lesions.

	Significant lesions[*] % (95% CI)	Advanced neoplastic lesions[†] % (95% CI)
Sensitivity	93.1 (90–96)	98.0 (95–100)
Specificity	12.7 (10–15)	11.5 (9–14)
PPV	38.8 (36–42)	11.2 (9–13)
NPV	75.5 (67–84)	98.0 (95–100)

CI, confidence interval; CRC, colorectal cancer; NPV, negative predictive value; PPV, positive predictive value.

^{*} Neoplastic lesions (CRC; advanced adenoma, defined as adenoma ≥ 10 mm in size, with villous component or high grade dysplasia; and non-advanced adenoma); inflammatory bowel disease; non-malignant stenosis; and angiodysplasias.

[†] Advanced adenoma and CRC.