NEW YORK SOCIETY FOR GASTROENTEROLOGY & ENDOSCOPY
48th Annual
NEW YORK COURSE
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Update on Detection of Colon Cancer:

Targets, Techniques, and Technology

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Disclosures

Olympus

Micro-Tech

Braintree Sebela

GI Windows

Virtual Health Partners

Rom-Tech

MD Medical Navigators

Myabroadmds

Topics for Consideration

1. Trends in CRC screening
   - Progress made and updated performance targets
   - Change surrounding mt-sDNA testing
2. Process advances to improve detection and reduce barriers to CRC screening and detection
   - Access to care esp. after positive mt-sDNA testing
   - Prep
   - Nurse involvement in detection
3. Technological advances to improve adenoma and SSL detection
   - Water exchange
   - Enhanced imaging impact on adenoma, SSL, advanced lesion recognition
   - Distal attachments
   - AI computer vision

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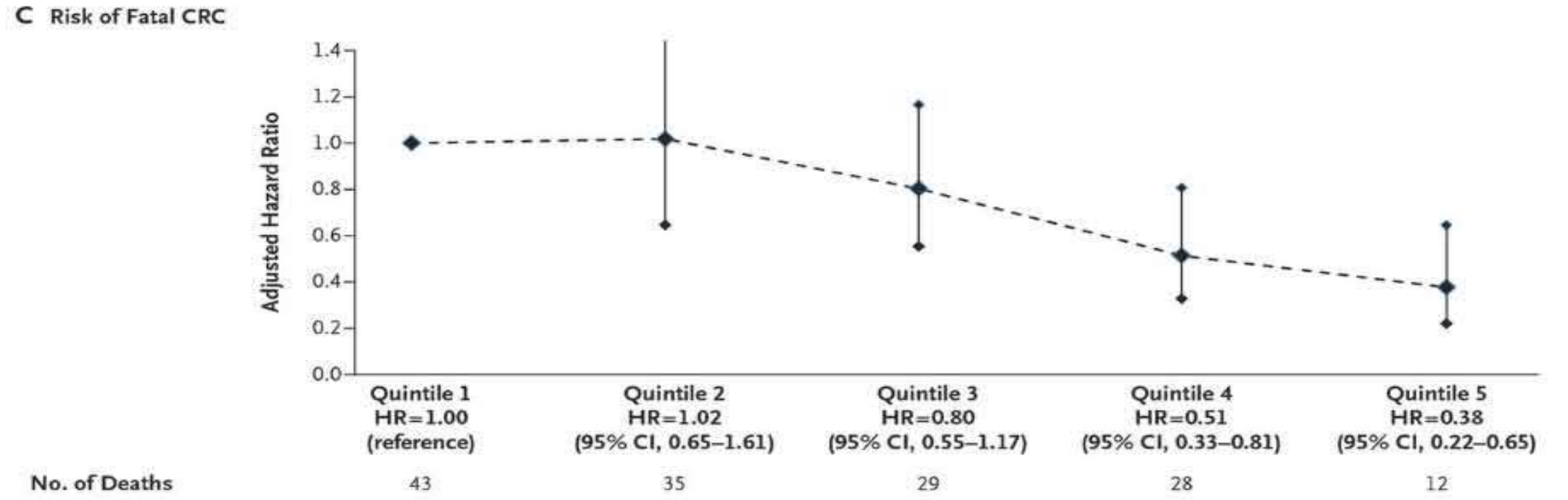
The Search

Finding more polyps and early stage CRC

1. Trends in CRC Screening

Adenoma Detection Rate and Risk of Colorectal Cancer and Death



Corley et al. N Engl J Med 2014; 370:1298-1306

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Increased Adenoma Detection Rates Can Reduce Risks of Colorectal Cancer (CRC)

- The authors evaluated 314,872 colonoscopies performed by 136 gastroenterologists using data from an integrated health care delivery organization

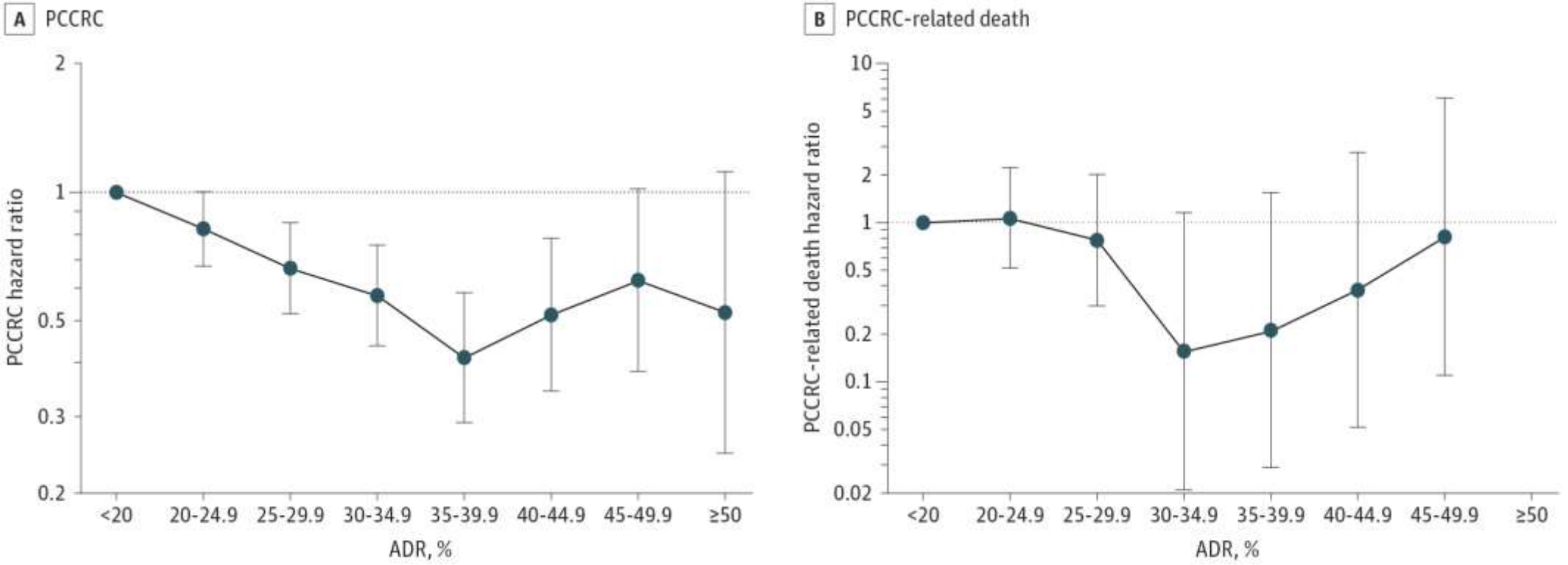
Each 1% increase in the ADR was associated with:

- **3% decrease in the risk of interval CRC** (hazard ratio, 0.97; 95% CI, 0.96-0.98)
- **5% decrease in the risk of a fatal interval CRC** (hazard ratio, 0.95; 95% CI, 0.94-0.97)

Corley DA et al. *N Engl J Med*. 2014;370:1298-1306.

ADR and Risk of Interval Cancer

- Kaiser Permanente Northern California, Kaiser Permanente Southern California, and Kaiser Permanente Washington
- 43 endoscopy centers, 383 eligible physicians, and 735 396 patients 50-75 w negative COL between January 2011 and June 2017, follow-up through December 2017
- ADR above median of 28% associated with lower risk of PCCRC (1.79 vs 3.10 cases per 10 000 person-years)
- Lower risk of PCCRC death (0.05 vs 0.22 cases per 10 000 person-years)



Schottinger JE, et al. *JAMA.* 2022;327(21):2114–2122.

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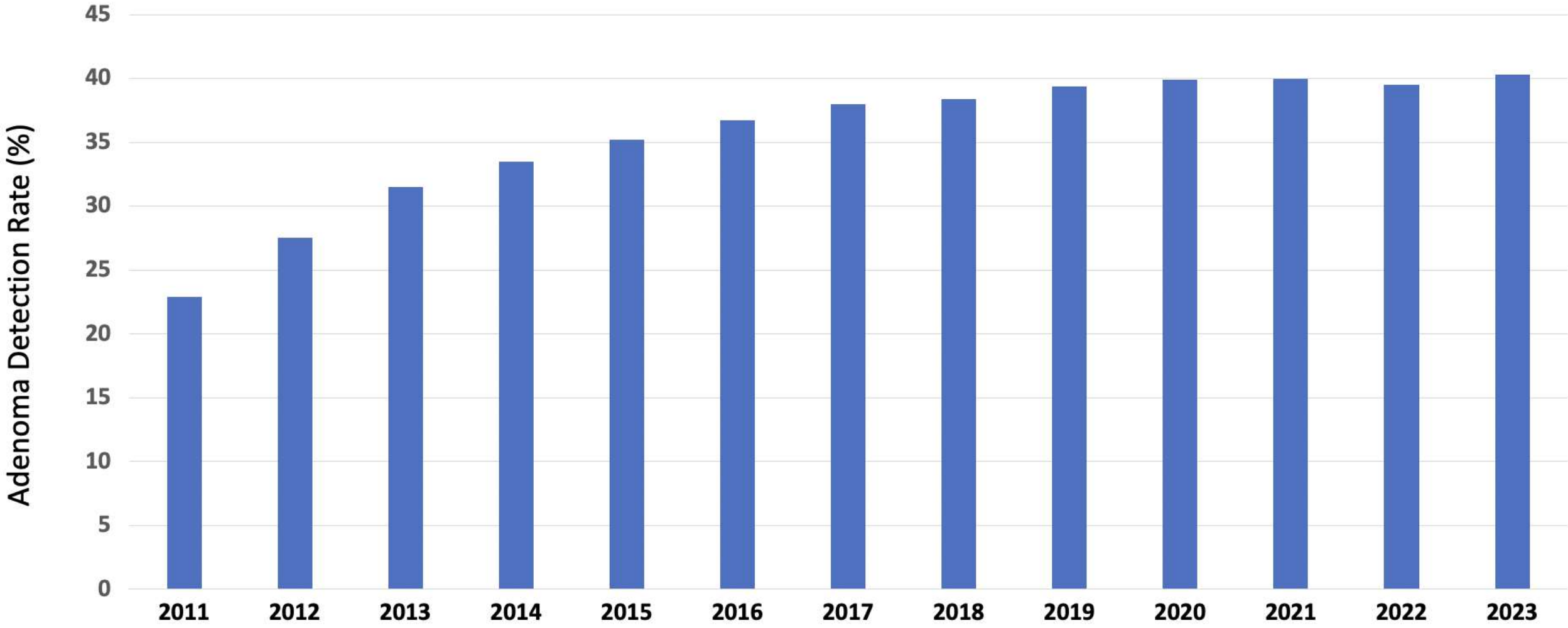
GIQuIC Adenoma Detection Rate



GIQuIC

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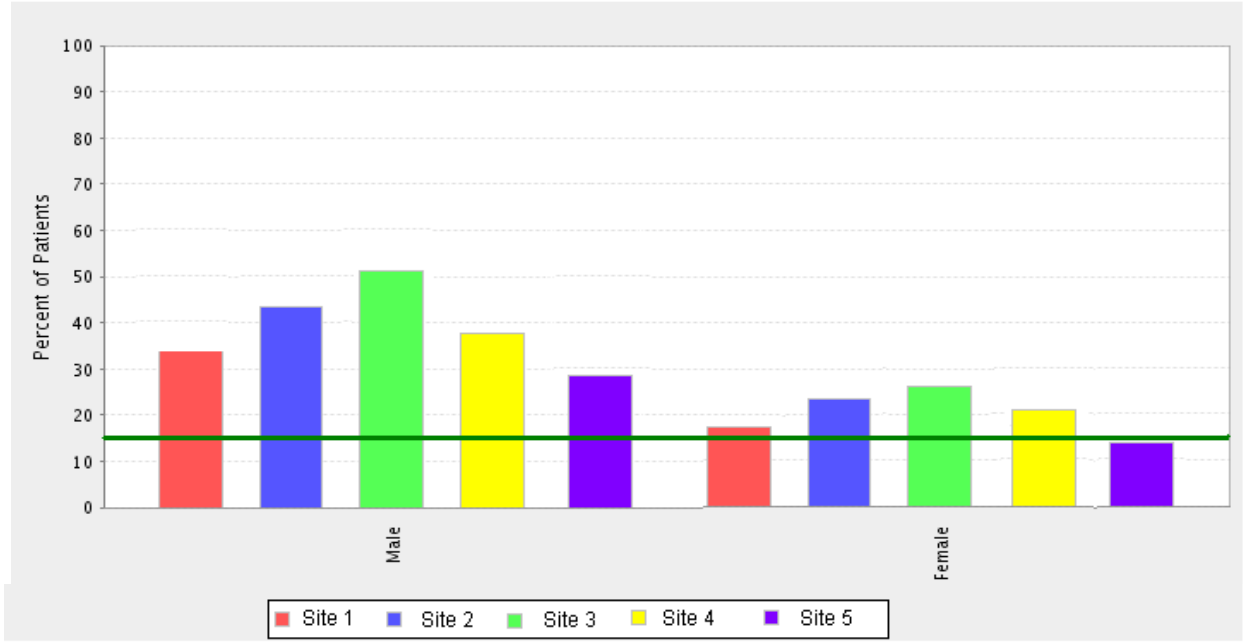
GIQuIC Custom Reports

Adenoma Dection Rates

Patients grouped by gender
Time Period: 01/2010 - 12/2010; **Site:** Demo (1795)



Adenoma Dection Rates

Note: Time periods at the end of the graph and data table have been omitted because there were no patient records during that time.

Benchmark Group	Time Period	Male	Femail
Site 1	2010	33%	18%
Site 2	2010	42%	25%
Site 3	2010	51%	28%
Site 4	2010	39%	20%
Site 5	2010	29%	15%

Date of report: 30-Jul-2010 12:18:45 GMT-04:00 run by User: Signature User (rsignature) at Site: Demo (1795) in Demo

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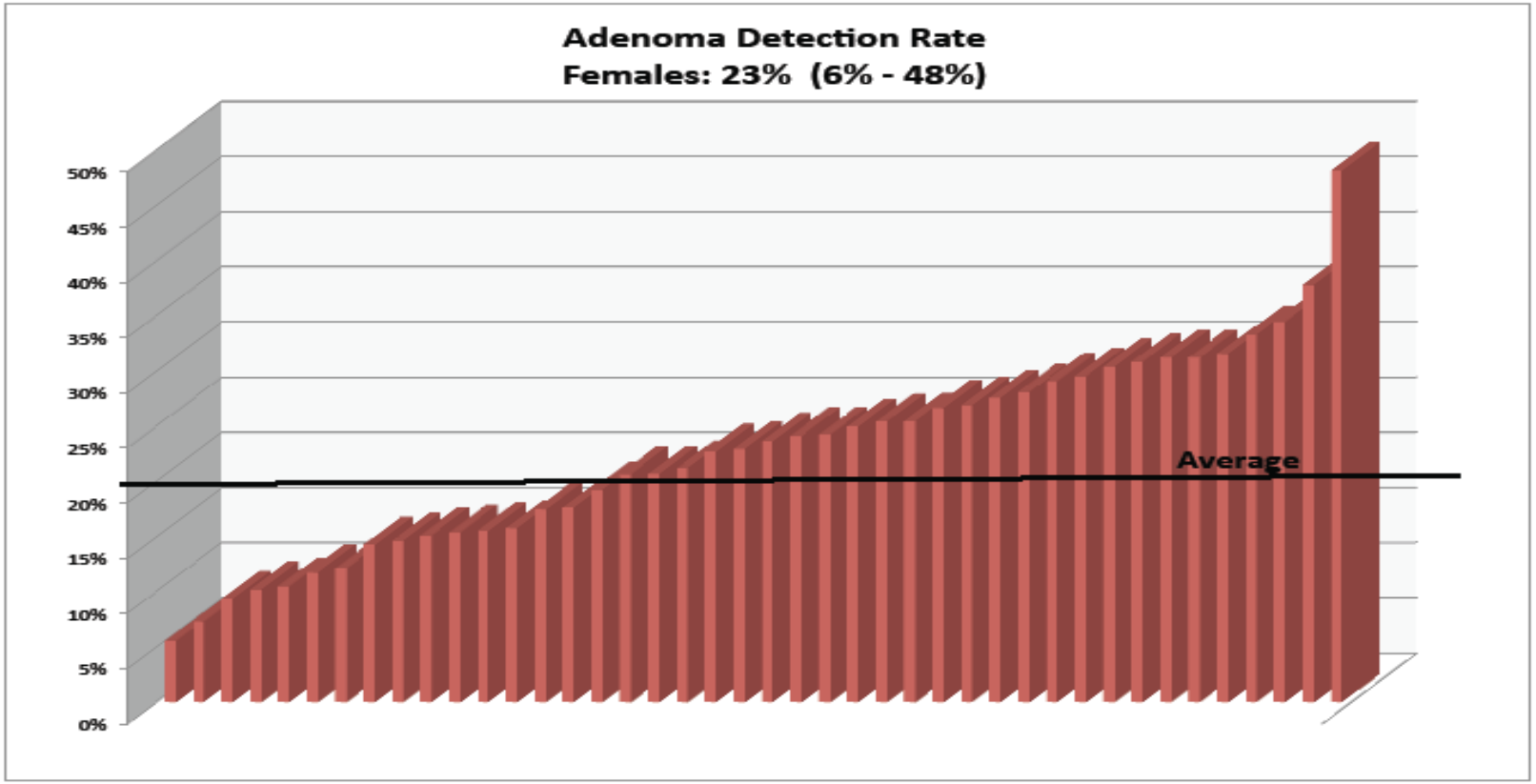
Performance Varies Widely
Female ADR: 23% (6%-48%)



Updated Adenoma Detection Rate Target

- ADR during colonoscopies in men and women ≥ 45 for **all-indications (Screening, diagnostic, and surveillance)**
  - Excludes Patients with positive non-colonoscopy screening tests, genetic cancer syndromes (eg, polyposis),IBD, or undergoing colonoscopy for therapy of known neoplasms

- NEW ADR Benchmark is **35%**
  - ≥ 40% for men ≥45 yrs
  - ≥ 30% for women ≥45 yrs

- ADR for patients ≥45 with abnormal stool test: 50%

Rex, et al. Quality indicators for colonoscopy; *Gastrointest Endosc. 2024;* 100: 352-381.

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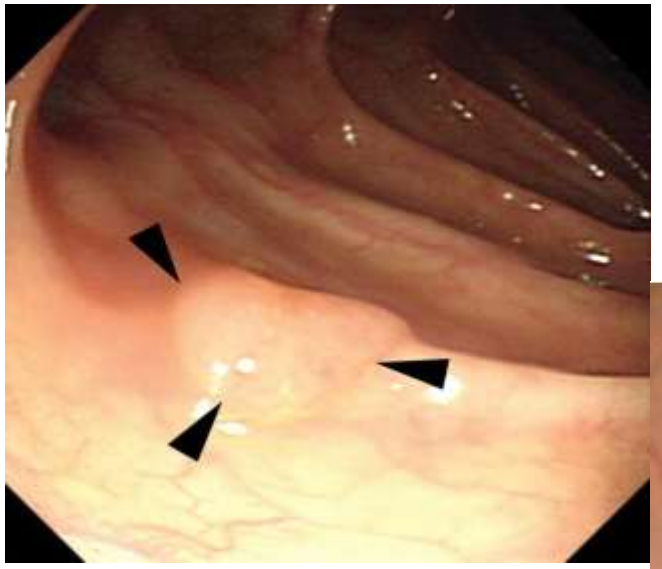
Sessile Serrated Lesion Detection Rate

- SSLDR should be measured
- Benchmark is **6%**



Rex, Douglas K., Anderson, Joseph C., Butterly, Lynn F., Day, Lukejohn W., Dominitz, Jason A., Kaltenbach, Tonya, Ladabaum, Uri, Levin, Theodore R., Shaukat, Aasma, Achkar, Jean-Paul, Farraye, Francis A., Kane, Sunanda V., Shaheen, Nicholas J., et al. Quality indicators for colonoscopy; Gastrointest Endosc, 2024; Volume 100, Issue 3, 352-381.

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Sessile Serrated Polyp Detection Rate and PCCRC

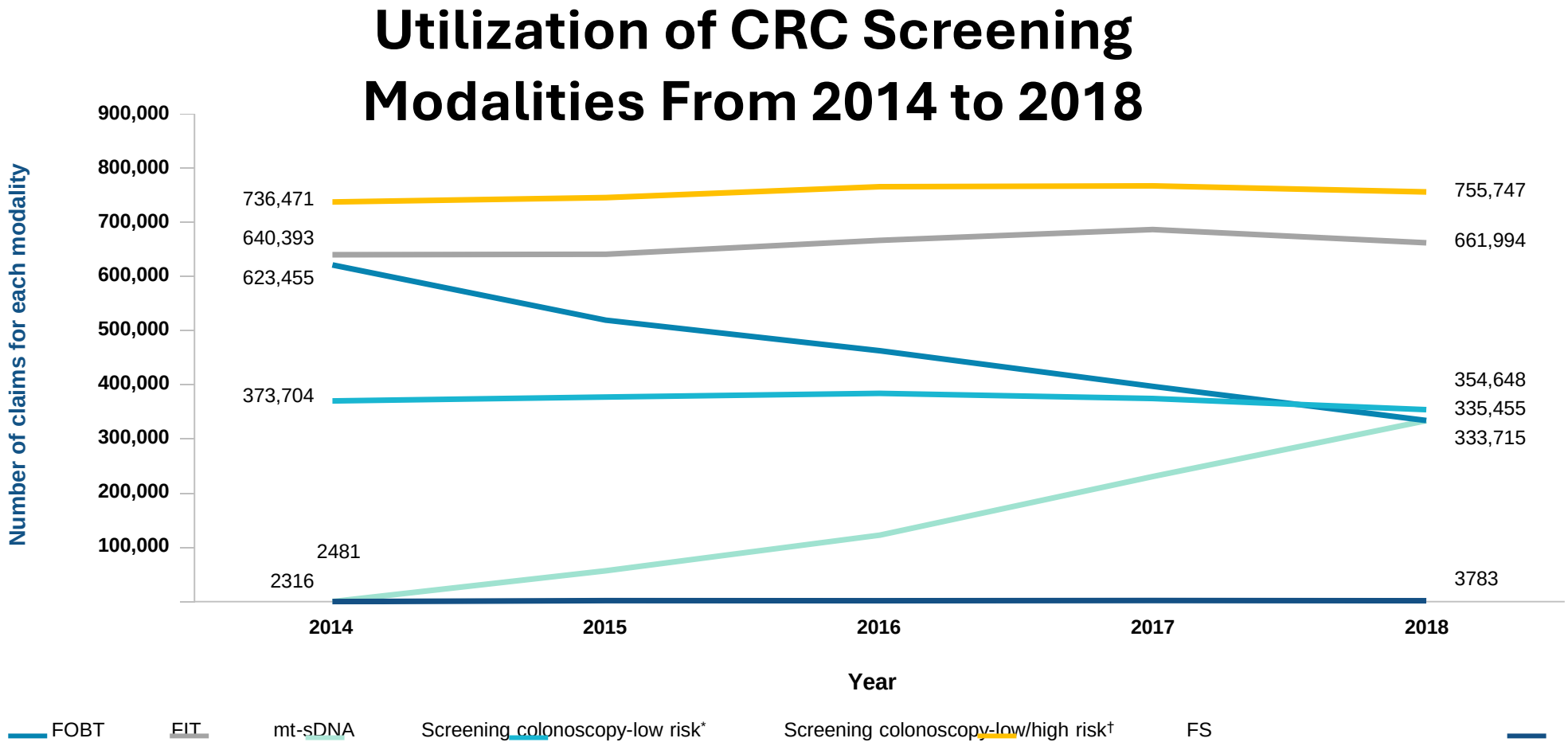
- Sessile serrated polyp, traditional serrated adenoma, large [≥1 cm] or proximal hyperplastic polyp >5 mm
- Average SSDR from GIQuIC: 5 million COL, 4000 endoscopists: **6%**
- Associated with PCCRC:
- NH Colonoscopy Registry: Compared to endoscopists with SSDR<3%:
  - Lower risk of PCCRC:
    SSDR 3% to <9% (HR 0.57; 95% CI .39-.83)
  - SSDR 9% or higher (HR .39; 95% CI .20-.78)

Shaukat A, et al. Am J Gastroenterol. 2021 1;116(1):95-99. Anderson JC, *Gastrointest Endosc*. 2022;96(2):310-317.

Update on multi-target stool DNA test screening

- Access to colonoscopy a current challenge, esp. in underserved communities.
- Increase in uptake of mt-sDNA testing
  - Efficiency and cost efficiency benefits of mt-sDNA testing relative to FIT and emerging blood assay “liquid biopsy”
  - Cologuard Plus NEJM pivotal trial – increased age specific specificity and reduced false positive rate,
    94% of cancers detected, 43% of advanced polyps.
  - Higher proportion of cancers detected are stage 1-- @ 75%
- Generates problem of prompt access to colonoscopy following a positive stool-based test
- Problem of inappropriate use of stool-based tests in high risk screening cases more likely to have polyps.

Utilization of mt-sDNA Over Time



Limburg PJ, et al. *Curr Med Res Opin*. 2021;37(4):605-607.

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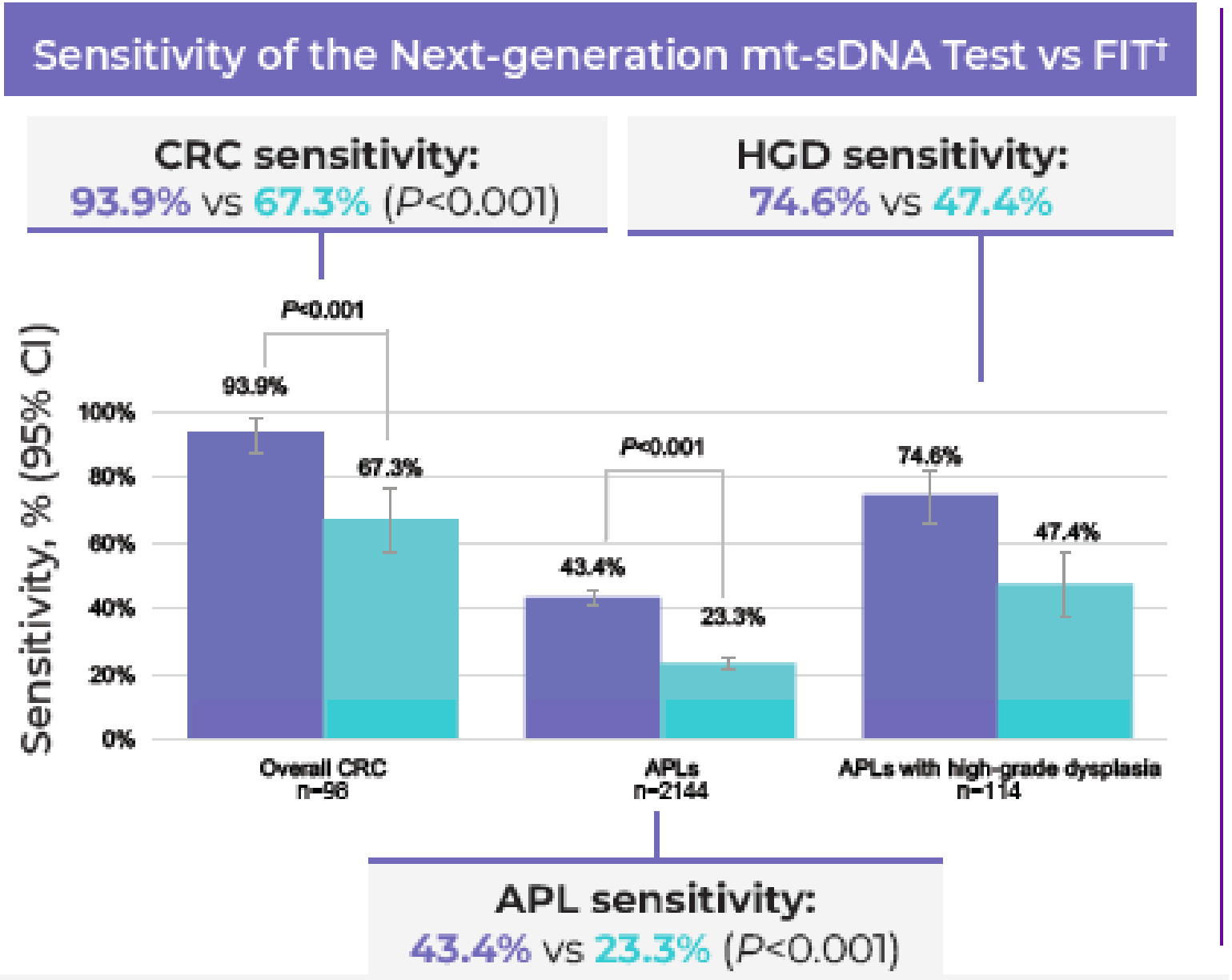
The Cologuard Plus™ Test: Blue Study Data



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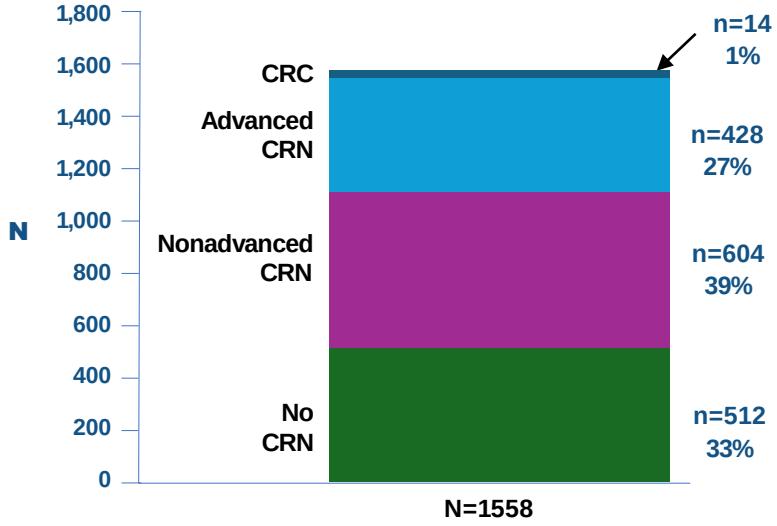
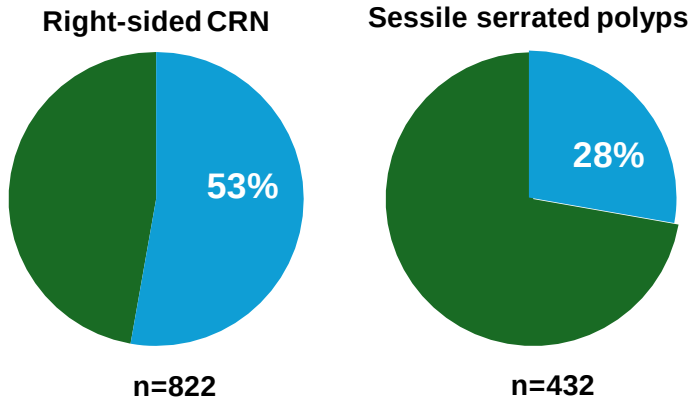
Predictive Value of mt-sDNA for Colorectal Neoplasia is Preserved Regardless of Patient's Exposure to Prior Colorectal Cancer Screening Colonoscopy

- Among the patients positive for mt-sDNA who underwent subsequent diagnostic colonoscopy, neoplastic lesions and CRCs were found in 67%
  and 1% of patients
- PPV for neoplastic lesions was 67% and 53% for right-sided CRN, respectively
- The median age at mt-sDNA testing, which led to diagnosis of CRC, was 66 (IQR 60-73) years
- More than 70% of CRC were detected at early stage (AJCC stage 0-II disease)

Yield of Neoplastic Findings at Follow-up Colonoscopy for mt-sDNA-positive Tests



Positive Predictive Value (PPV)



Eckmann JD, et al. *Am J Gastroenterol*. 2020;115(4):608-615.

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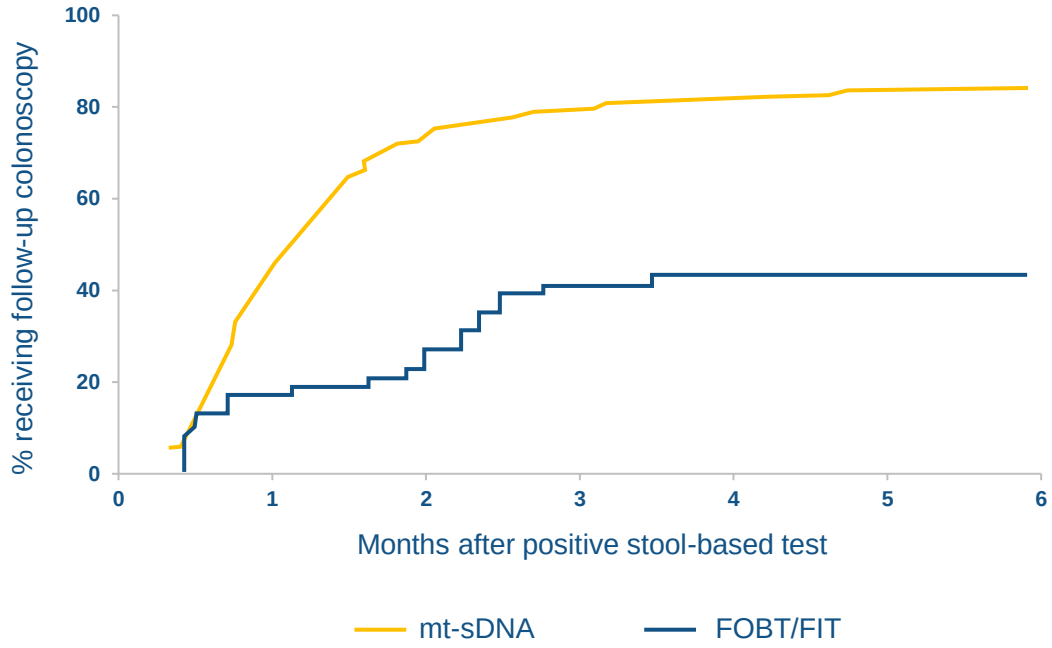
Incidence of Screening Colonoscopy Decreased Significantly but Increased Significantly for mt-sDNA Testing Between 2016 to 2018

Majority of individuals underwent follow-up colonoscopy within the initial 3 months of a positive stool-based test

Colonoscopy Follow-up Rates

	Positive result N (%)	6-month follow-up colonoscopy rate
mt-sDNA	322 (12.2%)	84.9%
FIT/FOBT	53 (18.7%)	42.6%
P-value for 6-month follow-up		0.0002

CRC Screening Rates in Individuals Due for Screening



Finney Rutten LJ, et al. Prev Med Rep. 2020;20:101202.

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Panel Discussion:

- Is there anything different in practice for patients having colonoscopy following a positive mt-sDNA test?

- How are colonoscopy performance metrics tracked and reported in your unit? Is there any intervention to address poor performers?

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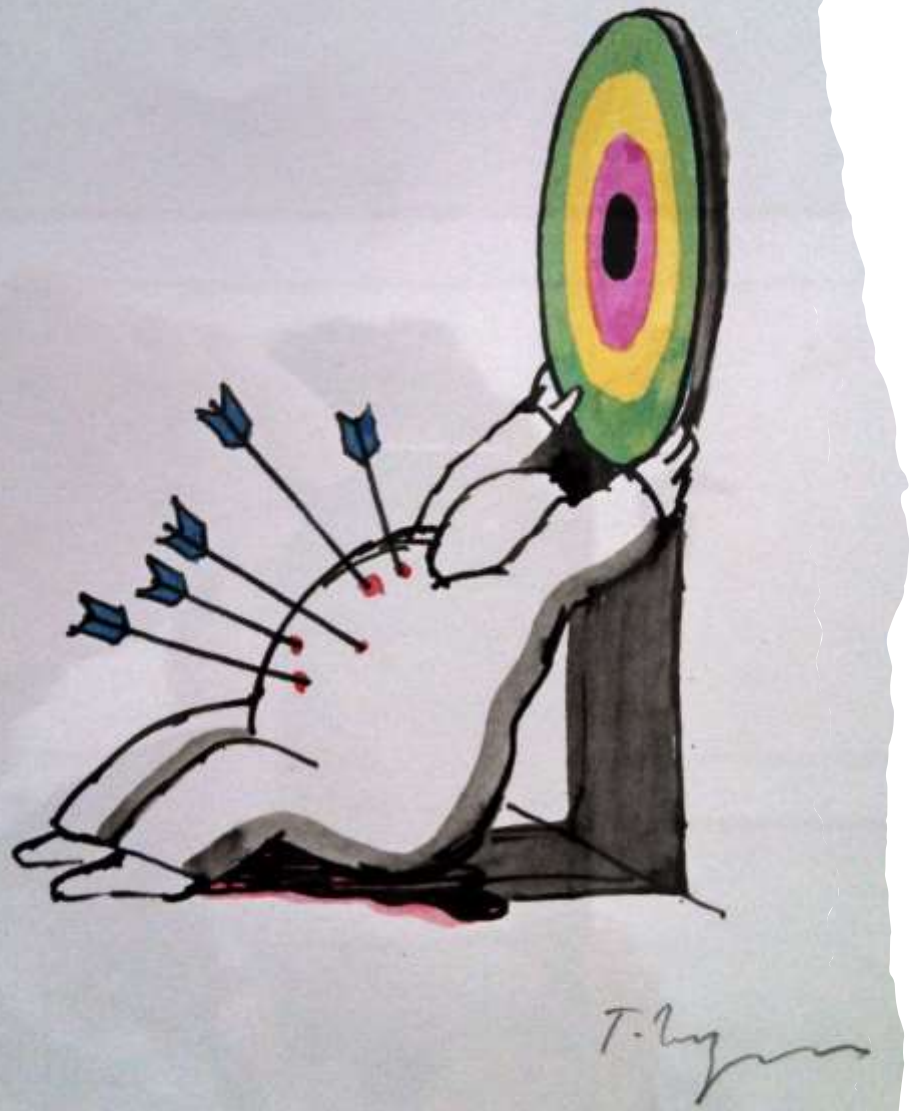

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2. Process advances to reduce barriers and improve detection effectiveness

- CRC Outreach to address barriers in underserved communities
- Attention to the bowel prep
- Role of nurses in enhancing detection

ASGE CRC Outreach Program

- People on lower end of socioeconomic scale are more likely to get CRC regardless of other risk factors and have added access barriers to screening colonoscopy
- Among underseved populations, follow-up/completion colonoscopy rate for those who have positive stool based testing as screening is just 50-70%
- Earlier diagnosis can help address racial/ethnic disparities & increase survival

ASGE CRC Screening Project Advisory Council

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Javelle Wynter, MD, Columbia University Medical Center

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Overview & Goals

- Increase CRC screening for underserved
- Reduce amount of time from abnormal SBT result to follow-up colonoscopy
- Gain better understanding of barriers for timely follow-up colonoscopy
- Educate lawmakers & advocate need for sustainable sources of funding
- Develop playbook & model public policy for use in other states
- 600 “resulted” Cologuard tests (300 per in Georgia & Maryland)
- Navigate patients with abnormal SBT thru follow-up/other applicable care

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Project funded with unrestricted grant from Exact Sciences
and additional support from
Ironwood Pharmaceuticals & Sebela Pharmaceuticals'
Braintree Laboratories affiliate

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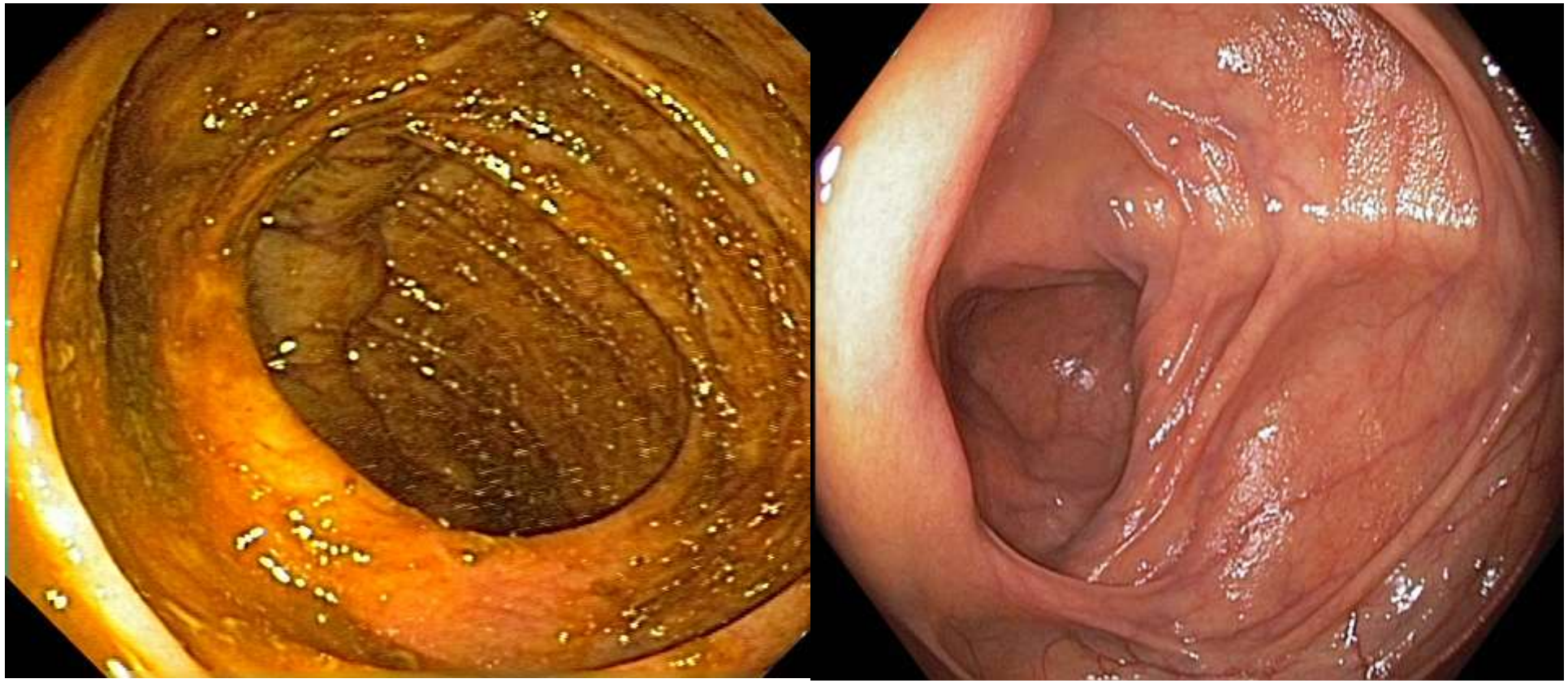
Bowel Prep:
Prerequisite to Imaging Based Detection—
by Human or AI

Make sure its clean!



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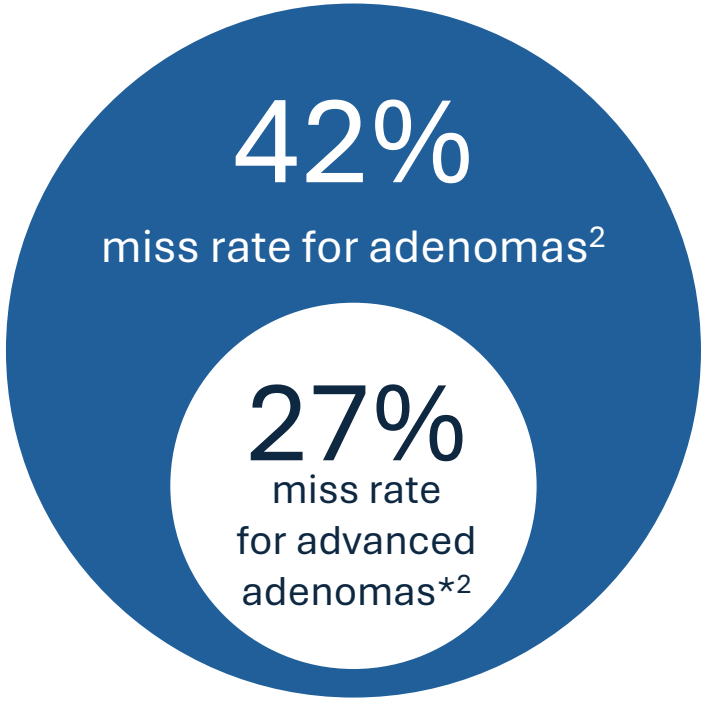
Impact of Inadequate Bowel Preparation: Increased Adenoma Miss Rates

Adenomas are more likely to be missed with suboptimal bowel preparation[1]



83% of patients with suboptimal prep DON'T return for a 2nd screening within 3 years[2]

1. Johnson DA et al. *Gastroenterology*. 2014;147:903-924.
2. Lebwohl B et al. *Gastrointest Endosc*. 2011;73:1207-1214.

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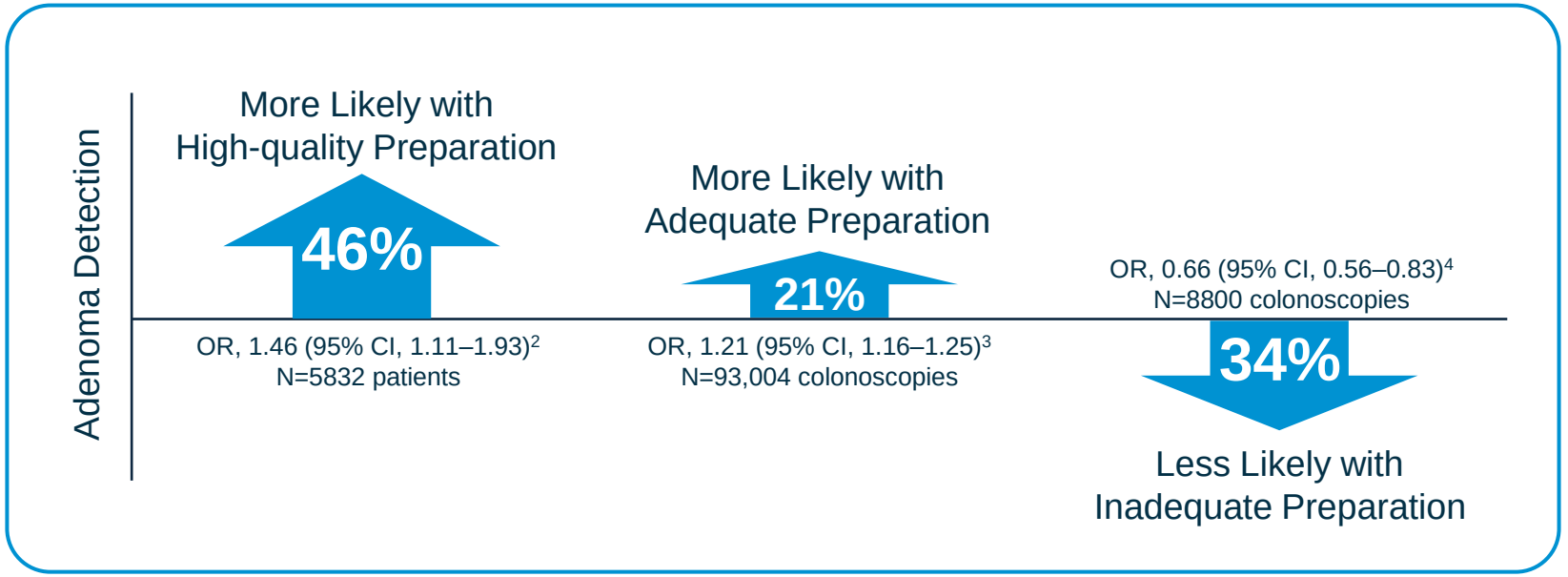
Higher-quality Colon Visualization Is Associated With Increased Detection of Adenomas[1]



- Increases in the ADR: associated with reduced risks of any type of interval CRC diagnosis[5]
- Target goal for adequate bowel preparation: ≥85% of examinations (per physician)[1]

1. Johnson DA et al. *Gastroenterology*. 2014;147:903-924. **2.** Froehlich F et al. *Gastrointest Endosc*. 2005;61:378-384; **3.** Harewood GC et al. *Gastrointest Endosc*. 2003;58:76-79. **4.** Sherer EA et al. *Gastrointest Endosc*. 2012;75:545-553. **5.** Corley DA et al. *N Engl J Med*. 2014;370:1298-1306.

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Would You See This Polyp Without an Excellent Prep?

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Overcoming practical obstacles to successful screening and CRC detection: a novel program

In 2024, Gastro Health Charlottesville implemented NAVGI 360™ into its practice to improve office workflow,
with four key objectives in mind:

1. Reduce no-shows and same-day cancellations
2. Improve workflow efficiency within the practice and reduce incoming call volume from patients
3. Streamline the provision of pre-procedure information and high-quality, cost-sensitive bowel prep kits to patients
4. Provide physicians and practice staff with visibility over the entire process, allowing them to track when patients
receive their prescriptions and monitor their progress

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Data on role of a nurse or second trained eye in the room— “HADe”

“A nurse can play a significant role in increasing the adenoma detection rate (ADR) by acting as a second observer during a colonoscopy, essentially providing an extra set of eyes to identify potential polyps or adenomas that the doctor might miss, thereby improving the overall quality of the procedure; studies have shown that nurse participation can lead to a higher detection rate of polyps and adenomas during colonoscopies. ”

According to Google AI!

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Lei, X. *et al.* The effect of nurse assisted colonoscopy on adenoma detection rates: A meta-analysis of randomized controlled trials. *Int J Colorectal Dis* 2024; **39**:19

- 11 randomized controlled trials involving 8278 pts.
- PDR between the single-observation and dual-observation groups (RR, 1.27; 95%CI, 1.05, 1.54; P=0.01)
- ADR between single observation group and dual observ. groups (RR, 1.15; 95%CI, 1.05, 1.26; P=0.004)

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Panel discussion:

- Are there wide variations in prep quality in your unit and have you had success with quality improvement efforts to address prep?

- Polyp and cancer detection in your unit-What is the nurse's role and perspective?

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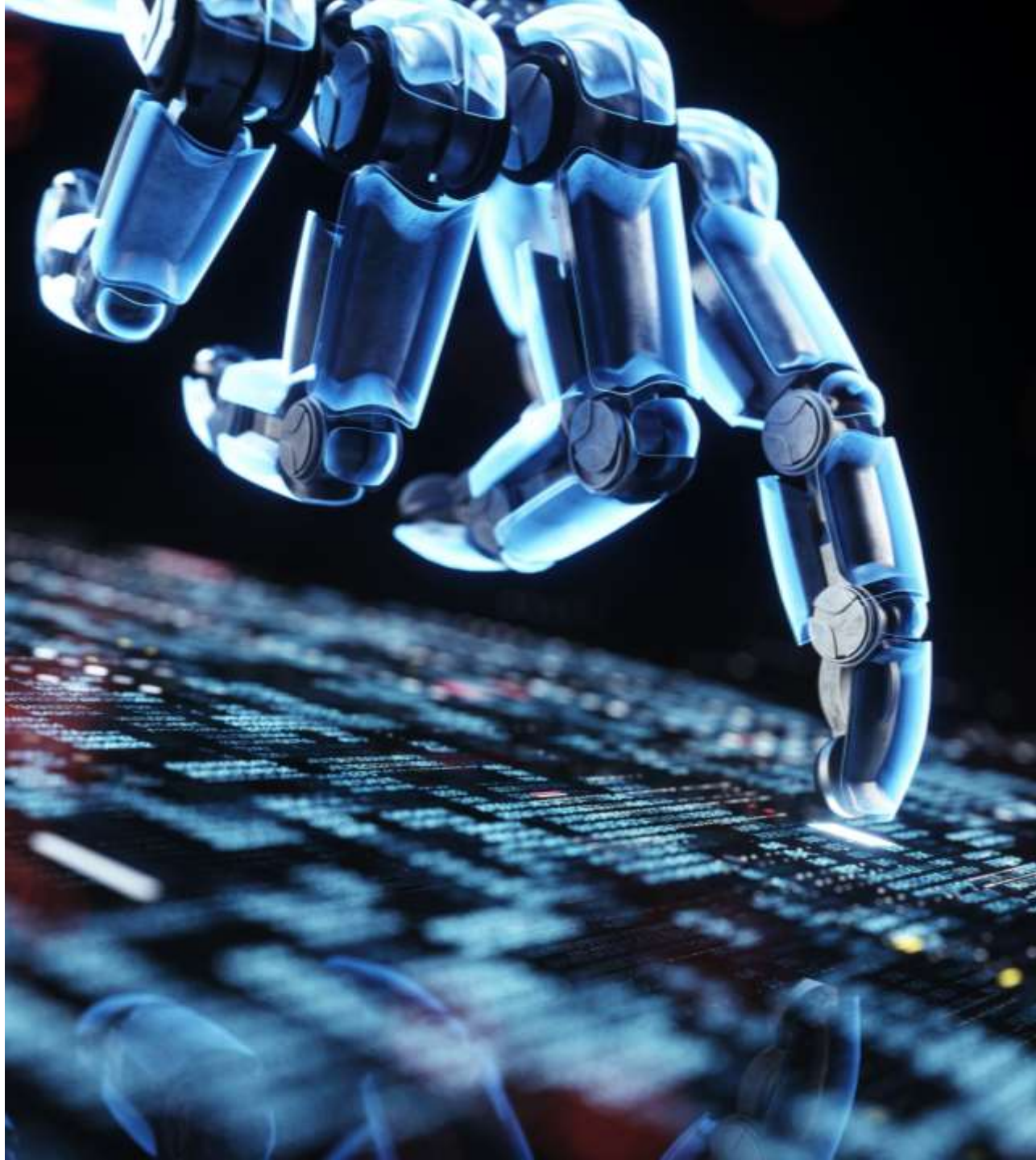
3. Technology Advances, Including AI

- Technique implementation
- Image enhancement
- Distal attachments
- CADe



Interventions to improve adenoma detection rates for colonoscopy

Shaukat, A, et al. GIE 2022;96:171-188

TABLE 1. Summary on interventions to improve ADR

Intervention	Compared with	Absolute increase in adenoma detection	Comments
Technique			
Water assistance	CO_2/air insufflation	6% water immersion 10% for water exchange	Water exchange increases insertion time but withdrawal time same as other techniques
Lengthening withdrawal time	<6 min	9% for 9-min WT compared with 6 min	Evidence supports emphasizing training in withdrawal technique rather than time
Retroflexion in cecum	No retroflexion	17% for right-sided adenomas	Overall success rate 91%, adverse vents .03%
Second look, either retroflexion in the cecum or second forward look in the proximal colon	Single forward look	10% for all adenomas, 5% for right-sided adenomas	Second forward look improves adenoma detection; no difference in retroflexed or straightforward second look
Dynamic change in patient position	No change in position	7%	Adequate distention during position changes is key, particularly with excellent preparation
Technology			
Distal attachment devices	Standard colonoscopy	5%-11%	May reduce procedure time
Enhanced imaging technology (narrow-band imaging, i-SCAN, linked-color imaging, blue-laser imaging, chromoendoscopy, and Methylene Blue-MMX (Cosmo Pharmaceuticals, Dublin, Ireland))	Standard or high definition white-light colonoscopy	5% to 18% absolute improvement in adenoma detection	Narrow-band imaging with 190 colonoscopes is superior to white-light colonoscopy
Computer aided detection technologies	Standard colonoscopy	10%-12% in adenoma, .2 in adenoma per colonoscopy	Added benefit of polyp histology recognition

Water exchange [WE] colonoscopy

17 trials with 41 study arms and 10,350 patients

ADR (95% CI):

WE	41.7% (95% CI, 32.5%-51.5%)
WI	34.4% (95% CI, 28.3%-40.9%)
AI	30.2% (95%CI, 24.4%-36.8%). [note this is in 2018]
CO2 insufflation	31.1% (95% CI, 19.0%-46.4%)

WE had a significantly higher entire colon overall ADR

when compared with:

WI	(OR, 1.31; 95% CrI, 1.12-1.55),
AI	(OR, 1.40; 95% CrI, 1.22-1.62) [note this is in 2018]
CO2 insufflation	(OR, 1.48; 95% CrI, 1.15-1.86).

Fuccio, L, et al. Water exchange colonoscopy increases adenoma detection rate: a systematic review with network meta-analysis of randomized controlled trials. GIE 2018; 88: 589-97.

ASGE/ACG Updated Quality Indicators

Withdrawal time: 8-9 minutes

- Withdrawal technique:
  - Adequate distention
  - Washing and clean up
  - Looking behind folds
  - Segmental inspection and subjective timing

Rex, Douglas K., Anderson, Joseph C., Butterly, Lynn F., Day, Lukejohn W., Dominitz, Jason A., Kaltenbach, Tonya, Ladabaum, Uri, Levin, Theodore R., Shaukat, Aasma, Achkar, Jean-Paul, Farraye, Francis A., Kane, Sunanda V., Shaheen, Nicholas J., et al. Quality indicators for colonoscopy; *Gastrointest Endosc*, 2024; 100: 352-381

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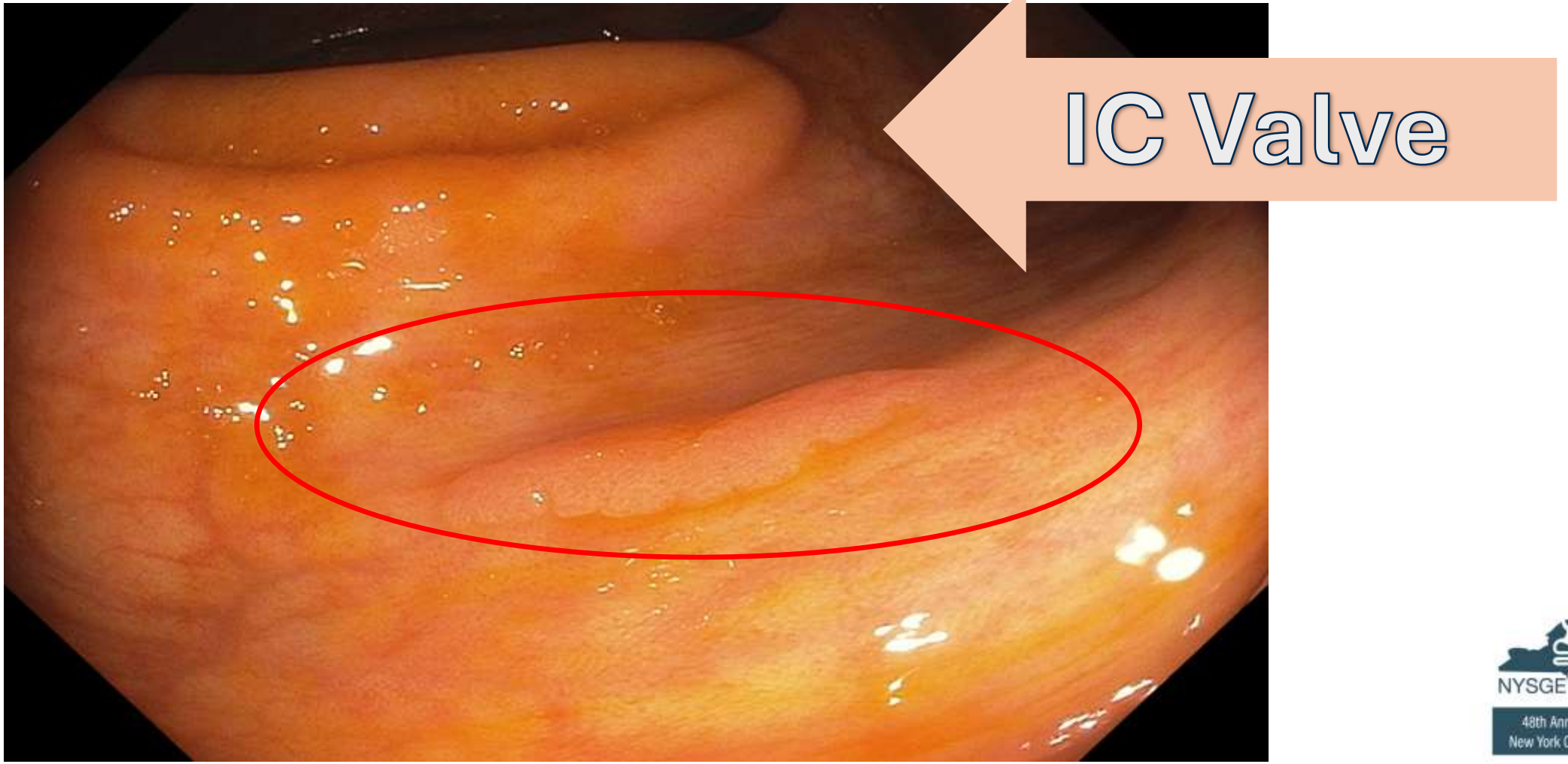
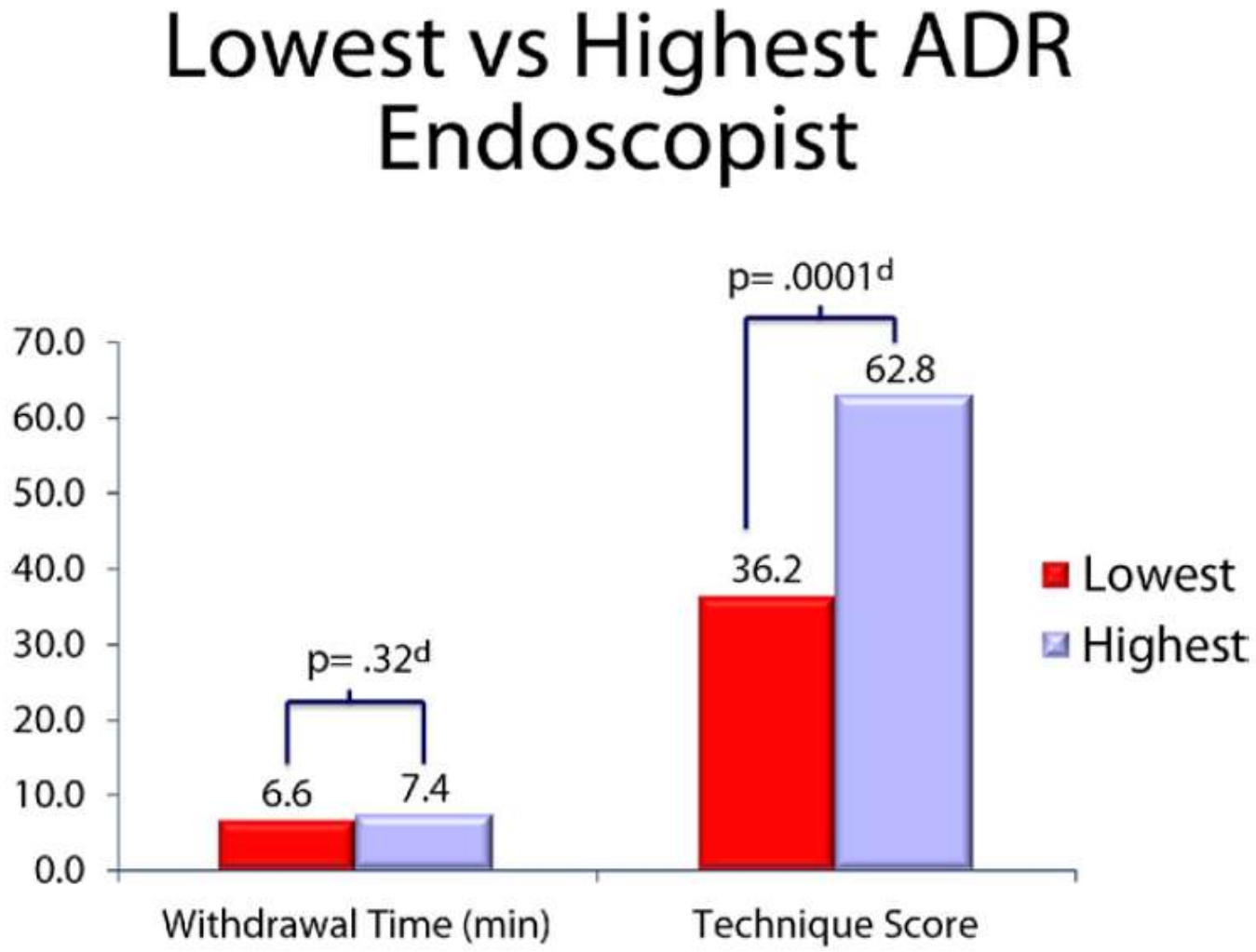
Other Low-Tech Techniques for More Complete Mucosal Inspection

- Reinsert if unseen folds passed during withdrawal or after “red-out”
- Retroflexion in cecum when feasible
- Routine 2nd pass of the right colon
- Consider changing patient position

Look More Completely!
Retroflexion can make an impact



Time Alone Isn't Enough: Technique Matters



Lee, *Gastrointest Endosc*, 2011;74:128-34.

AI and mucosal inspection

- AI in development to characterize prep quality, a factor closely linked to ADR
- AI to better assess and provide real-time alerts on limitations in mucosal inspection
    - Groen: Techniques in Endoscopy issue 2020

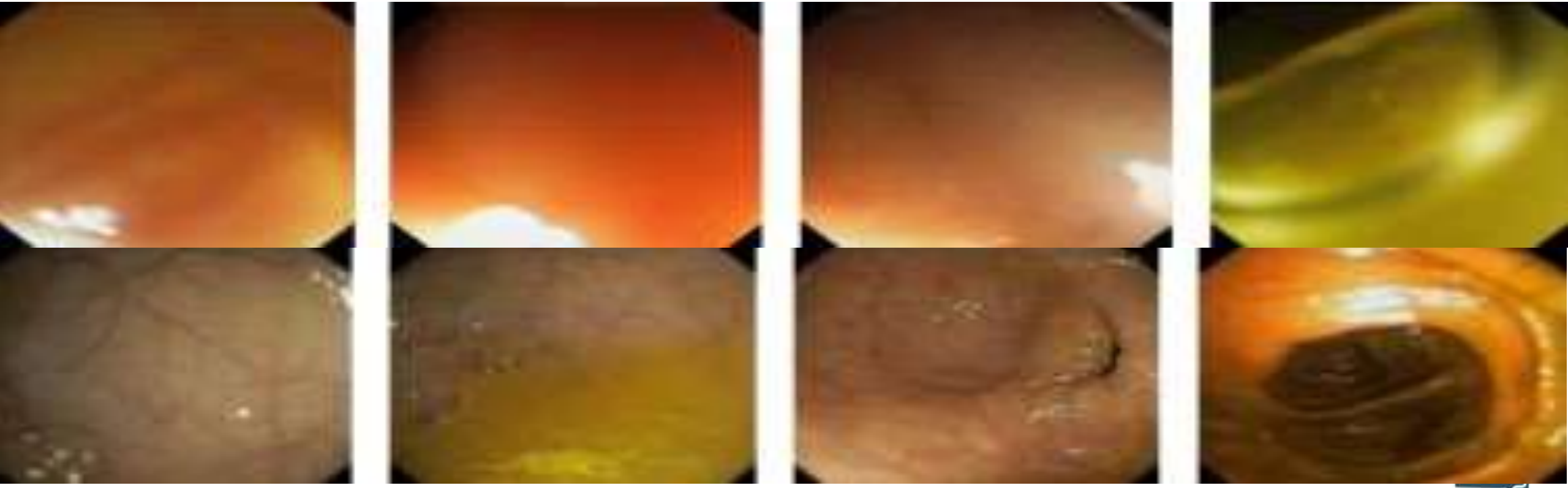
AI as real-time mucosal inspection monitor

- Human detection of parameters intuitive but not standardized:
  - not keeping the lens clear
  - not removing remaining debris
  - not looking behind large folds
  - rapid withdrawal
- These parameters can all be classified, quantified, recorded & presented as real-time feedback
- No commercially available inspection monitor today
- Components such as AI based BPPS assessment currently approved in Europe
- Real-time feedback on inspection needs to be validated with outcome parameters just like CADe—how will humans interact with the feedback in real-time?
- **Can nurses or techs currently serve as inspection quality monitor-reality checks and will endoscopists welcome or spurn the help? Similar AI-tools will face the same question when it arrives**

de Groen, PC Using artificial intelligence to improve adequacy of inspection in gastrointestinal endoscopy. Techniques and Innovations in Gastrointestinal Endoscopy 2020; 22: 71-79.

Red Out Reality Check!

- How often do you get a sharp view and what do you do when you don't?



Oh, de Groen; Med Image Analysis 2007;11:110

Optical contrast imaging advances

- Improvement in ADR, APC
- Recognition of SSLs
- Detection of advanced lesions
- Improved margin detection
- Does improved optical diagnostic skill produced higher detection?

High-Definition Meta-Analysis

Subramanian V. et al. *Endoscopy 2011; 43: 499–505*

Study name	Statistics for each study			Adenoma/total	
	IY	Lower limit	Upper limit	HD	SVE
East	0.110	–0.053	0.273	41/58	43/72
Pellise	0.010	–0.059	0.079	82/310	79/310
Burke	0.028	–0.029	0.085	105/426	93/426
Buchner	0.038	–0.000	0.071	347/1226	298/1204
Tribonias	0.073	0.026	0.171	111/193	99/197
Pooled	0.035	0.009	0.061		

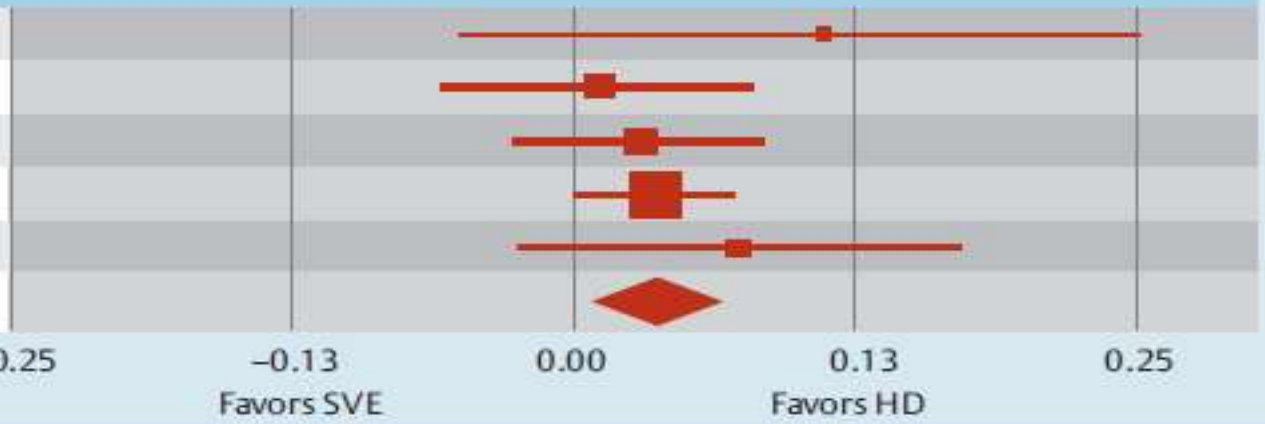


Fig. 4 Pooled incremental yield of high definition colonoscopy over standard video endoscopy for the detection of adenomatous polyps. HD, high definition; IY, incremental yield; SVE, standard video endoscopy.

HD does not provide a higher detection rate of advanced adenomas. However, significant more small polyps (<5mm) can be detected.

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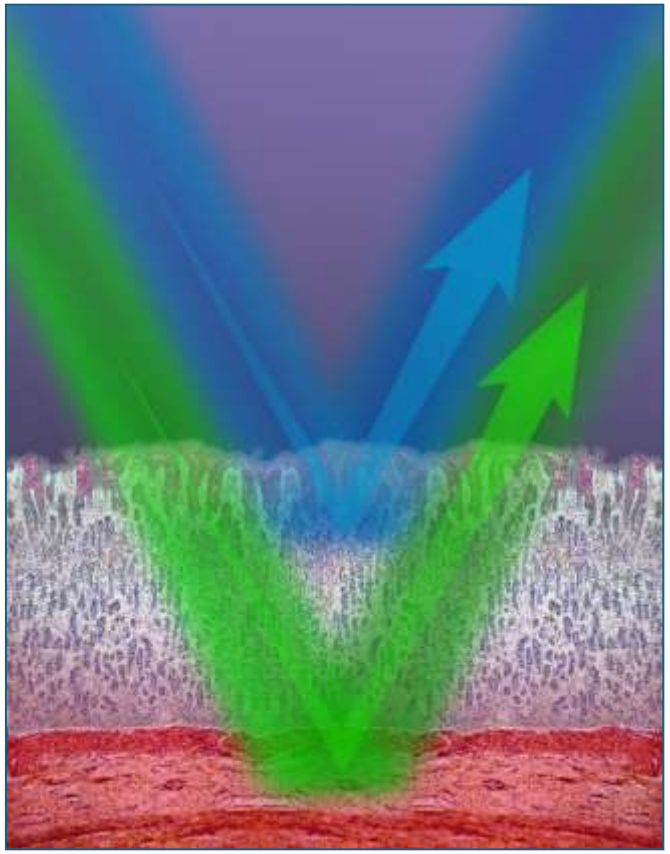
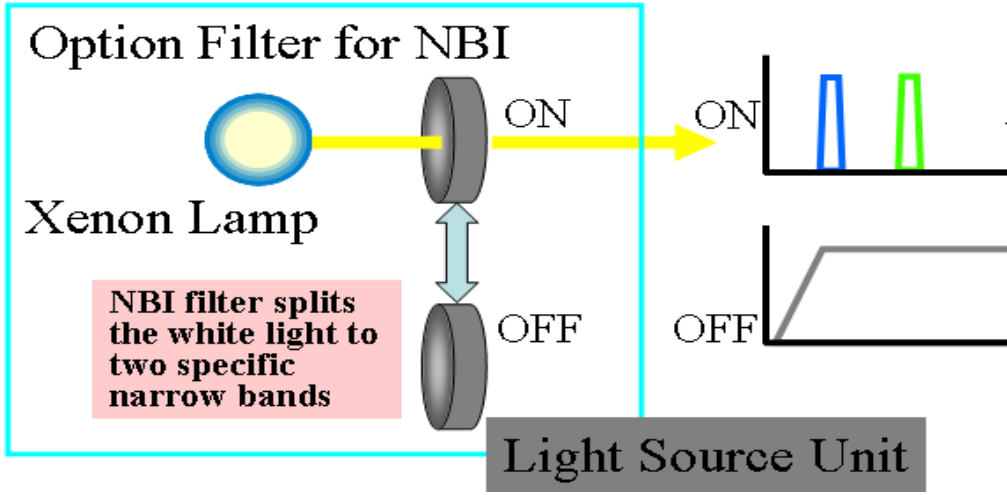
Narrow Band Imaging filters incident light to narrow 415 and 540 nm bands

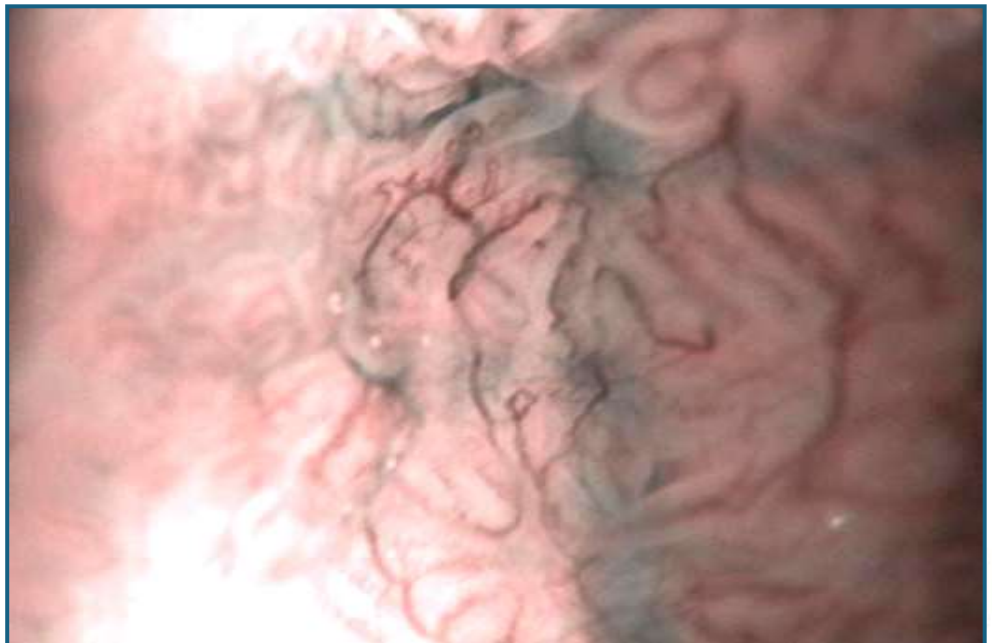
Blue light penetrates only superficially

Green light has deeper penetration



Hemoglobin absorbs blue light making superficial vessels appear black





Other Light Enhancement Technologies

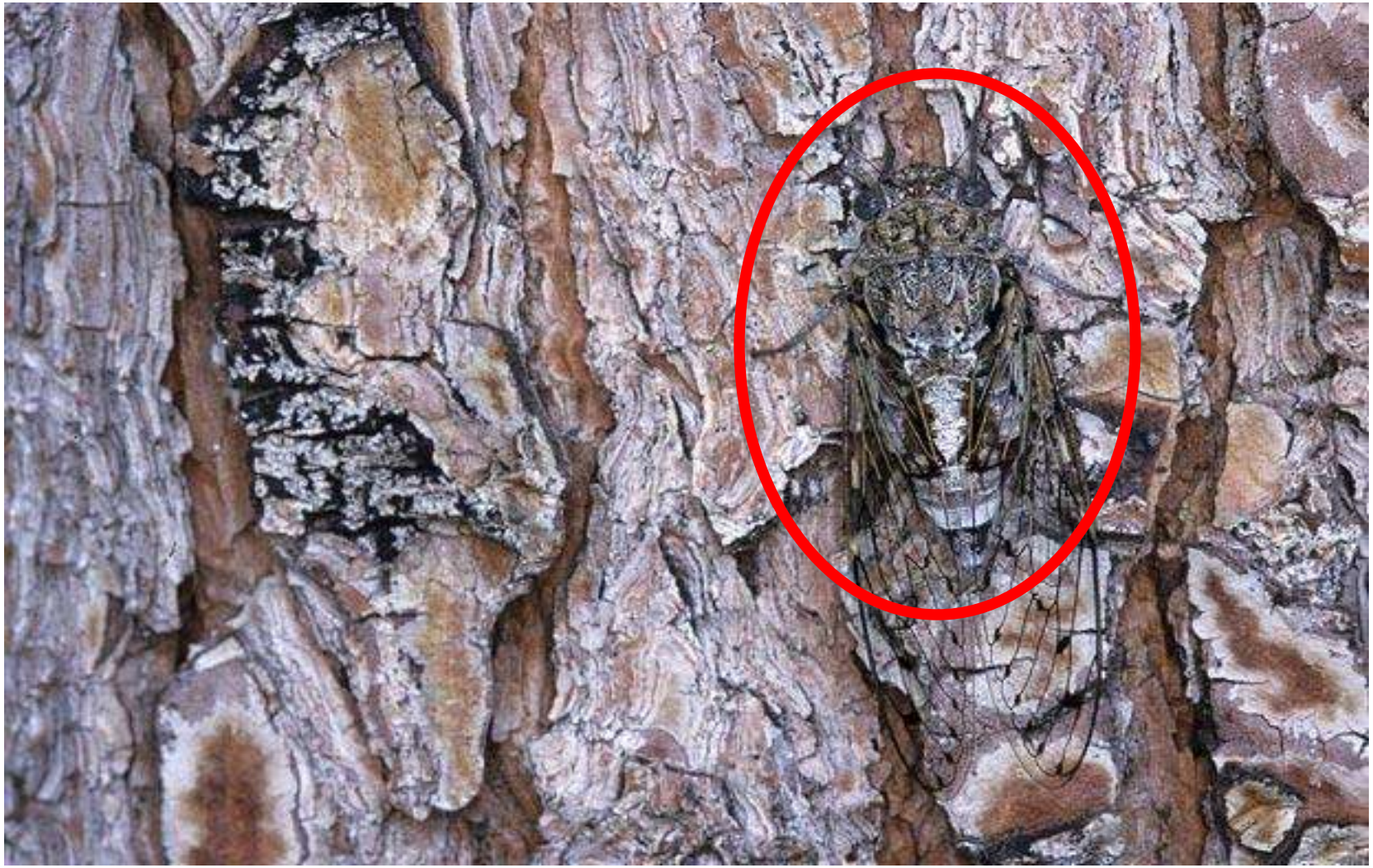
- I-scan
  - Surface enhancement
  - Contrast enhancement with multiple filters applied at the processor level
- FICE system
  - Fuji intelligent color enhancement

Contrast achieved via digital post-processing of images

Optical contrast step 1—look for color differences with background and demarcation

Hyperplastic Polyp

Look for Subtle Alterations in Color and Demarcation



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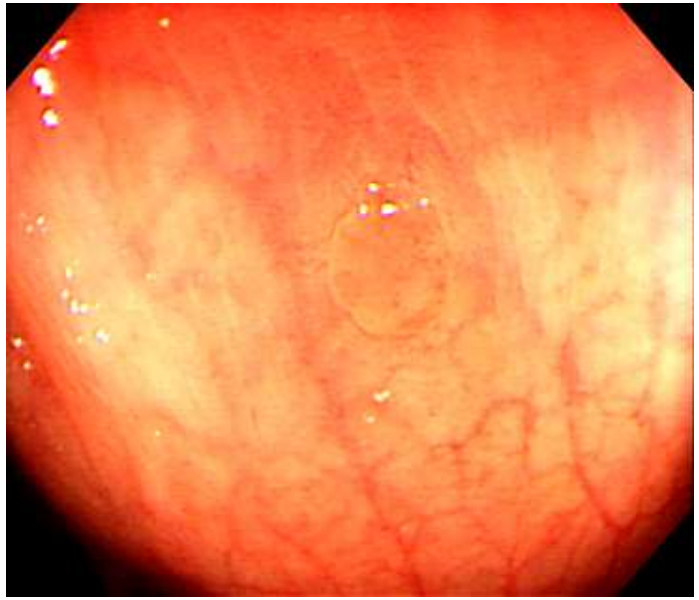
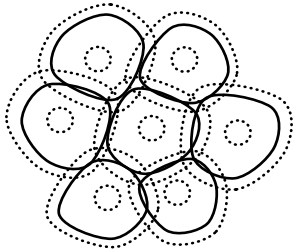
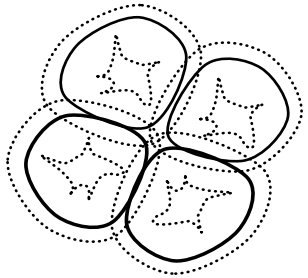
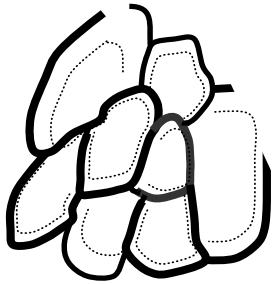
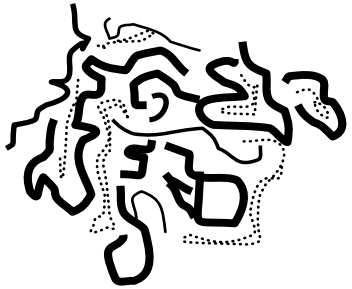
Optical Contrast Accentuates Color Difference



Standard white light colonoscopy image of a colon polyp

NBI of the same

	Schematic micro-vessel architecture	Micro-vessel characteristics	Vessel diameter (μ m) (minimum – maximum)
Normal mucosa		Mucosal capillary network (meshwork) arranged in a honeycomb pattern around the mucosal glands.	8.6±1.8 to 12.4±1.9 (6.4 - 20.9)
Hyperplastic		Mucosal capillary network (meshwork) arranged in a honeycomb pattern around the mucosal glands.	Usually less than 10
Adenoma		Vascular casts showed that the microvasculature have a similar organization to the normal colon. However, capillaries are elongated and have increased diameters compared to normal.	13.1+3.3
Carcinoma		Vascular casts of colonic carcinoma is characterized by a disorganized structure and increased density of microvessels. The increased number and density of microvessels results in formation of nodular clusters of capillaries.	18.3±0.1 to 19.8±7.6 (2.2 – 84.5)

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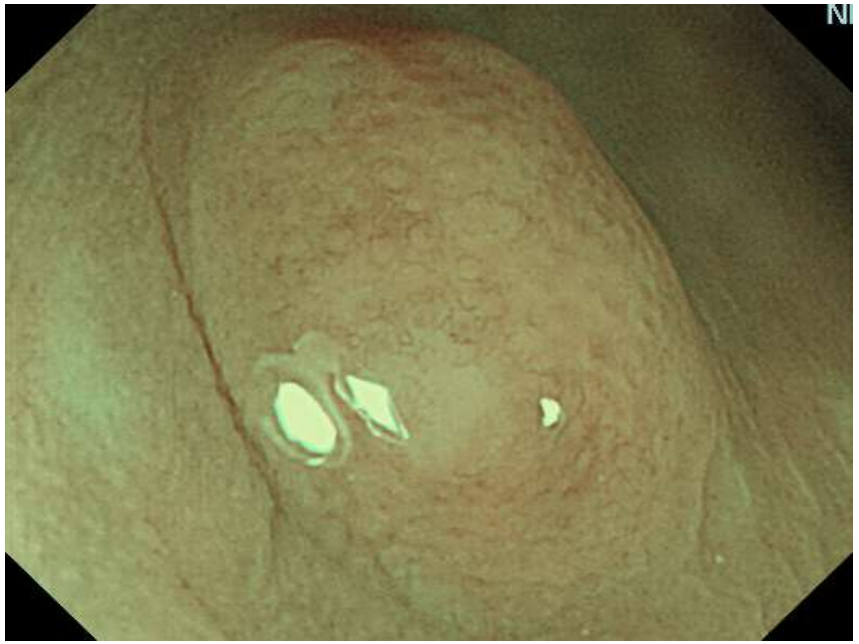
NBI International Colorectal Endoscopic (NICE) Classification for Prediction of Colorectal Polyp Histology

	TYPE 1	TYPE 2
Color	Same or lighter than background	Browner relative to background
Vessels	None, or isolated lacy vessels may be present coursing across the lesion	Thick brown vessels surrounding white structures
Surface Pattern	Dark spots surrounded by white	Oval, tubular or branched white structures surrounded by brown vessels
Likely Path	Hyperplastic	Adenoma

NICE 1:
Hyperplastic polyp white light and chromoendoscopy view



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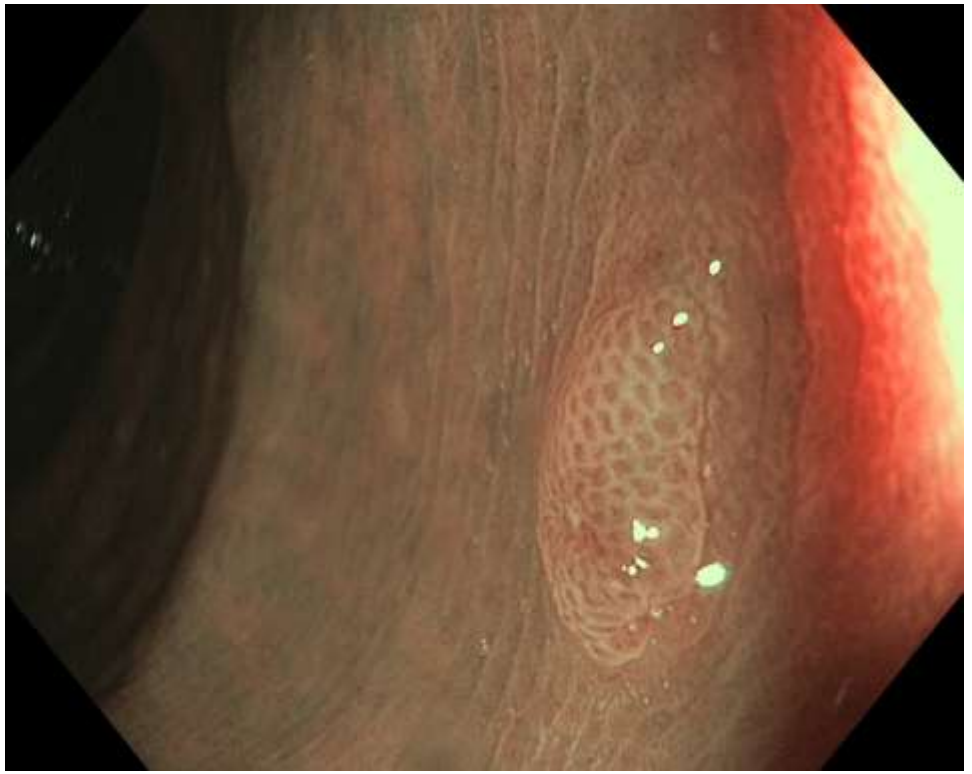
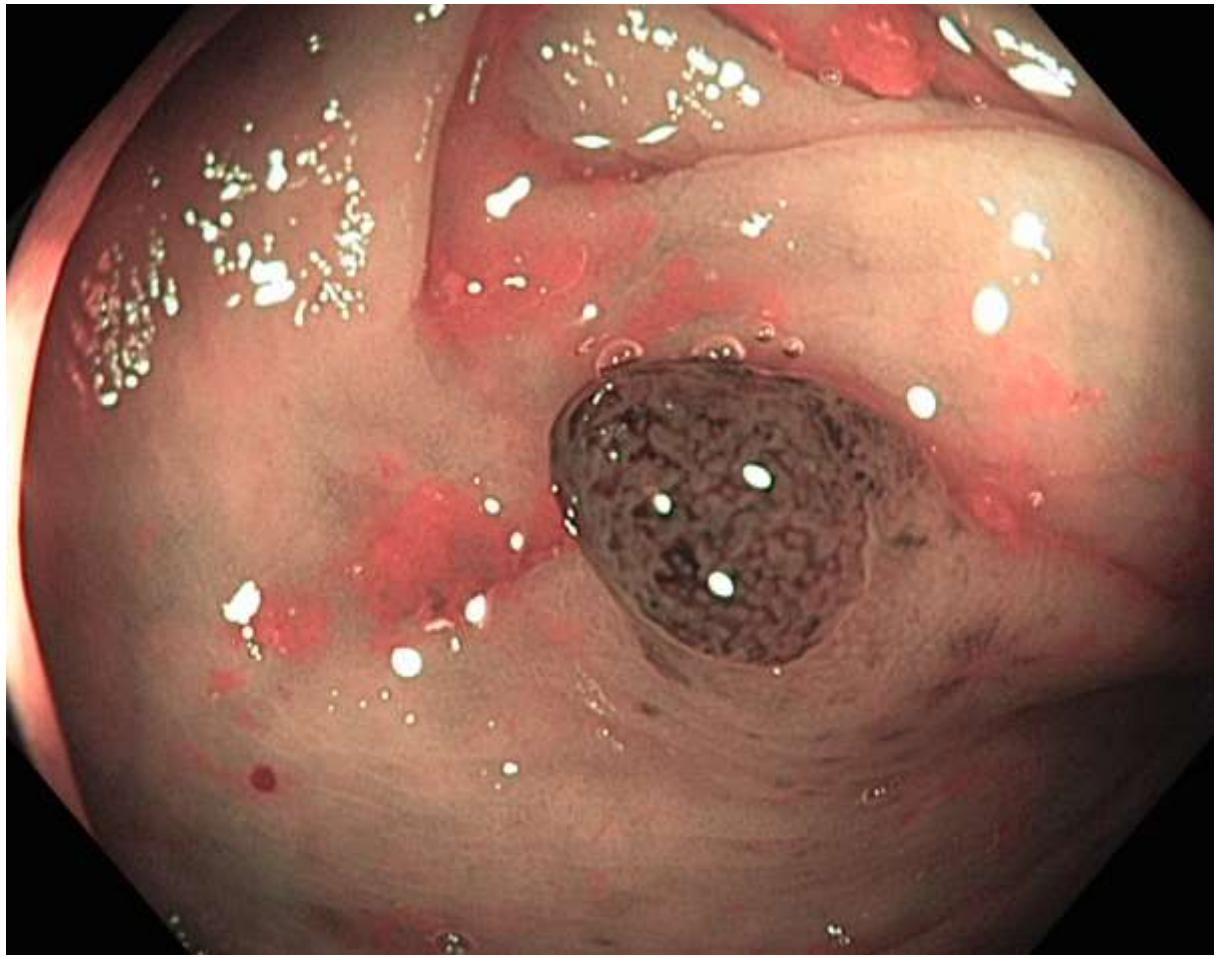
Two Varieties of NICE 1 Hyperplastic Polyps



Brown irregular thickened vessels clearly indicate colon adenoma



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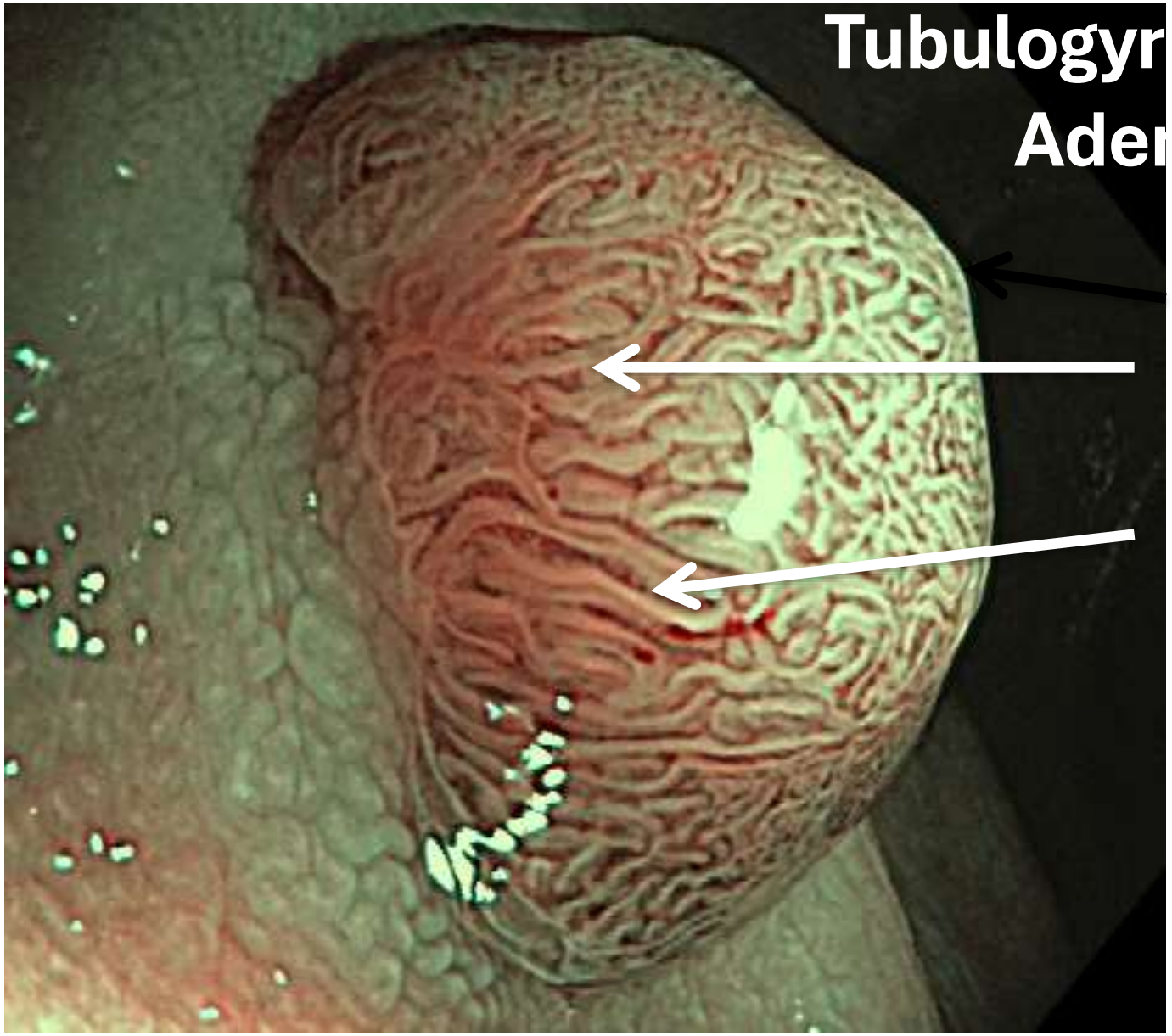
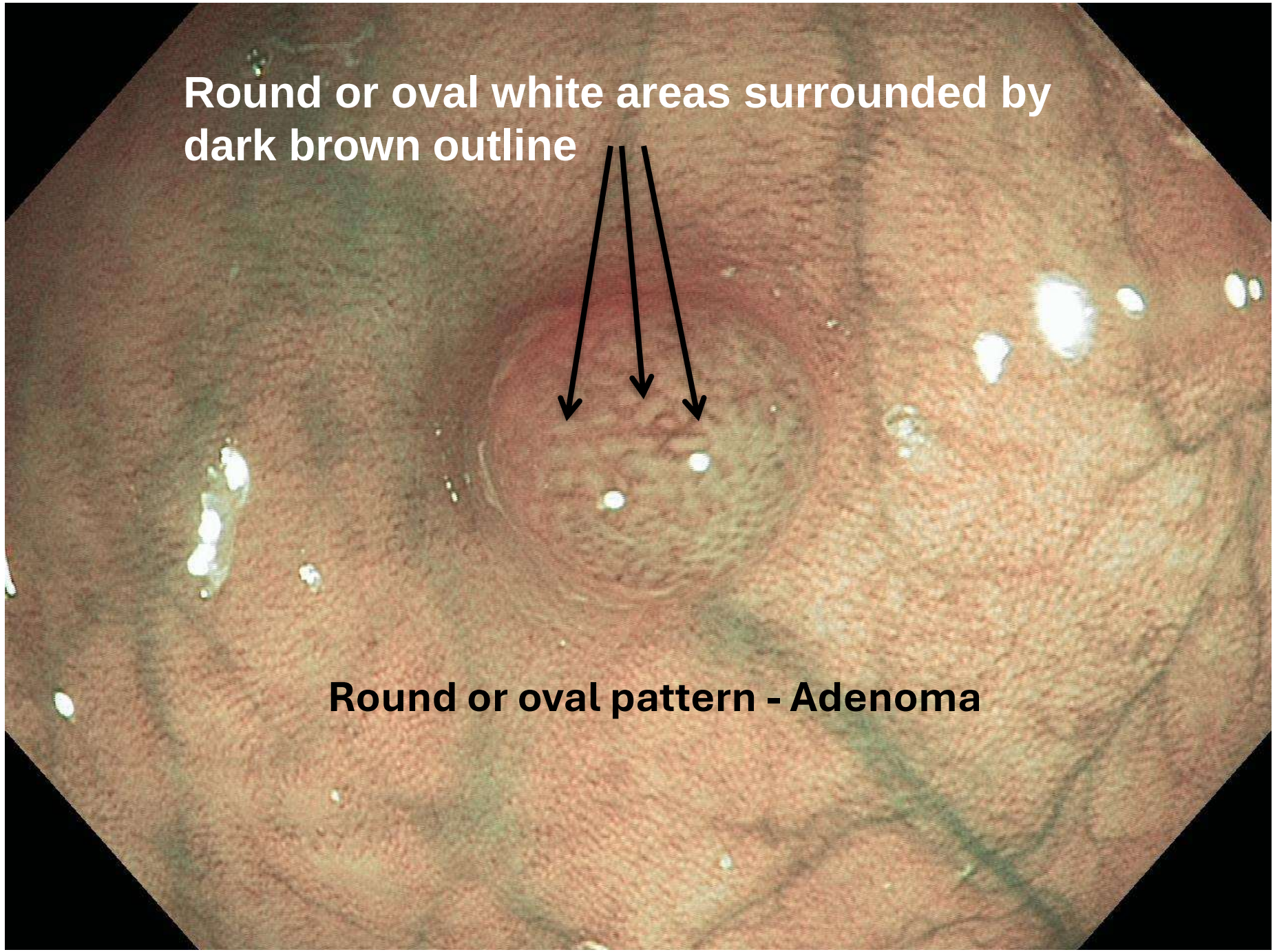


Dark vessels lining the pits highlight pit pattern



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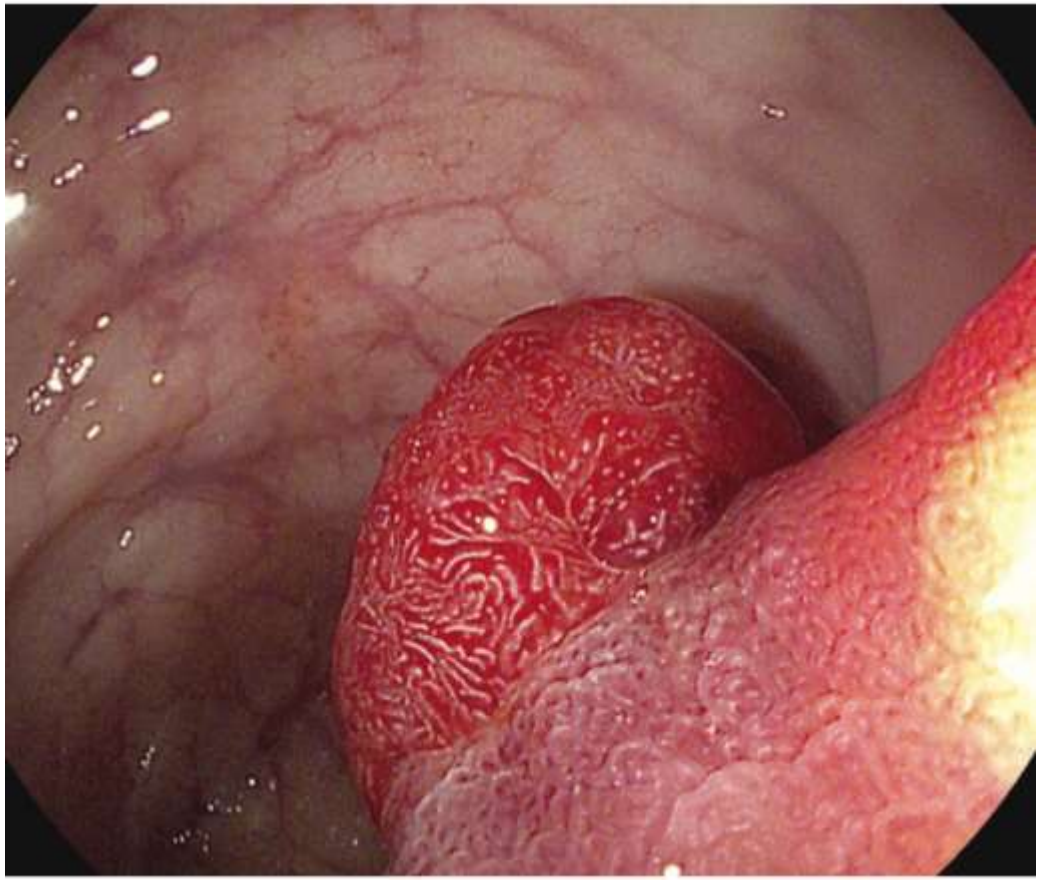
I-Scan Polyps: Adenoma



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Blue laser imaging [BLI] Adenoma

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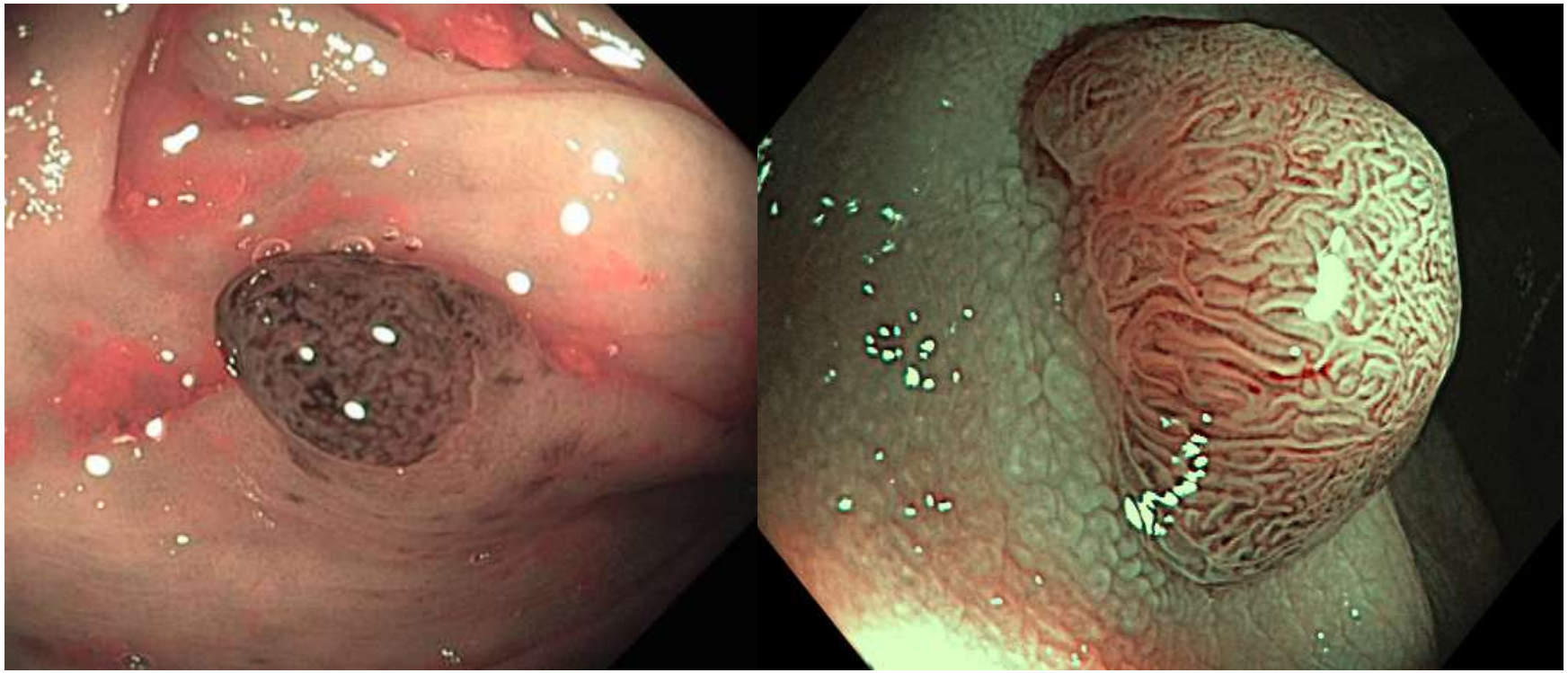
11:41:10 AM
1/60
AUTO
BLI
FR:F/T
MM:LM
RC:TRIG
3.8
12.8
12.8
EC-L590ZW
HT NR
C1
M1216B
33

NBI H180 vs H190

H180 image

H190 image



The Sharper Image!

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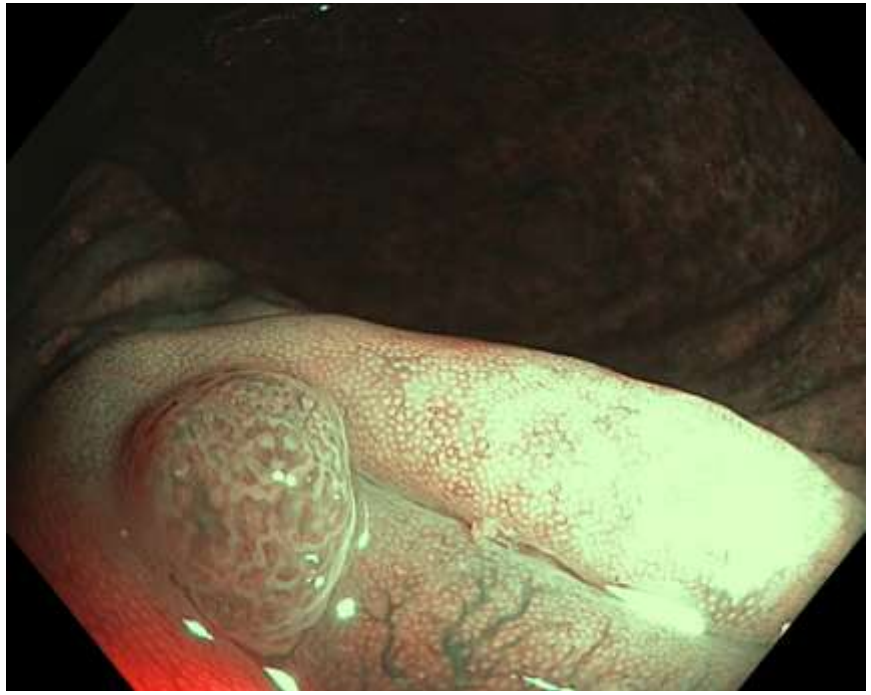
Standard vs Near Focus



Tublular &Variable Length White Structures and Central Dimple “Valley Sign”

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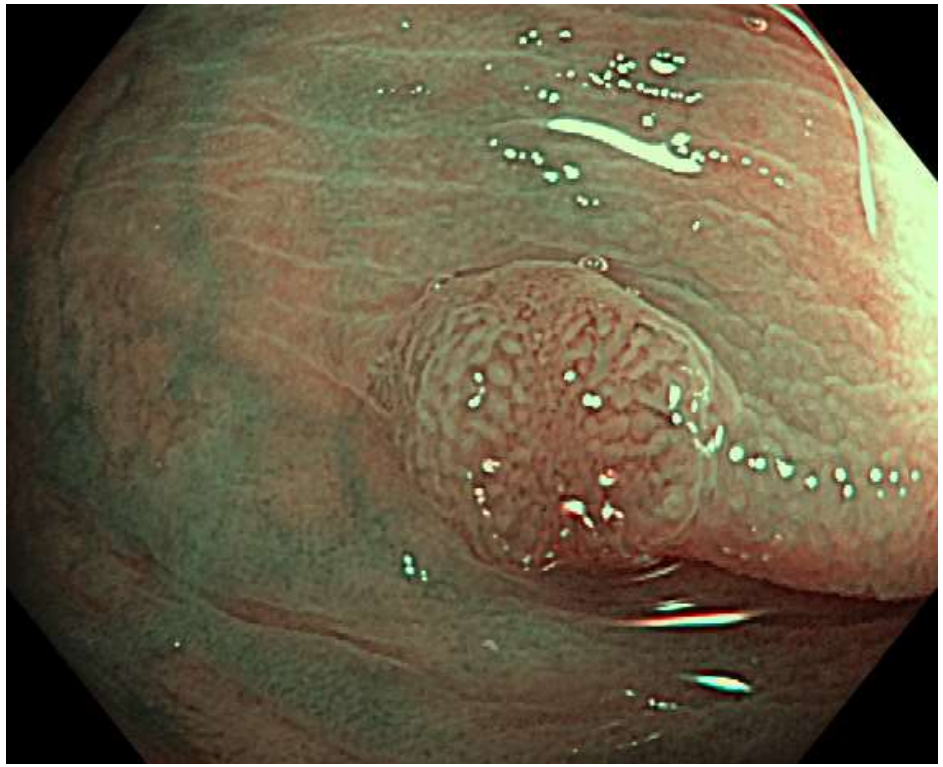
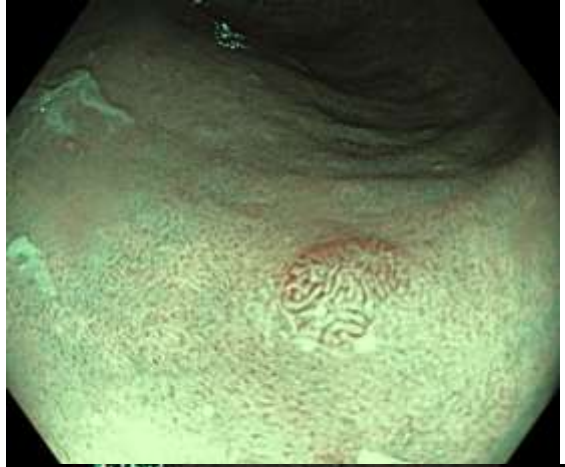
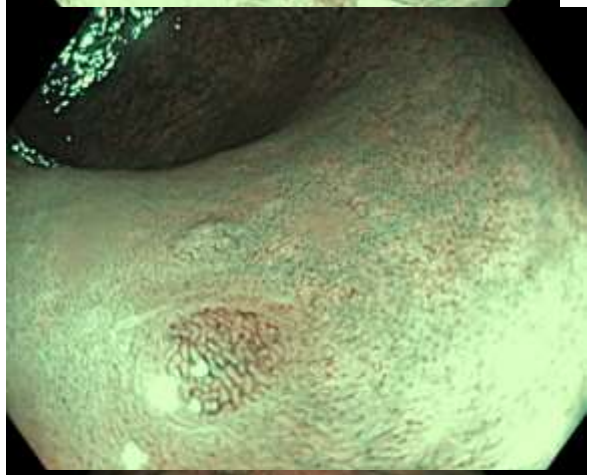
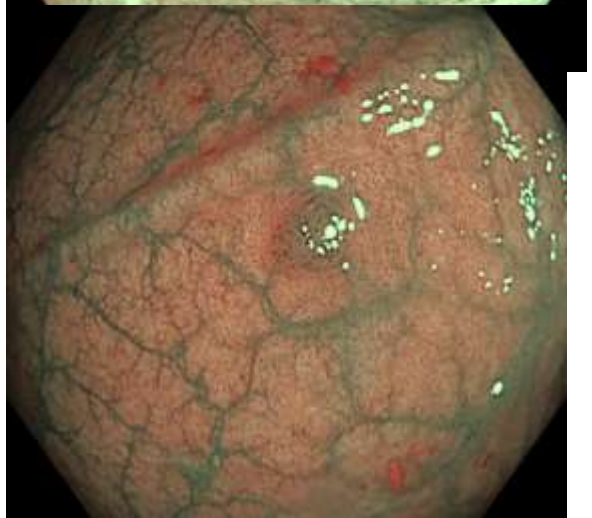
Valley Sign NBI H190







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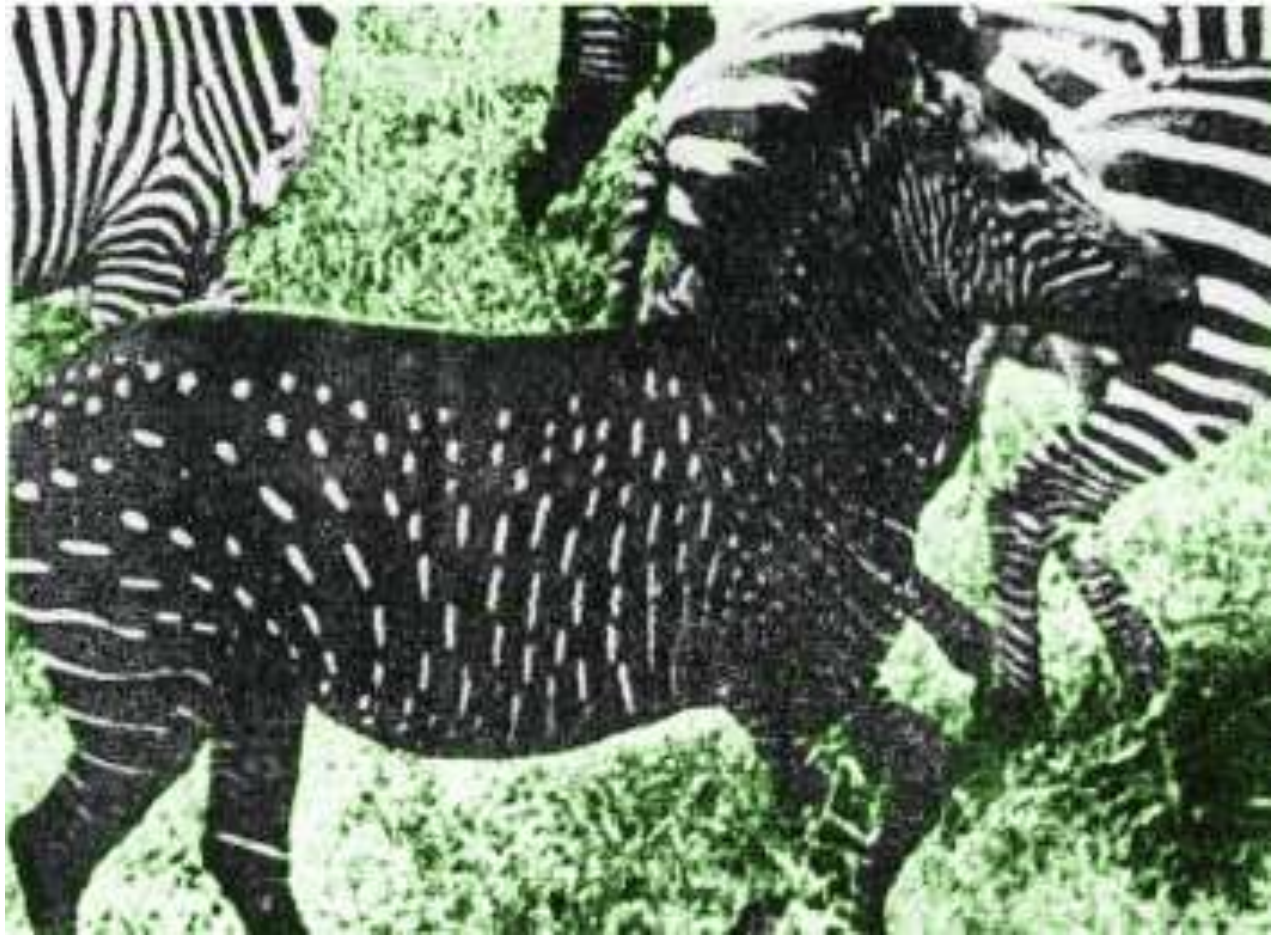
Spotting the Difference



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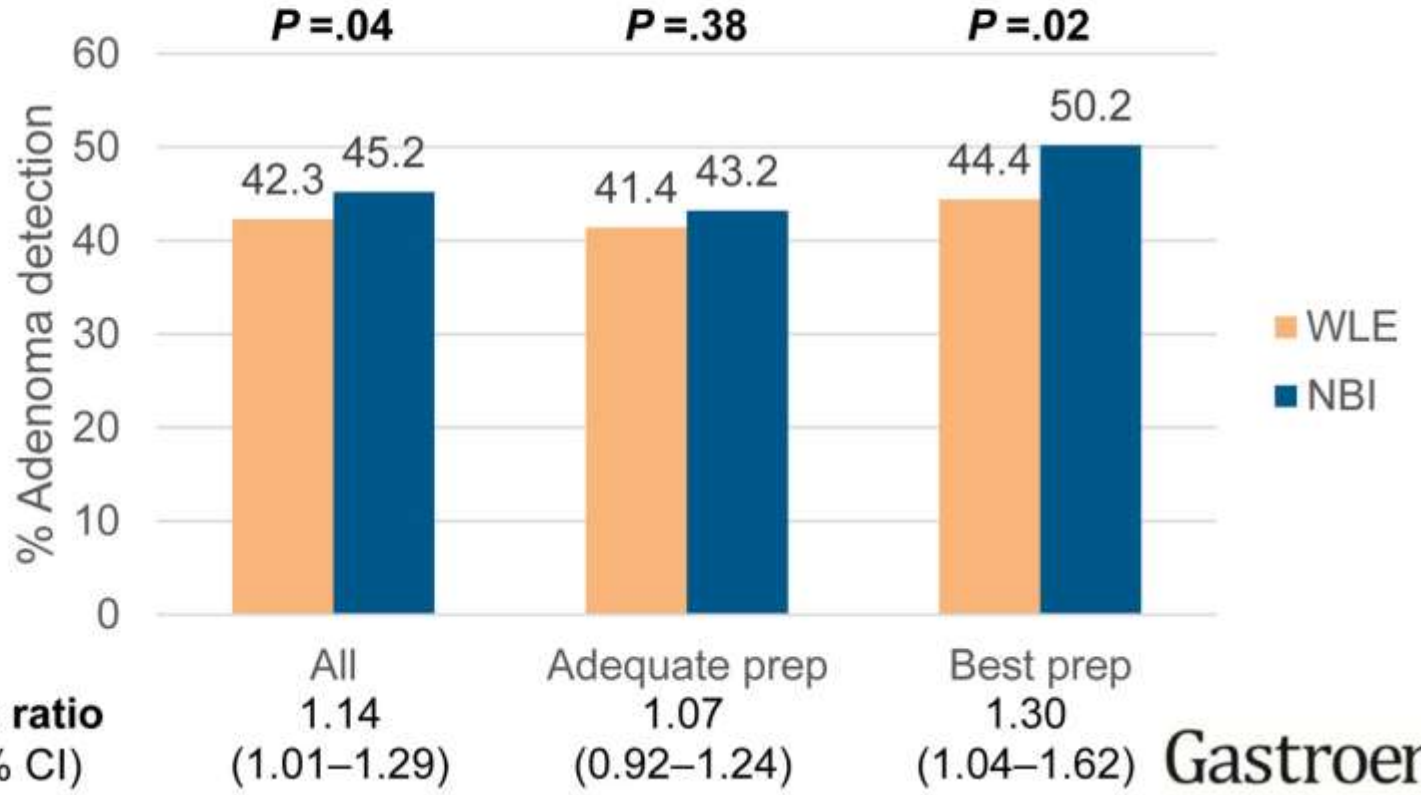
NBI Second Generation—Increases ADR

Individual patient level data meta-analysis for high definition White Light Endoscopy (WLE) vs Narrow Band Imaging (NBI) stratified by bowel preparation

11 international centers

4491 individual patient datasets



Gastroenterology

Atkinson, NSS, et al. Narrow-Band Imaging for Detection of Neoplasia at Colonoscopy: A Meta-analysis of Data From Individual Patients in Randomized Controlled Trials. Gastroenterology 2019;157:462–471

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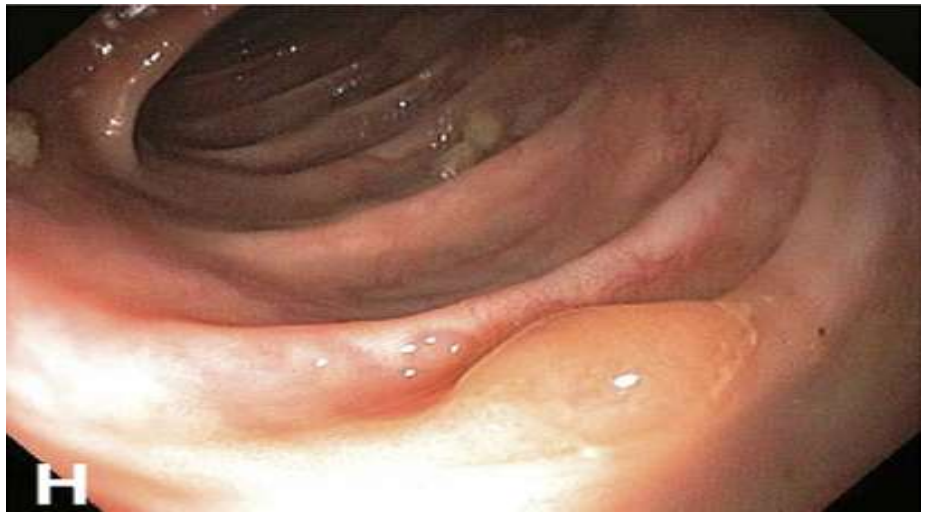
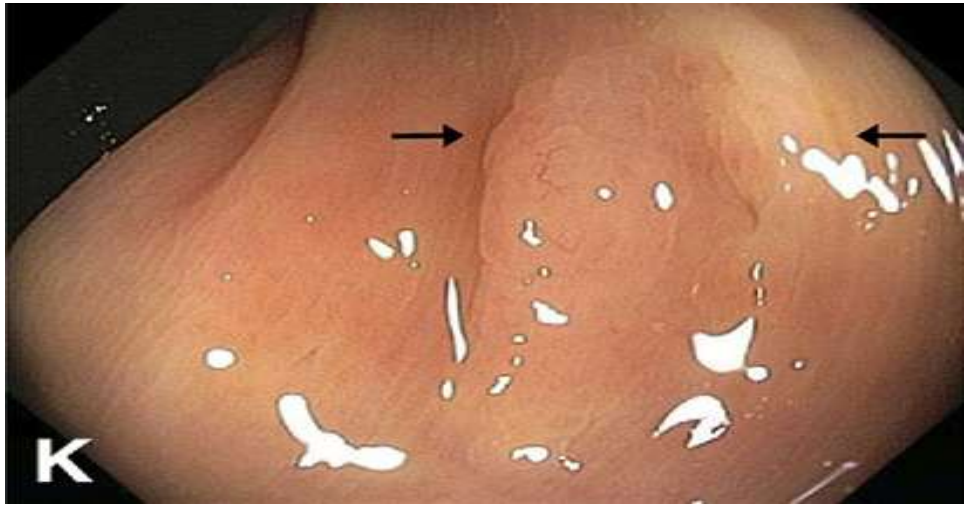
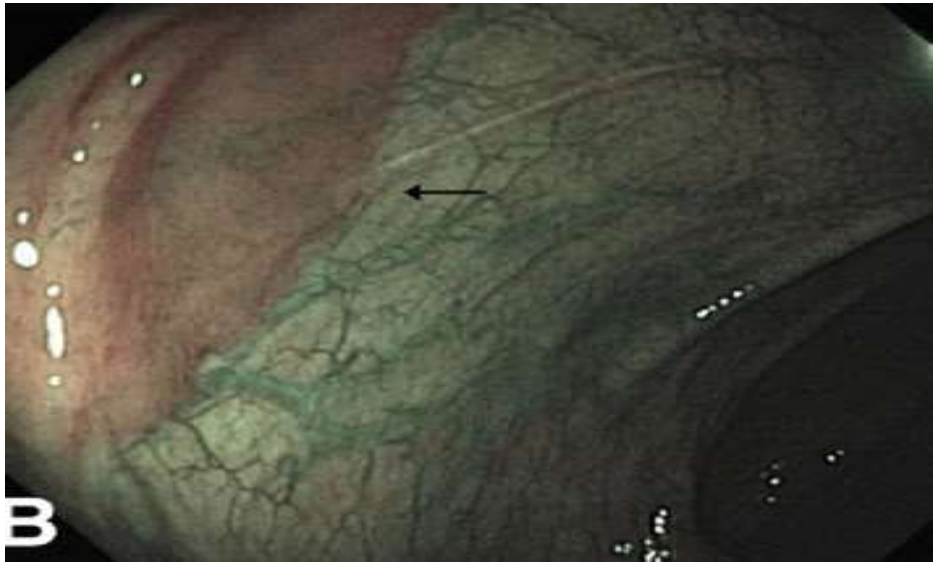
Imaging to Improve Recognition of SSL & Anal Lesions







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Features & Classification of SSP's

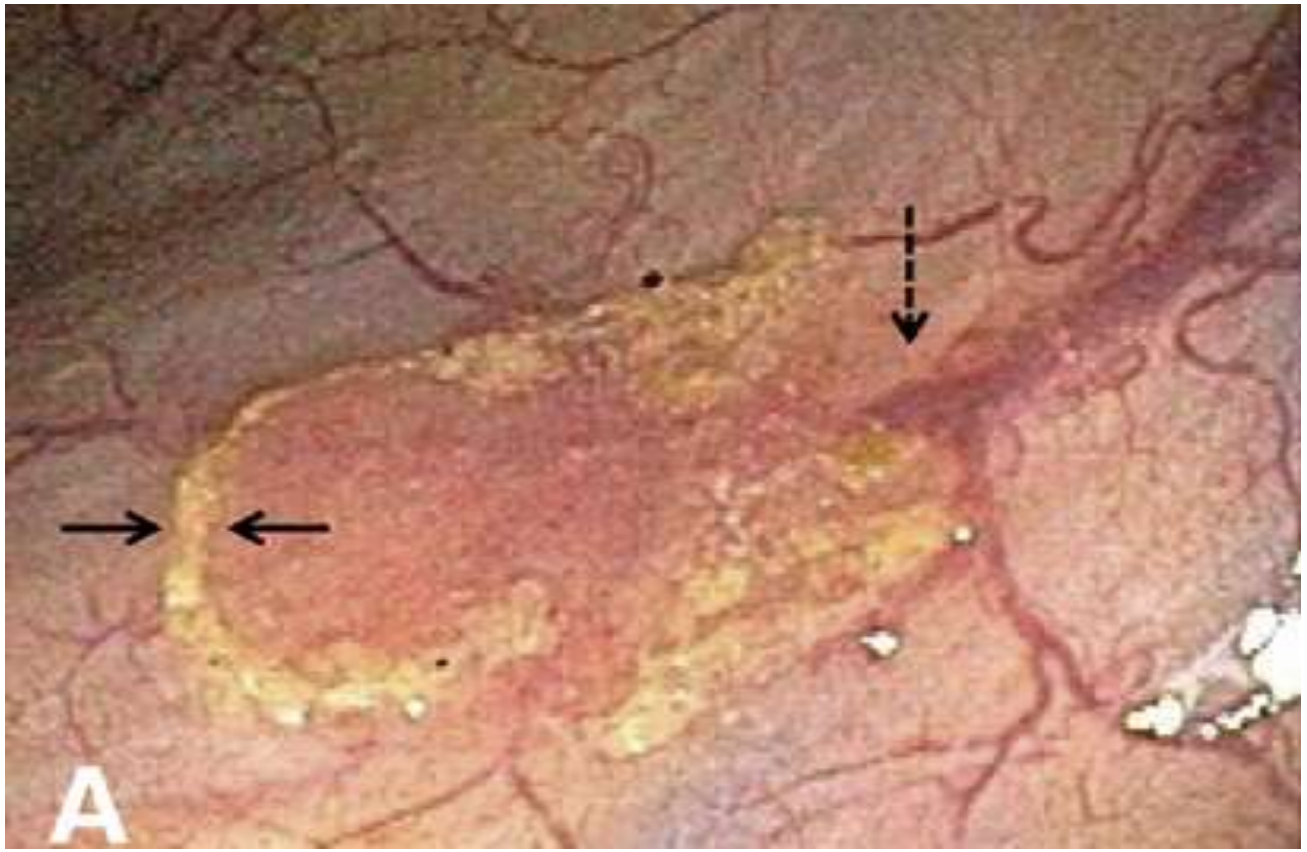
- Larger than HP's
- More right sided
- Mucous cap presence
- "Egg-drop soup" appearance
- Indistinct edges [WL and NBI]
- "Cloud–like" surface [WL and NBI]
- Irregular nodular surface [NBI]
- Dark spots on the crypts [NBI]

Tadepalli et al. GIE 2011; 74:1360-8
Hazewinkel et al GIE 2013; 77:916-24

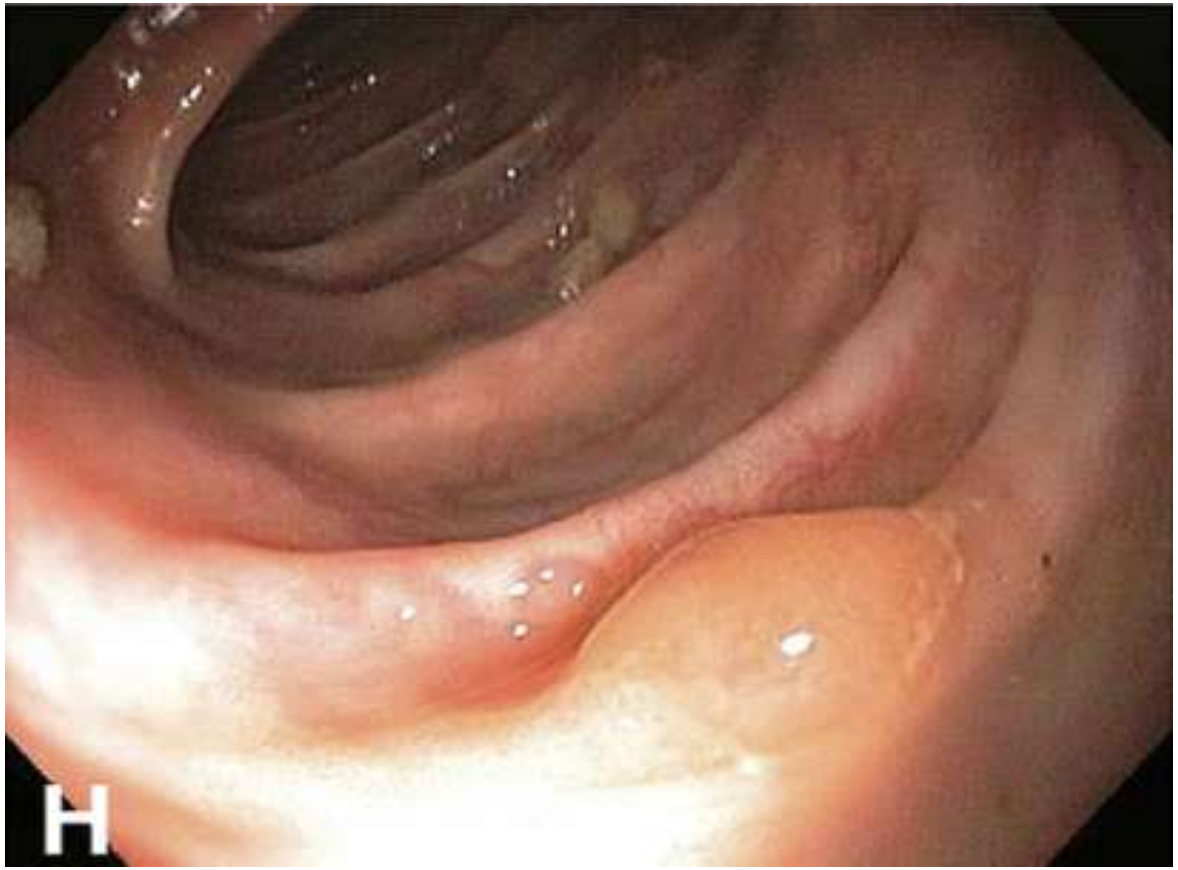
Mucous Cap

Focus on Areas of Debris:
Mucous & Debris / Egg-Drop Soup Sign

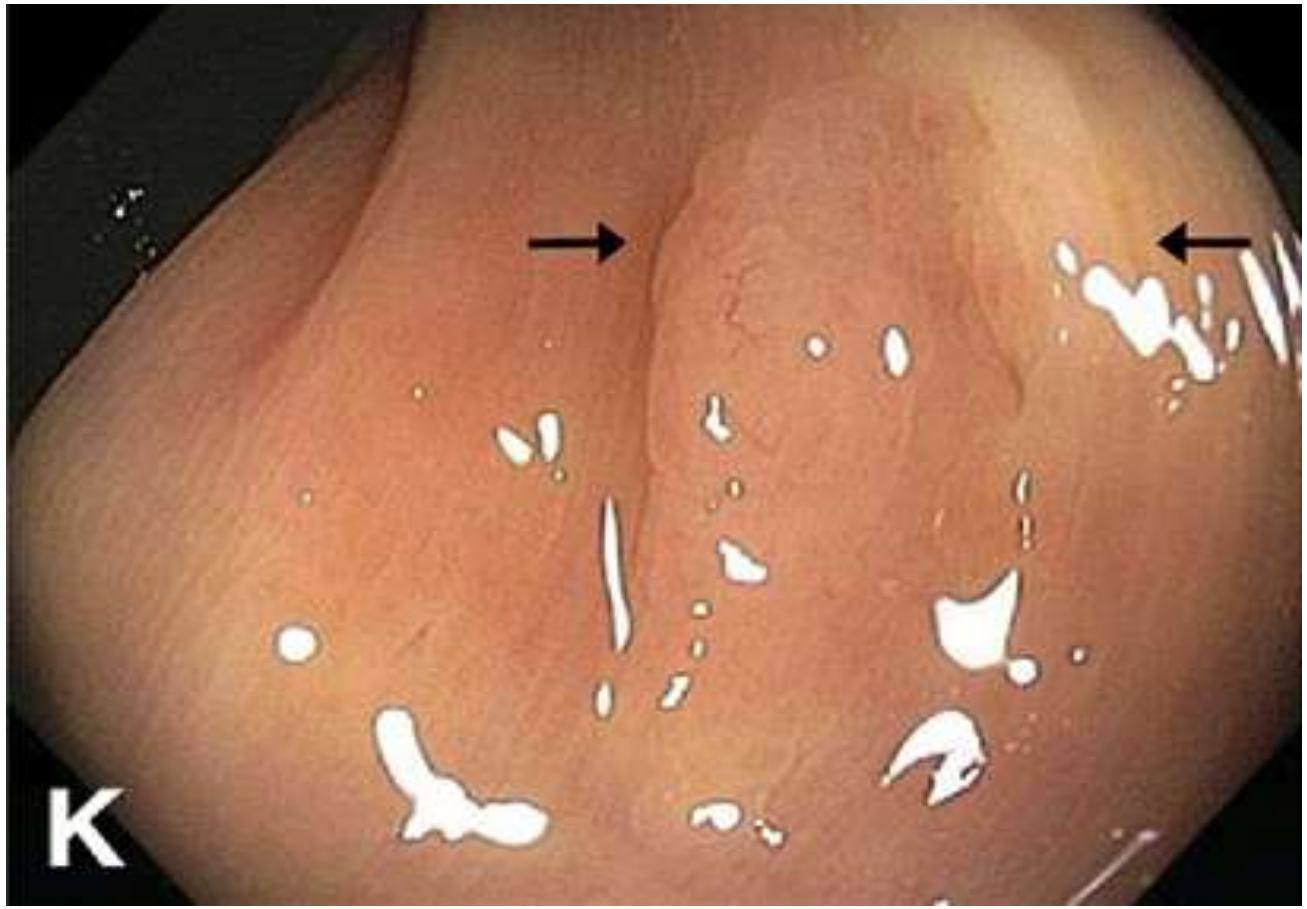
Peripheral Rim of Debris



Disrupted Contour of Mucosal Fold with Cloud Like Appearance



Serpiginous thin occasional vessel & Nodular Surface



Brown dots inside the crypts--SSL

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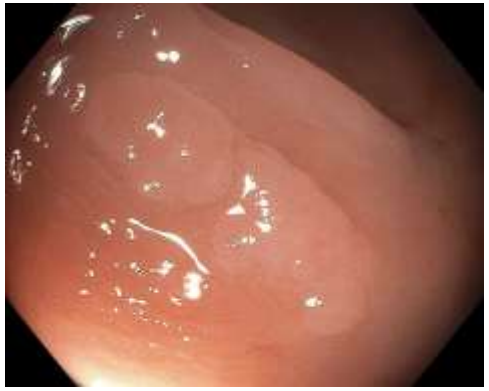

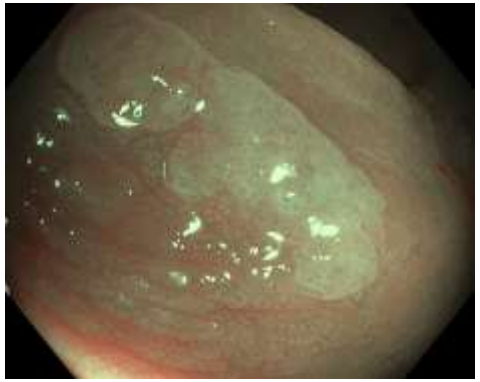

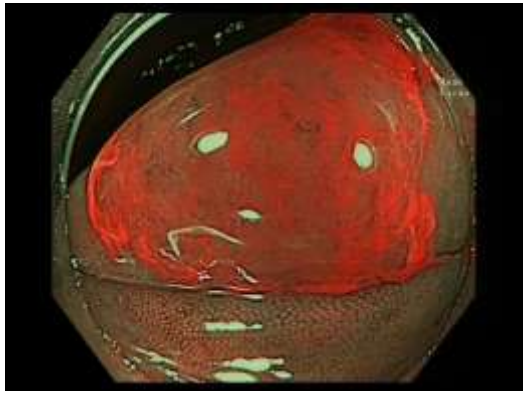

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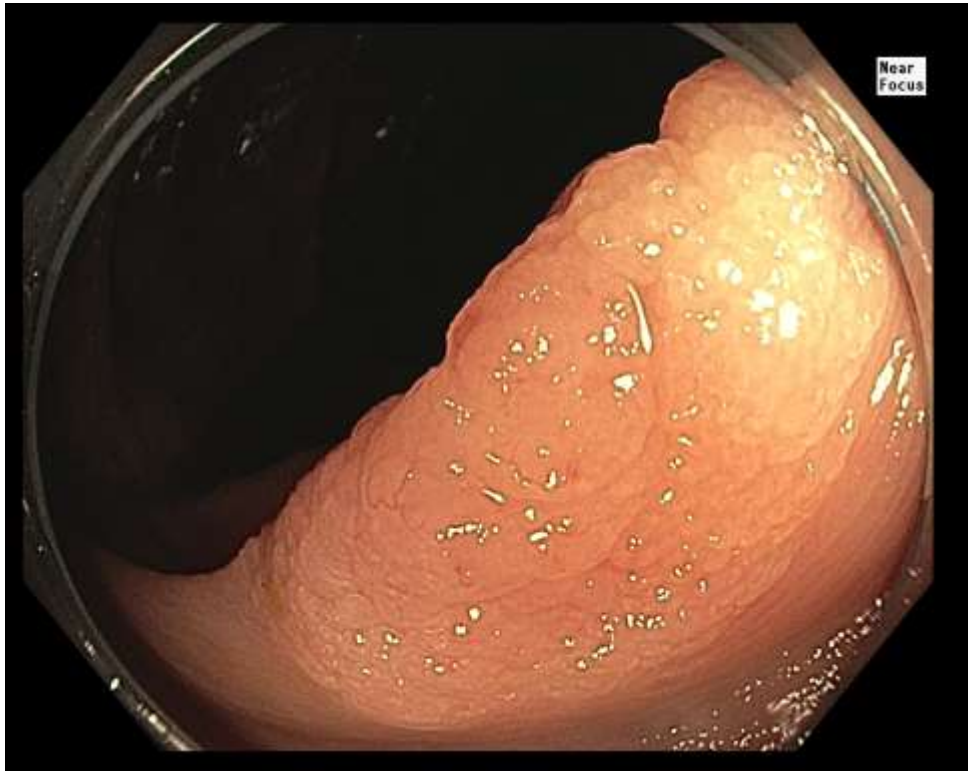
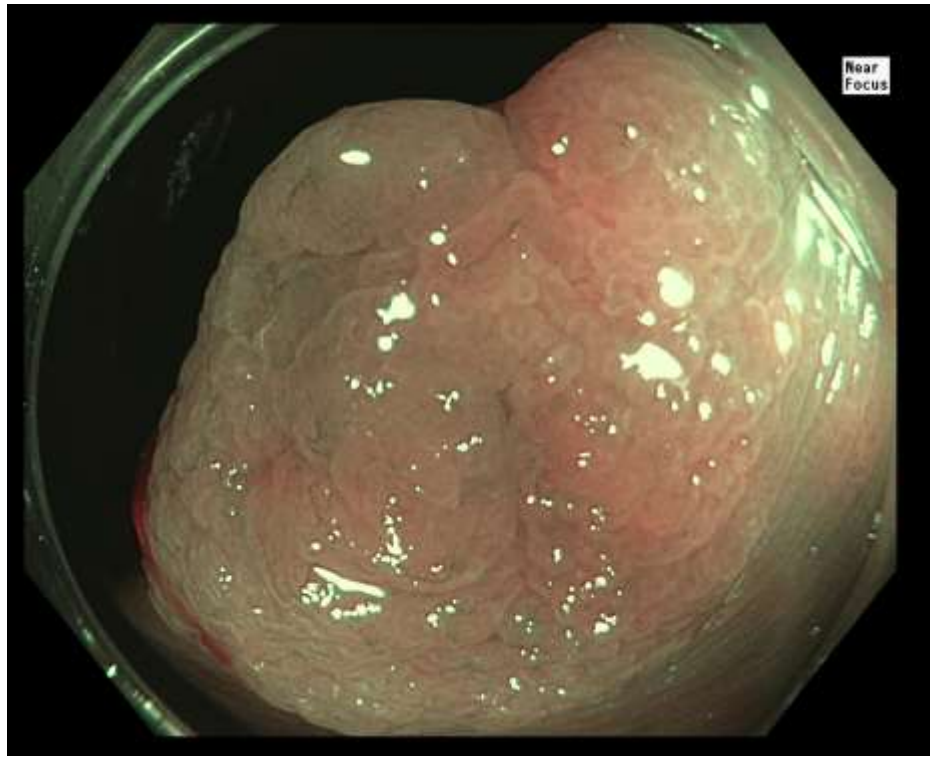
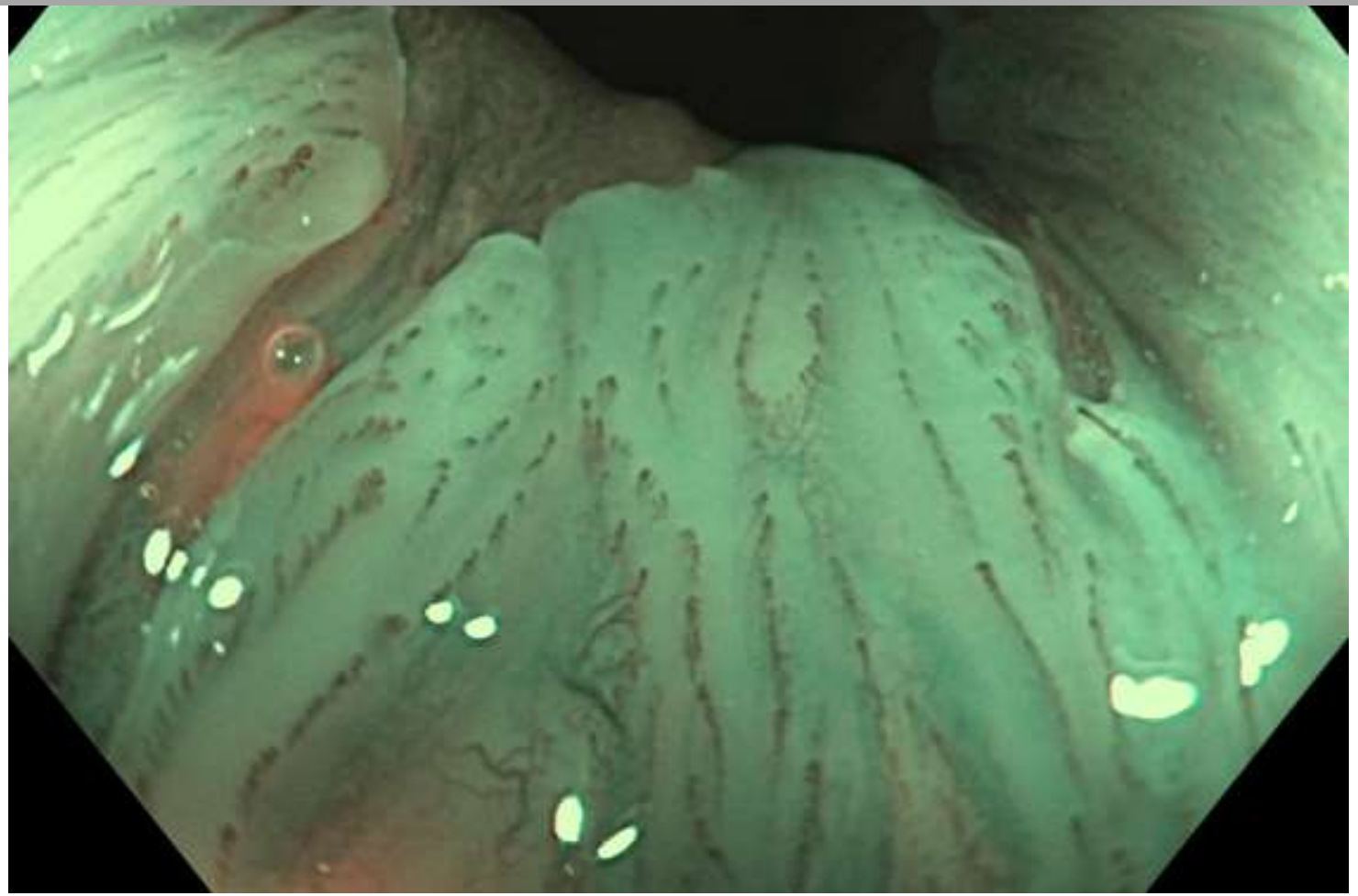

Near
Focus


Near
Focus

Don’t forget to inspect anal mucosa!



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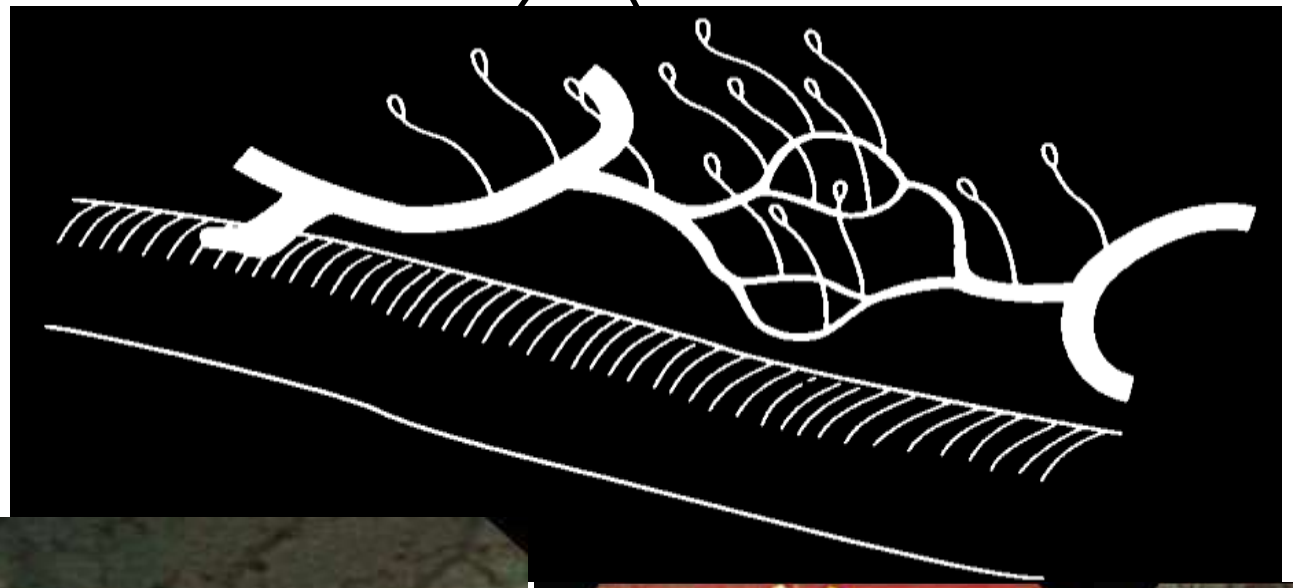
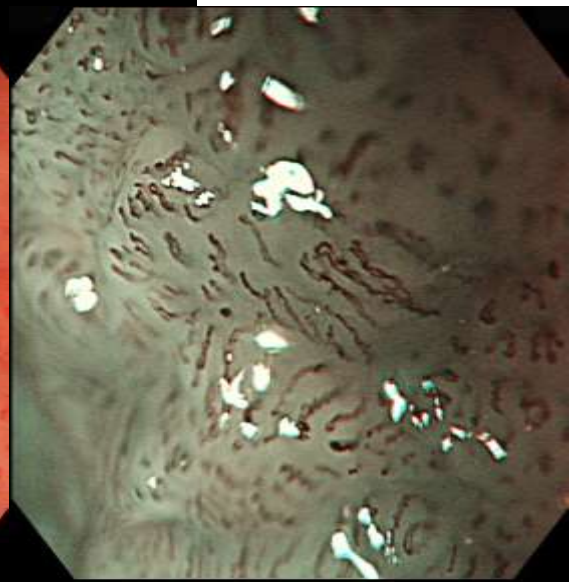
Squamous esophagus IPCL patterns (intra-epithelial papillary capillary loops)





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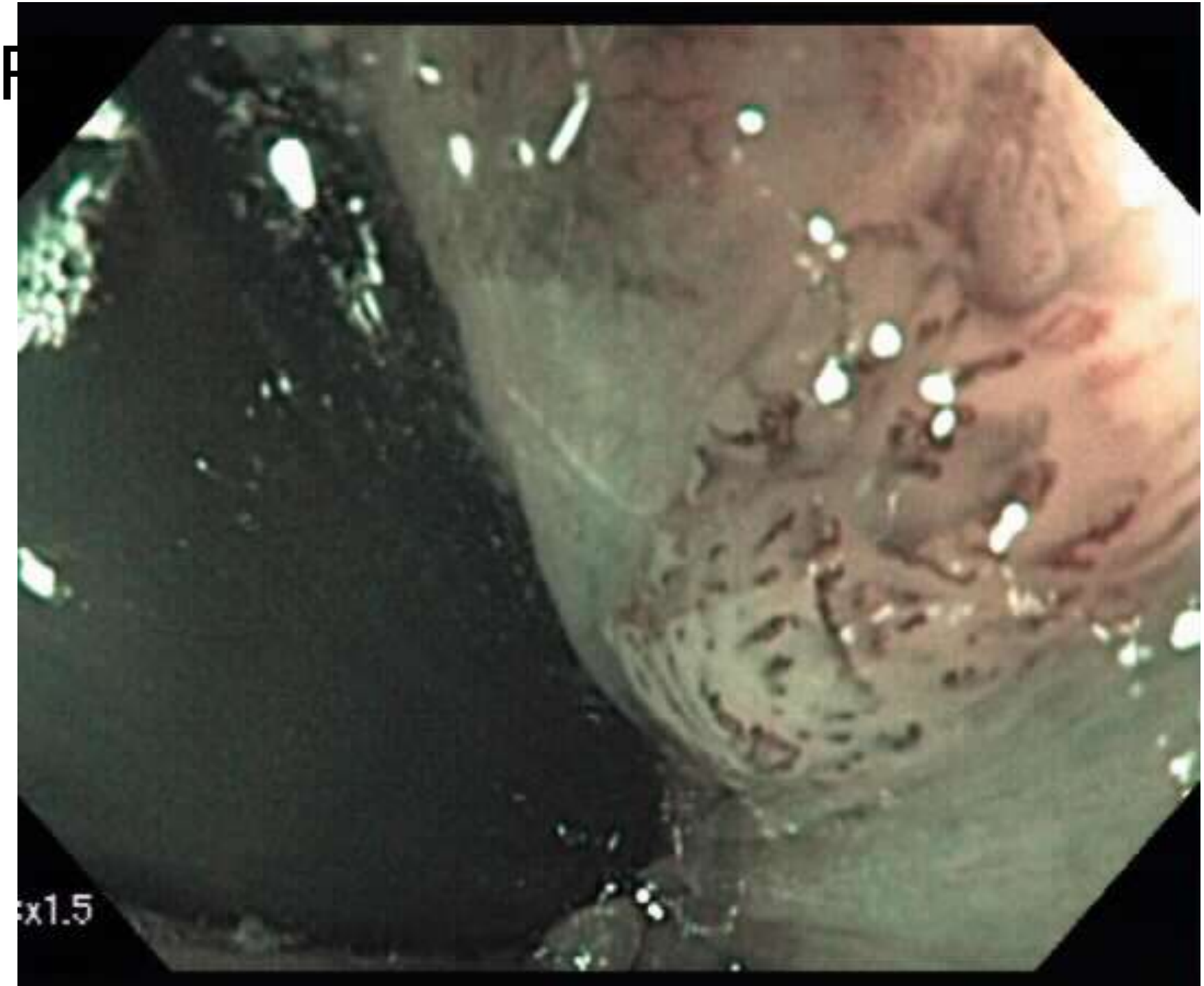
P



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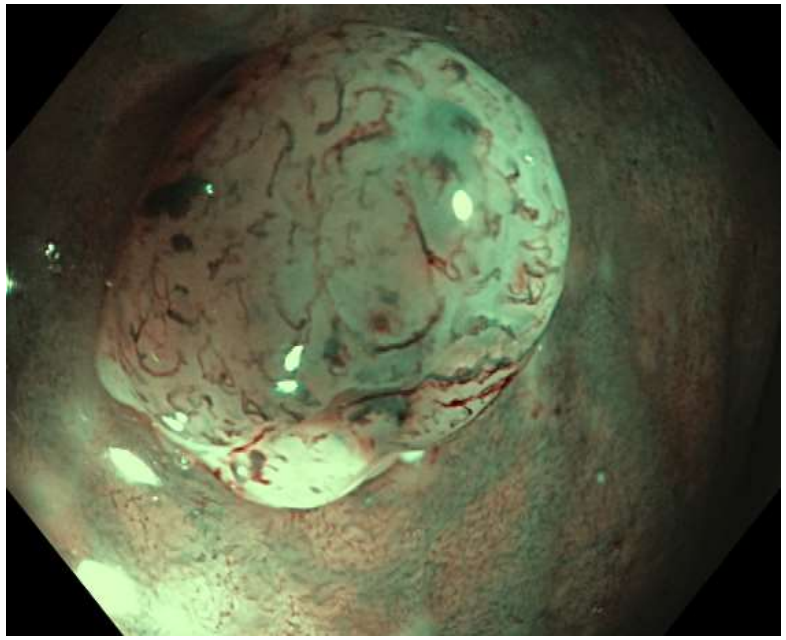

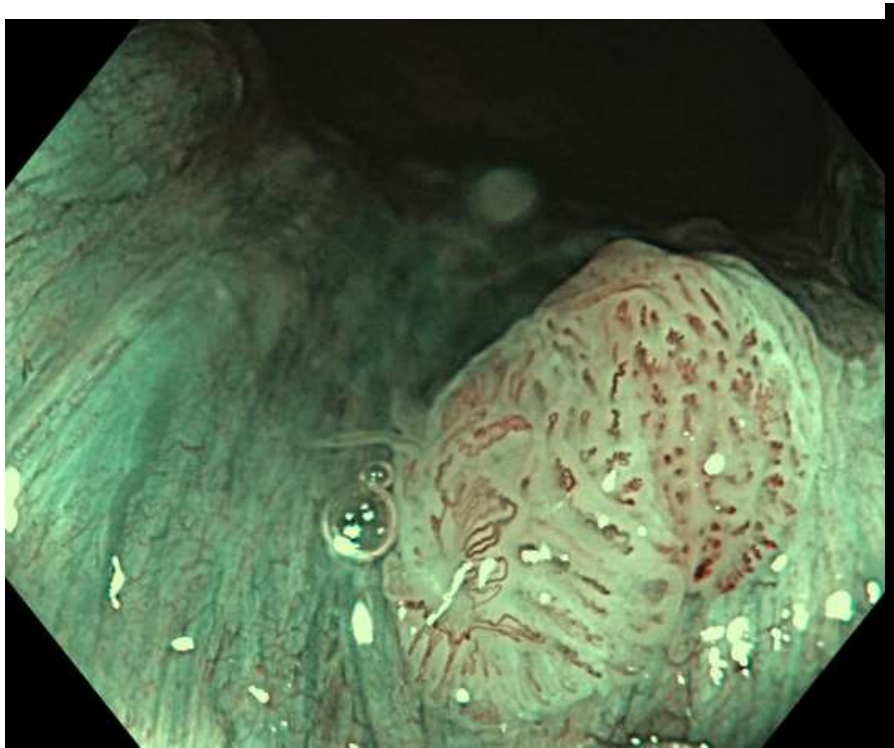

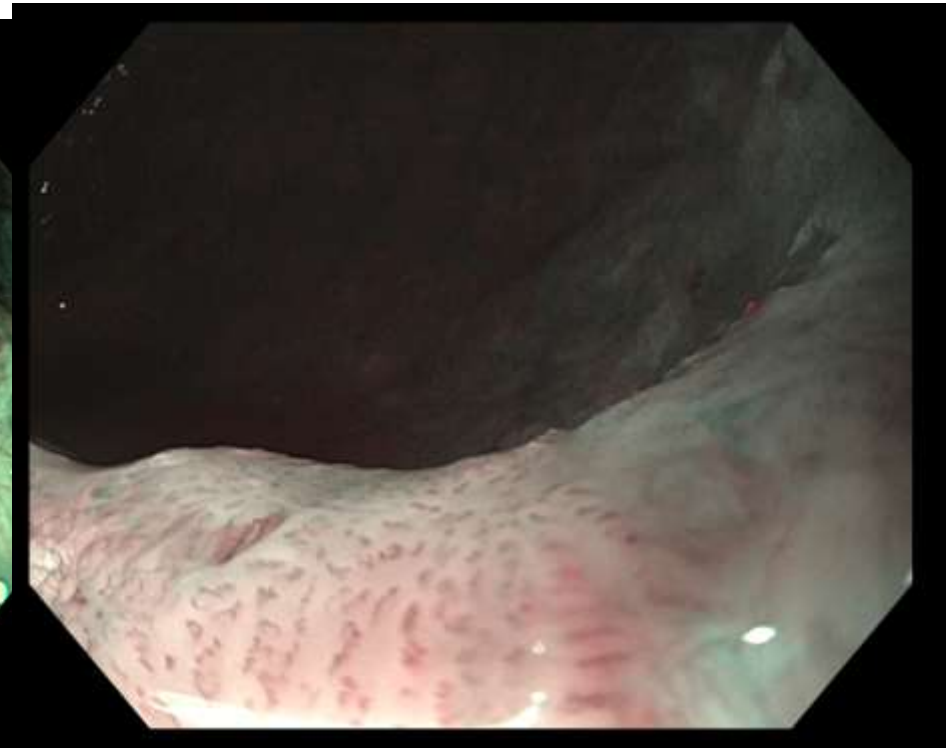

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Recognizing Advanced Histology in Colon Polyps

- Detect signs of advanced histology based on vessels, surface pattern and surface topography

- Indicate need for use of saline lift techniques when this is suspected or tattoo with referral for resection

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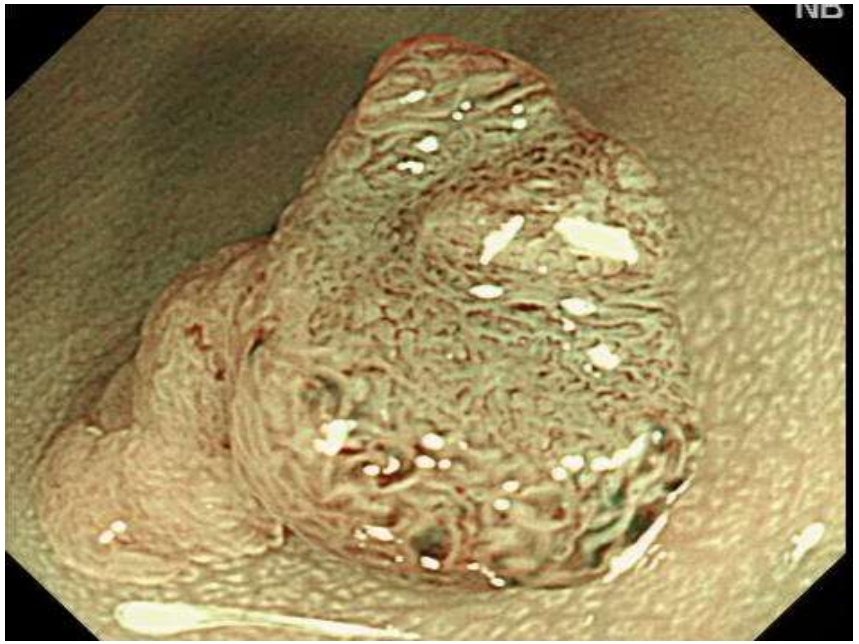
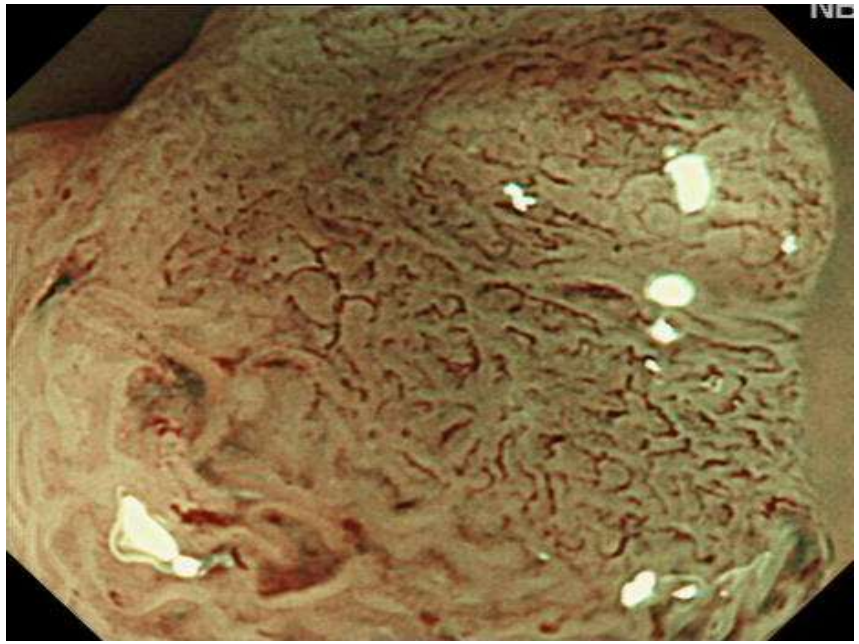
NICE III
Adenocarcinoma in situ





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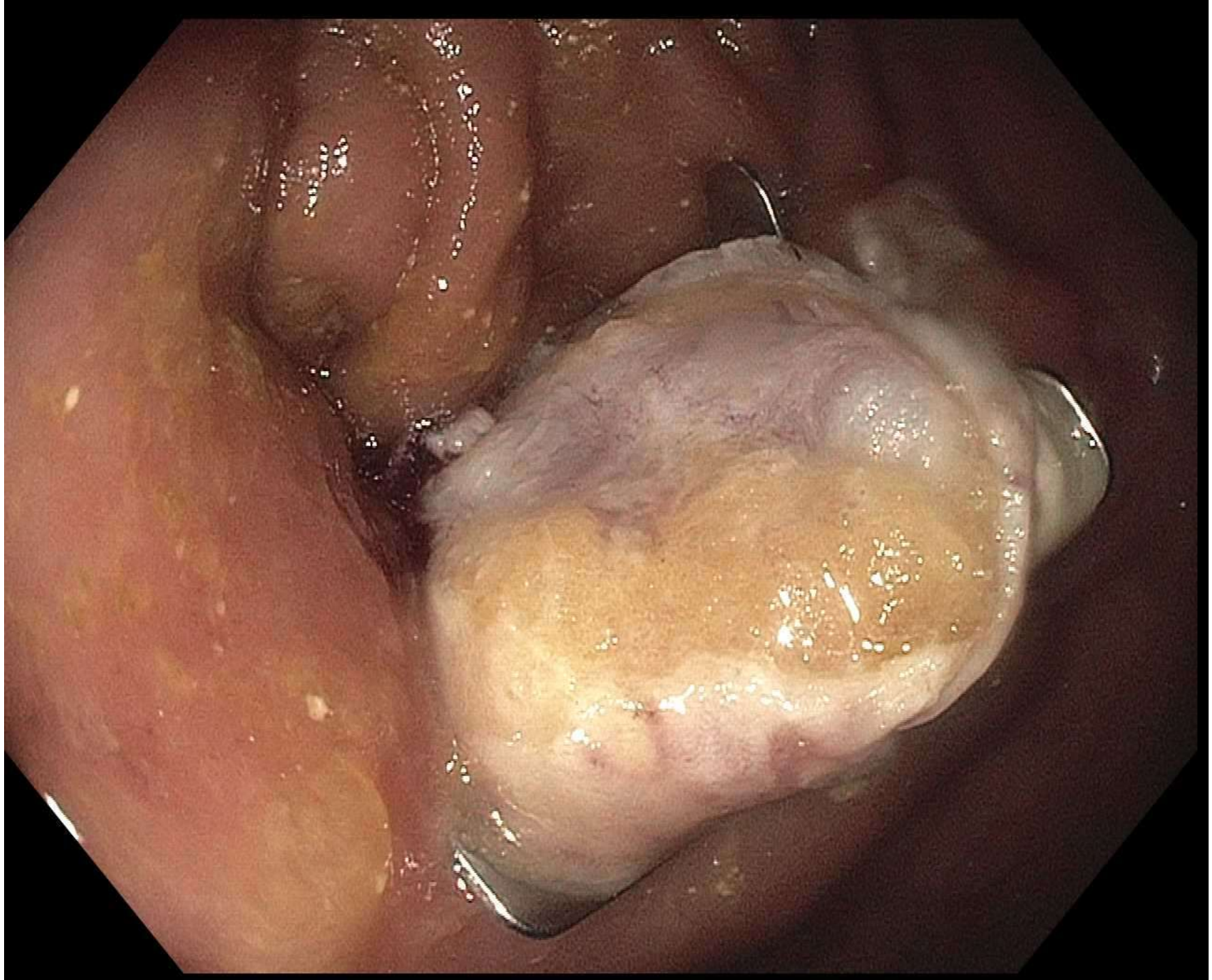

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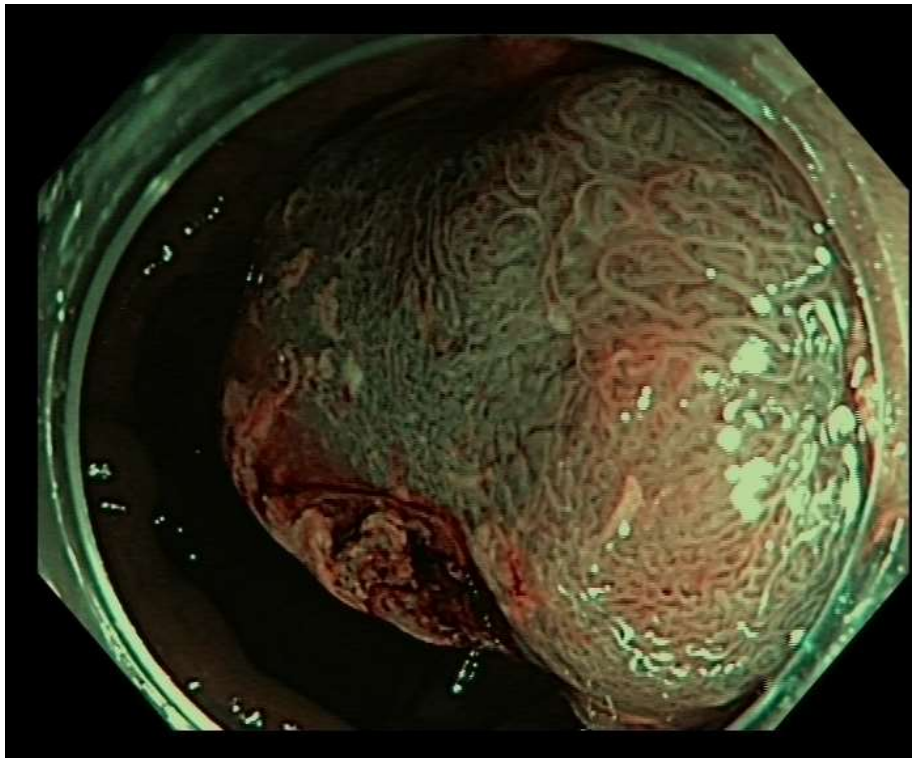
NICE 2 Valley vs NICE 3 Depression



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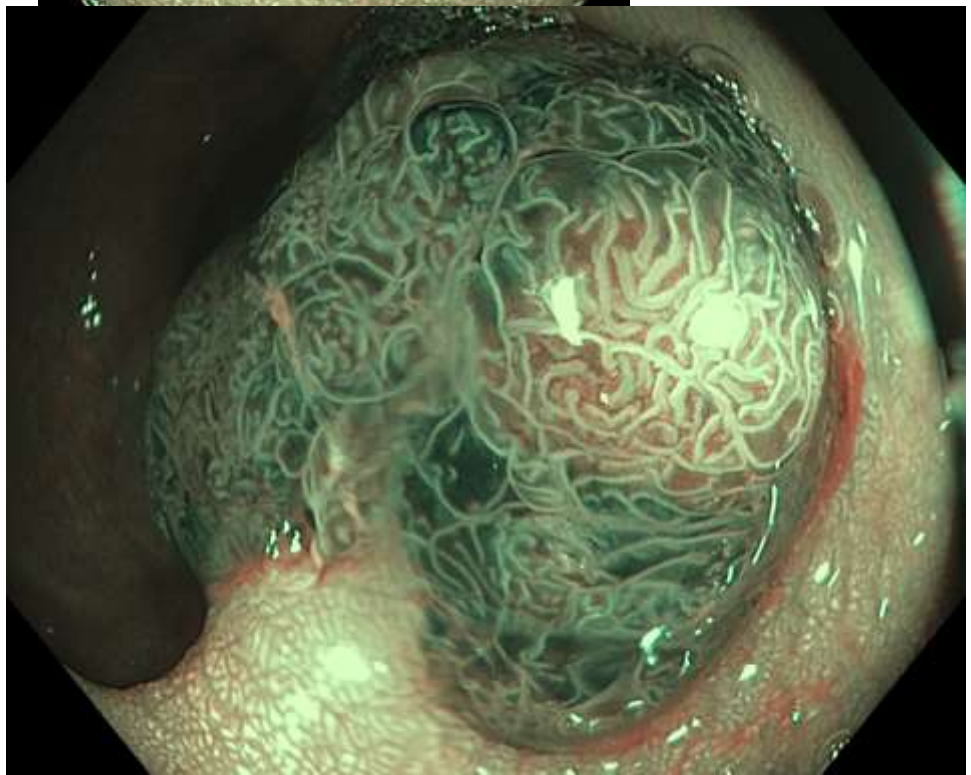
TV Adenomas on Stalk



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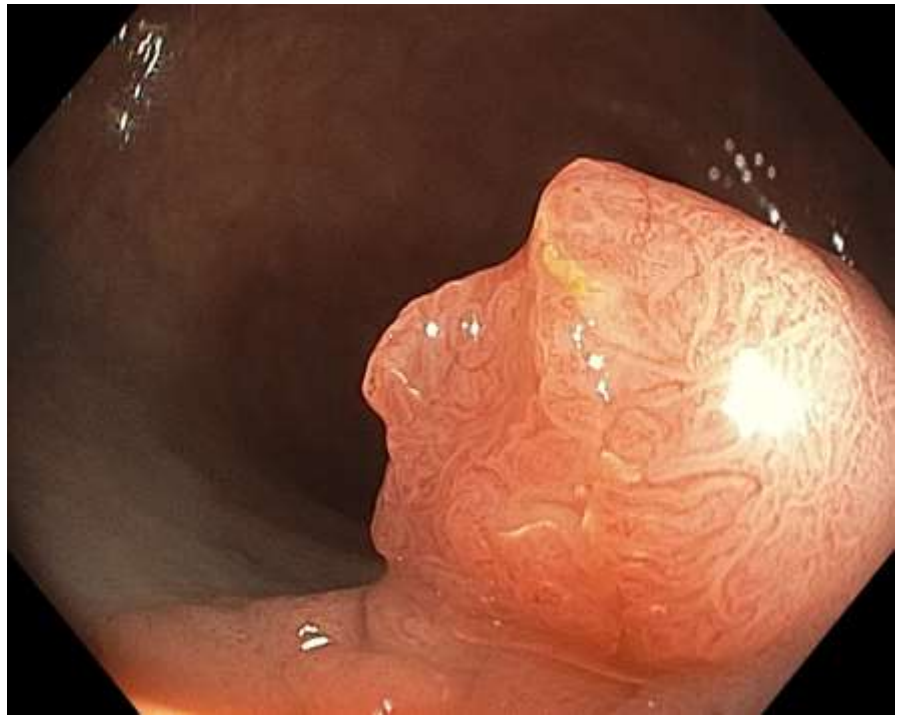

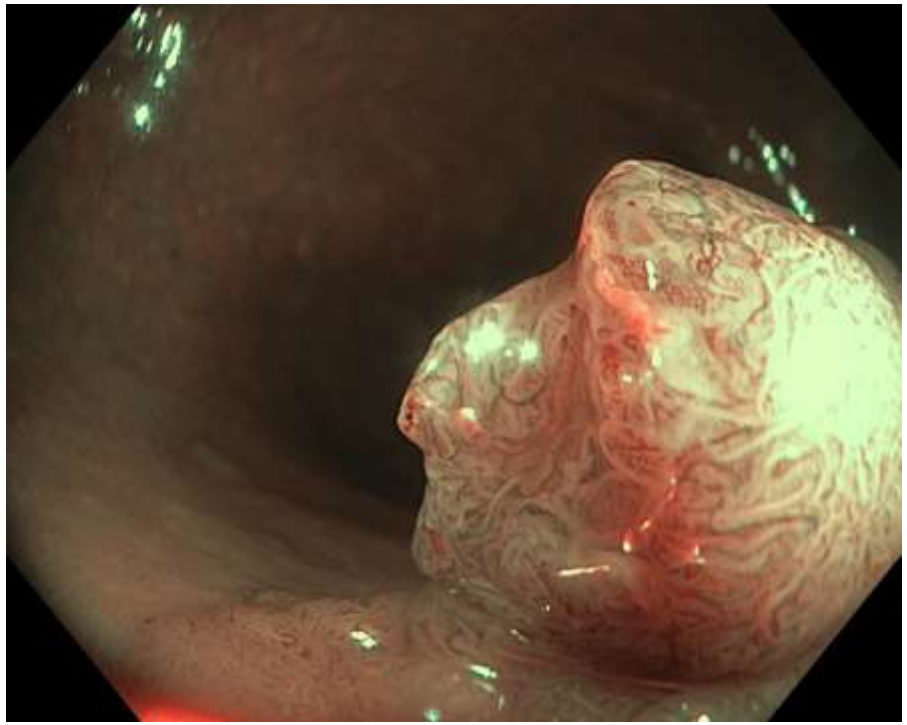

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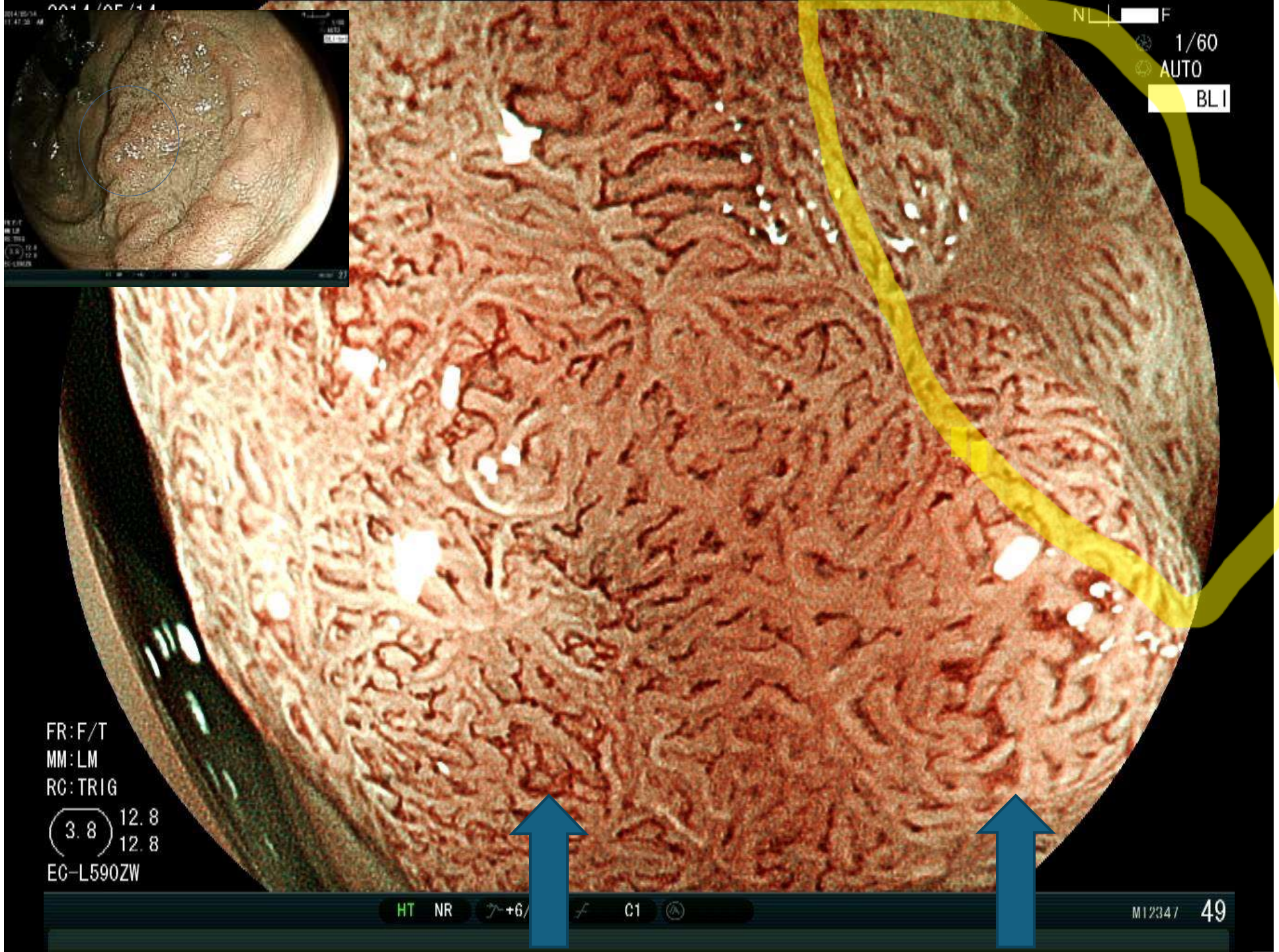

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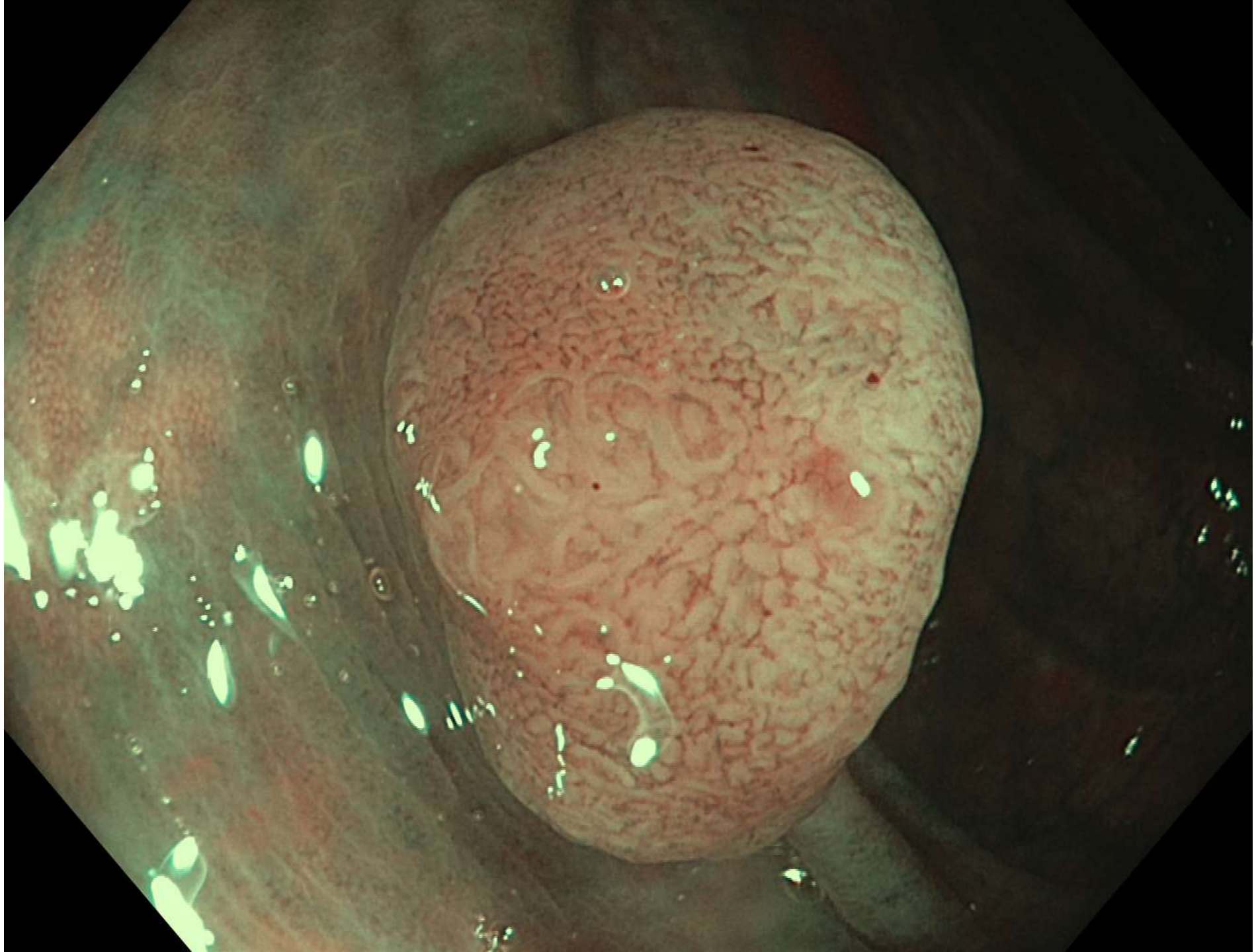

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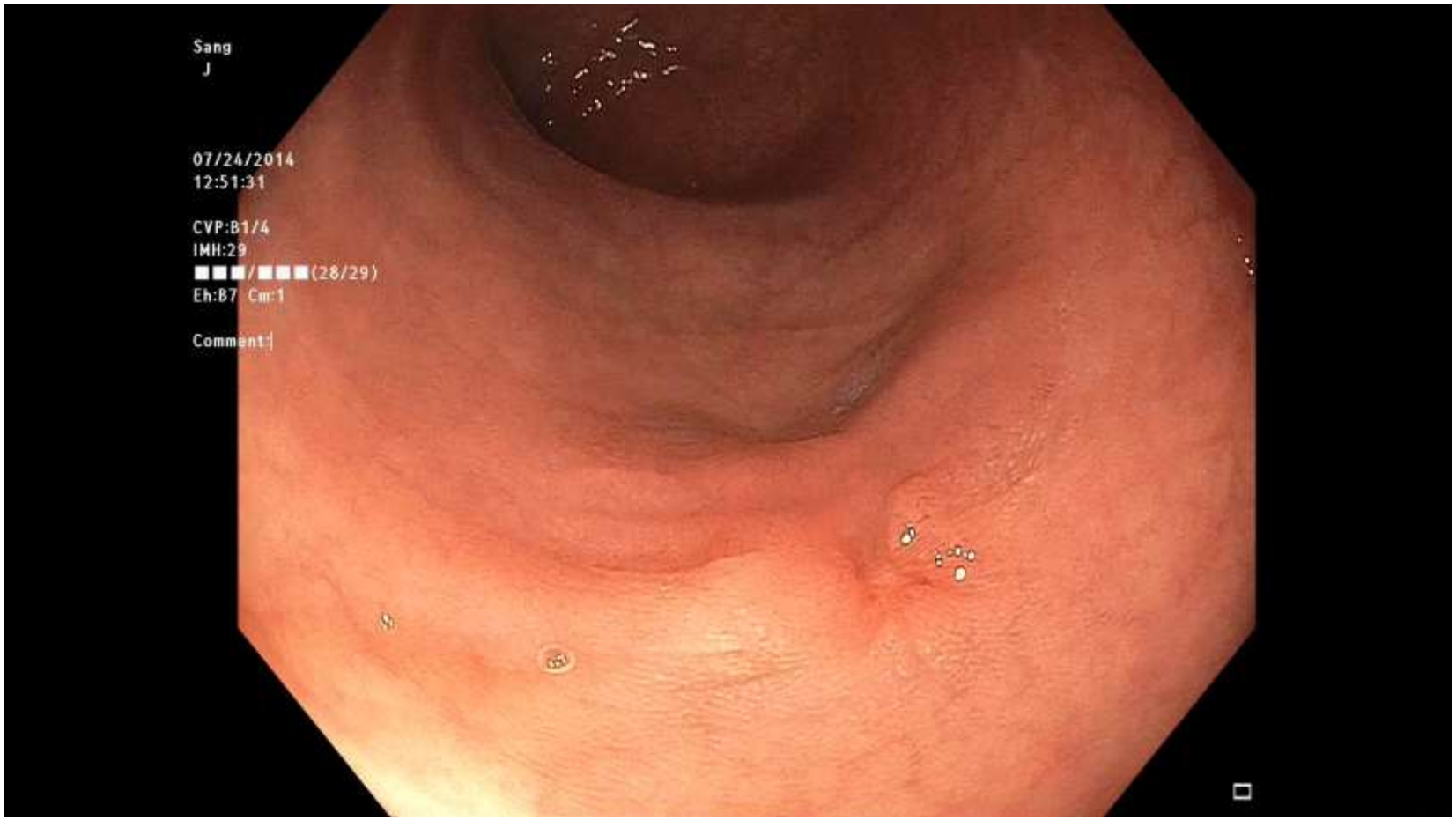
Margin Assessment to Prevent Incomplete Polypectomy

- Potential future key quality target
- Advanced imaging may lead to improvement

The Iceberg Effect

NBI Reveals Flat Adenomatous Projections of Polyp Visible on White Light



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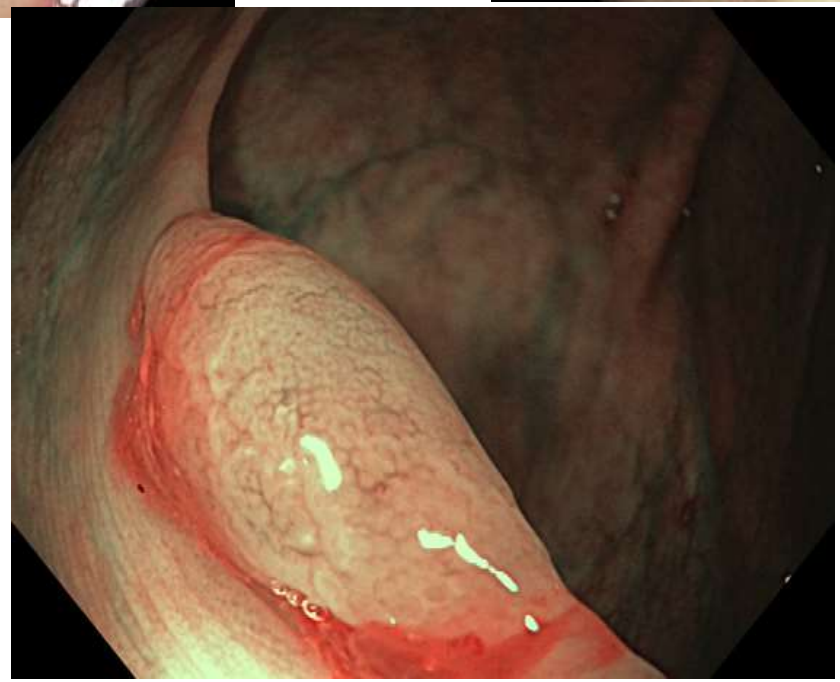
Pink Rim Accentuates Polyp Margins



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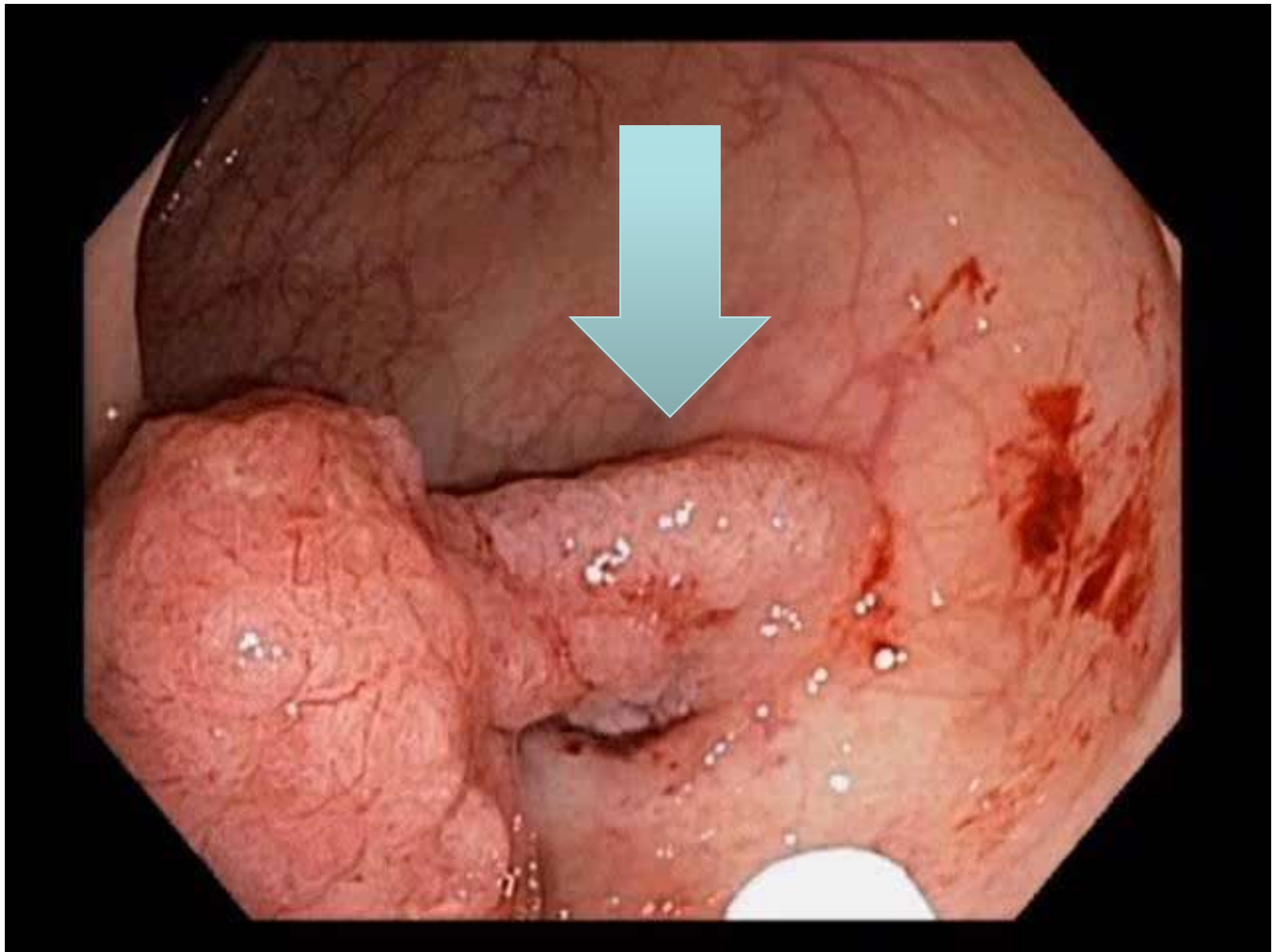
Low Tech Margins Assessment

- Small amounts of contrast added to saline cushion may separate pits



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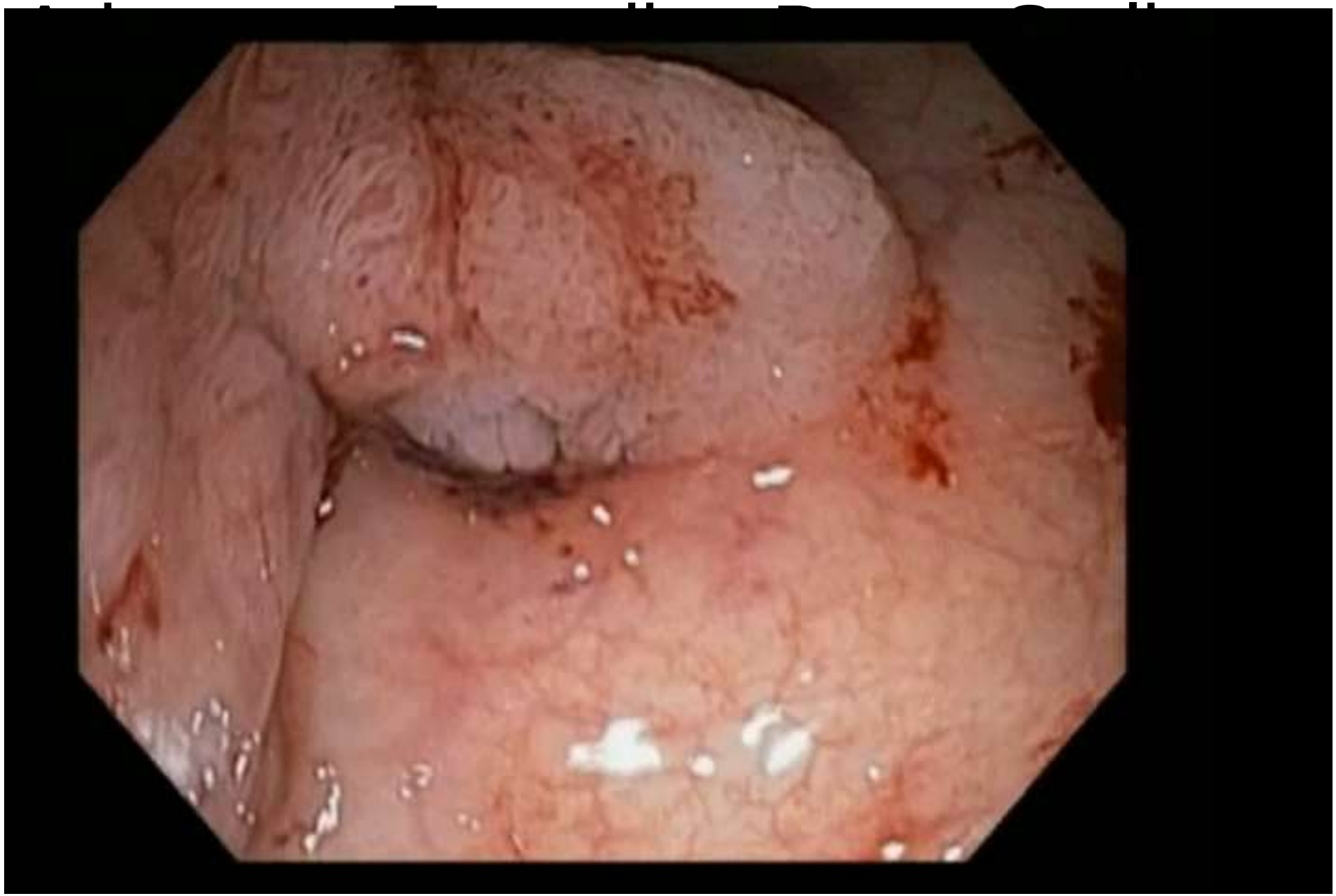

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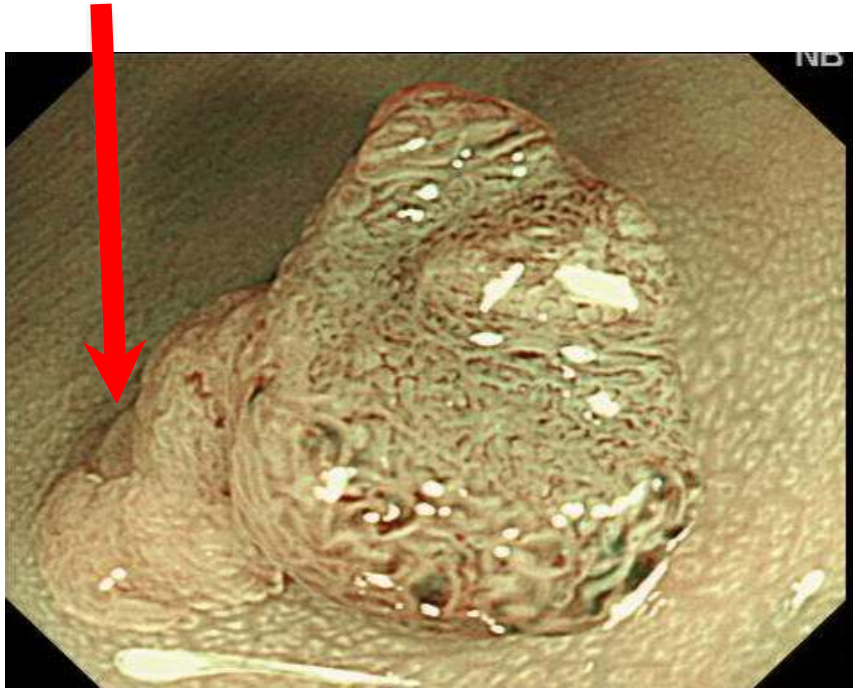
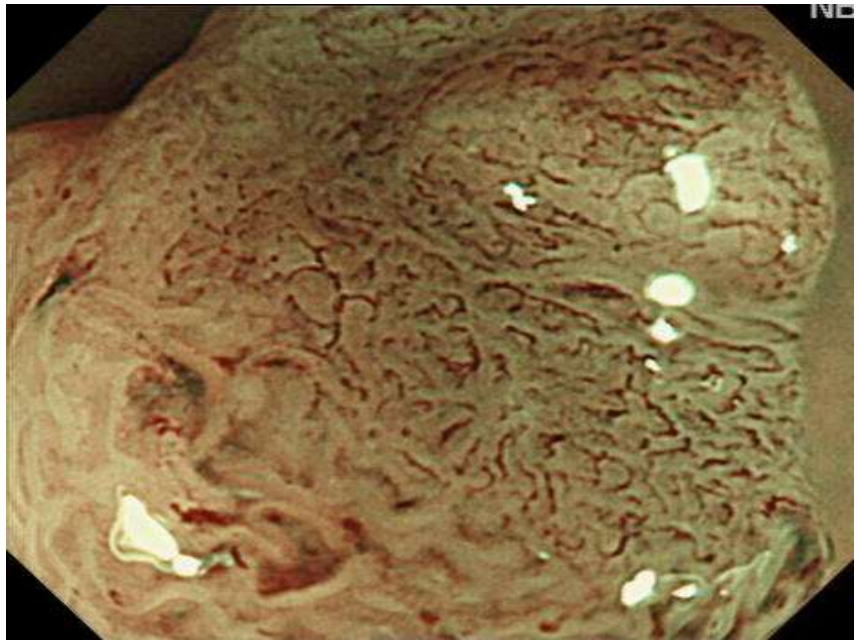
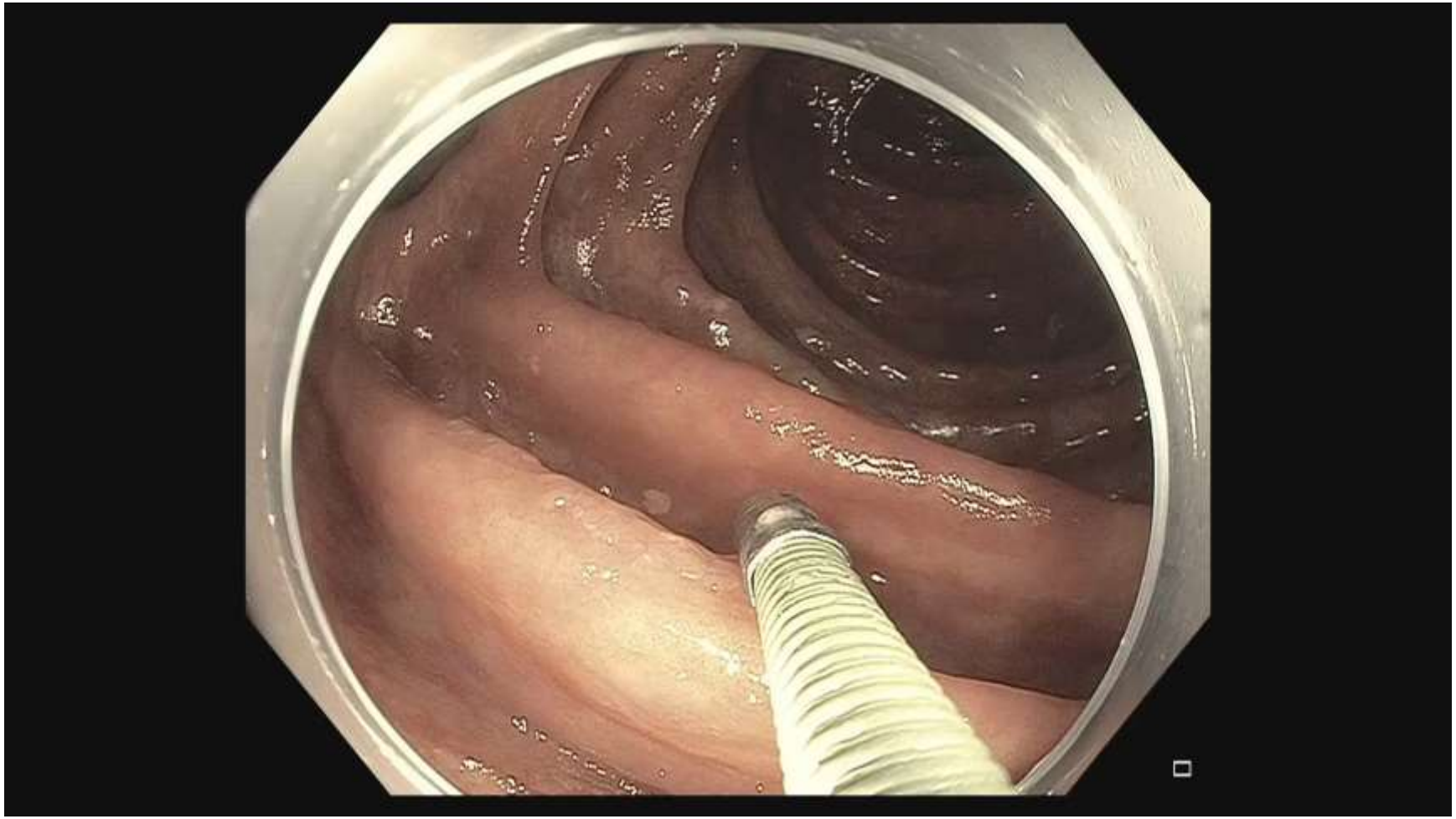
Imaging Critical to Improve Complete Resection





1. Type 3 mucosal and vessel pattern requires saline EMR to ensure deep margin
2. Lateral margin delineation assistance

Margin Assessment in SSA EMR



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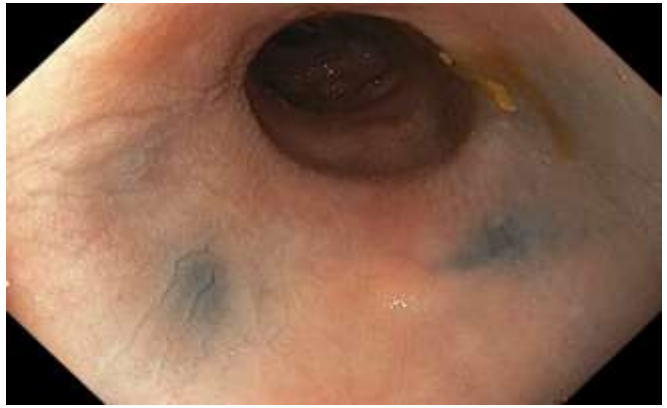
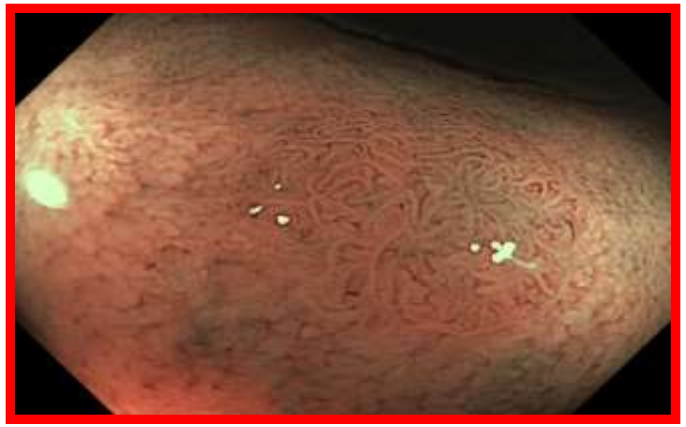
Subtle recurrent flat adenoma detected in between ink marks from prior piecemeal resection of rectal LST H190 WL, Even with NBI and close examination lesion not apparent until near focus view reveals adenoma.





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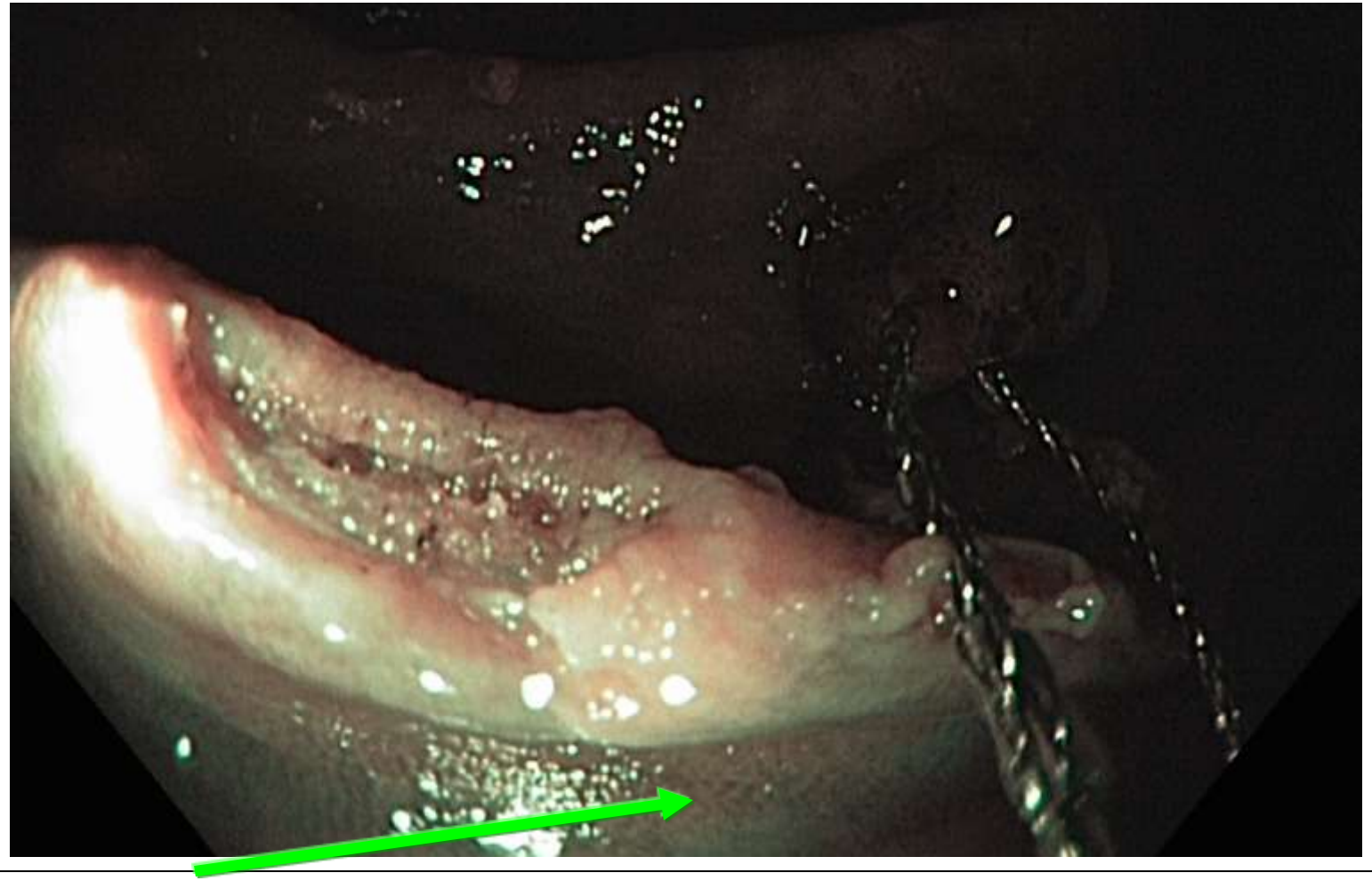
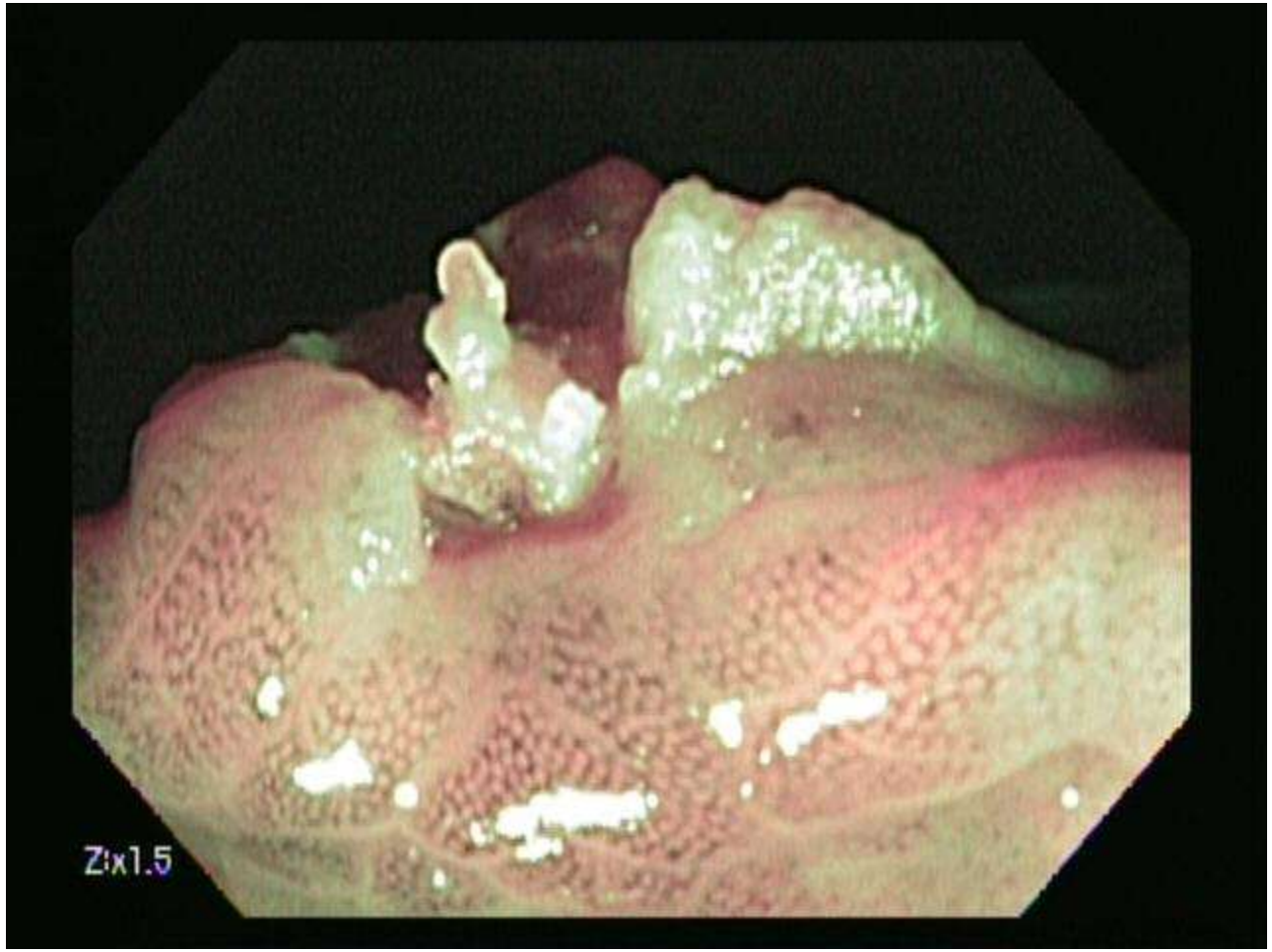
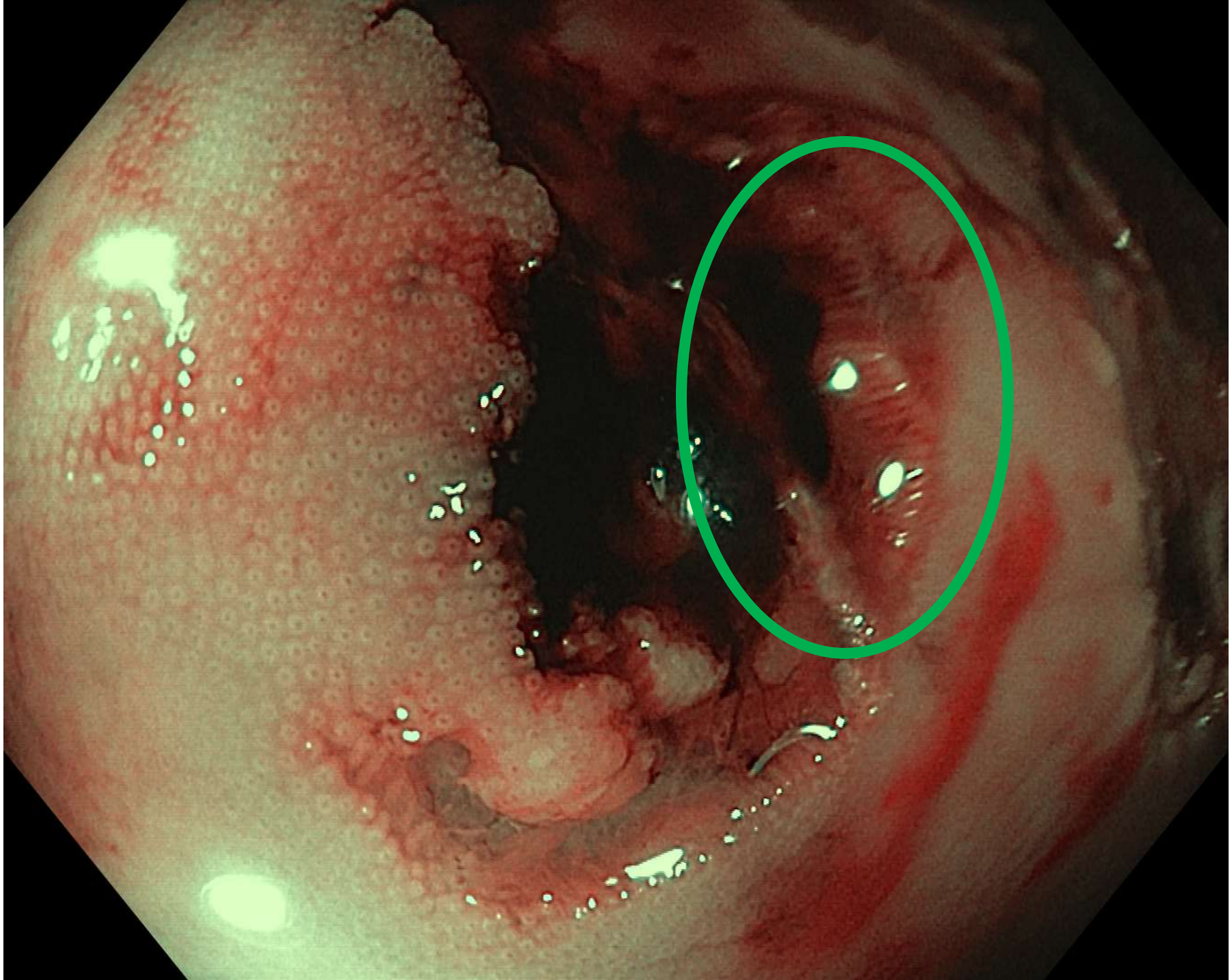
Polypectomy of Tubular Adenoma



Post-polypectomy inspection of polyp border: normal pit pattern confirms complete resection

Accentuation of Normal Pit Pattern to Confirm Clear Margins





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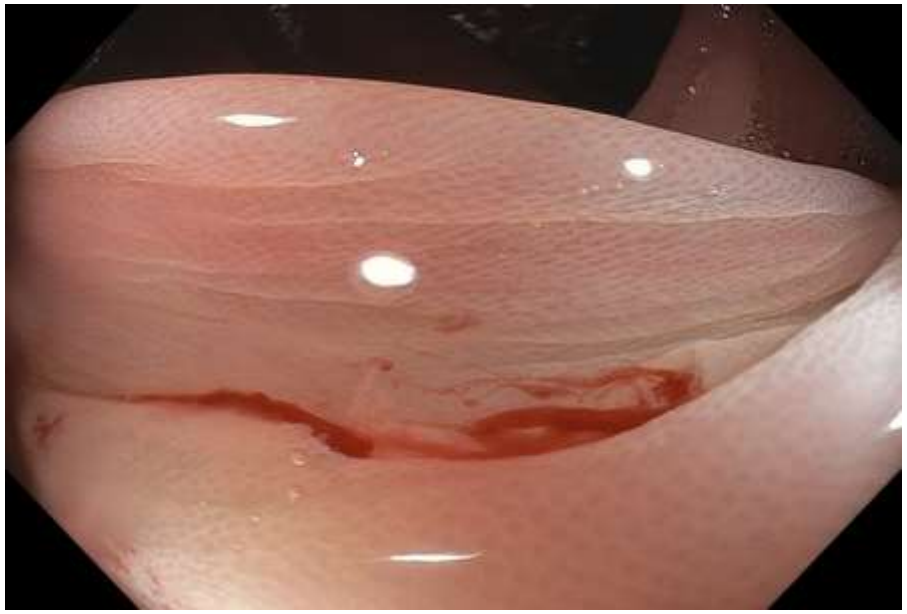
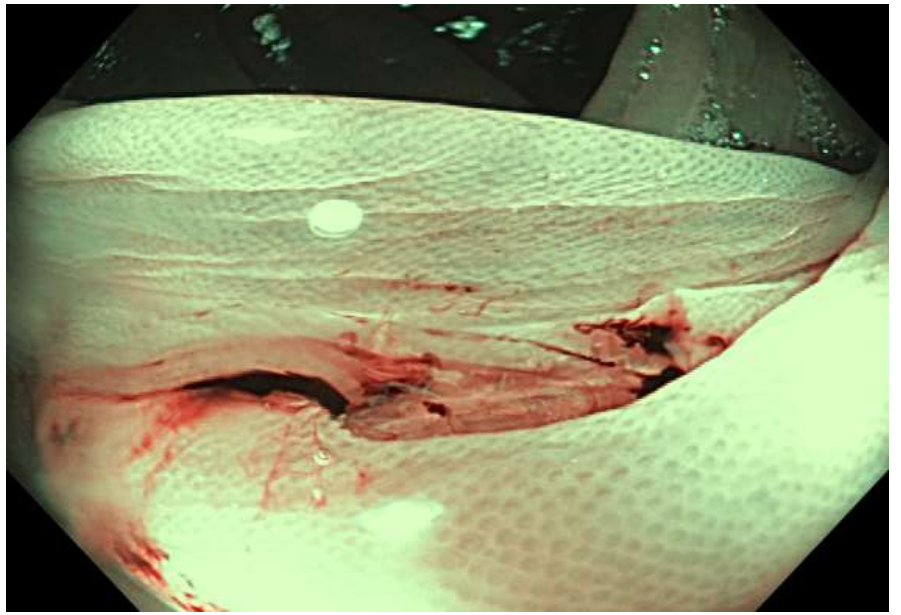
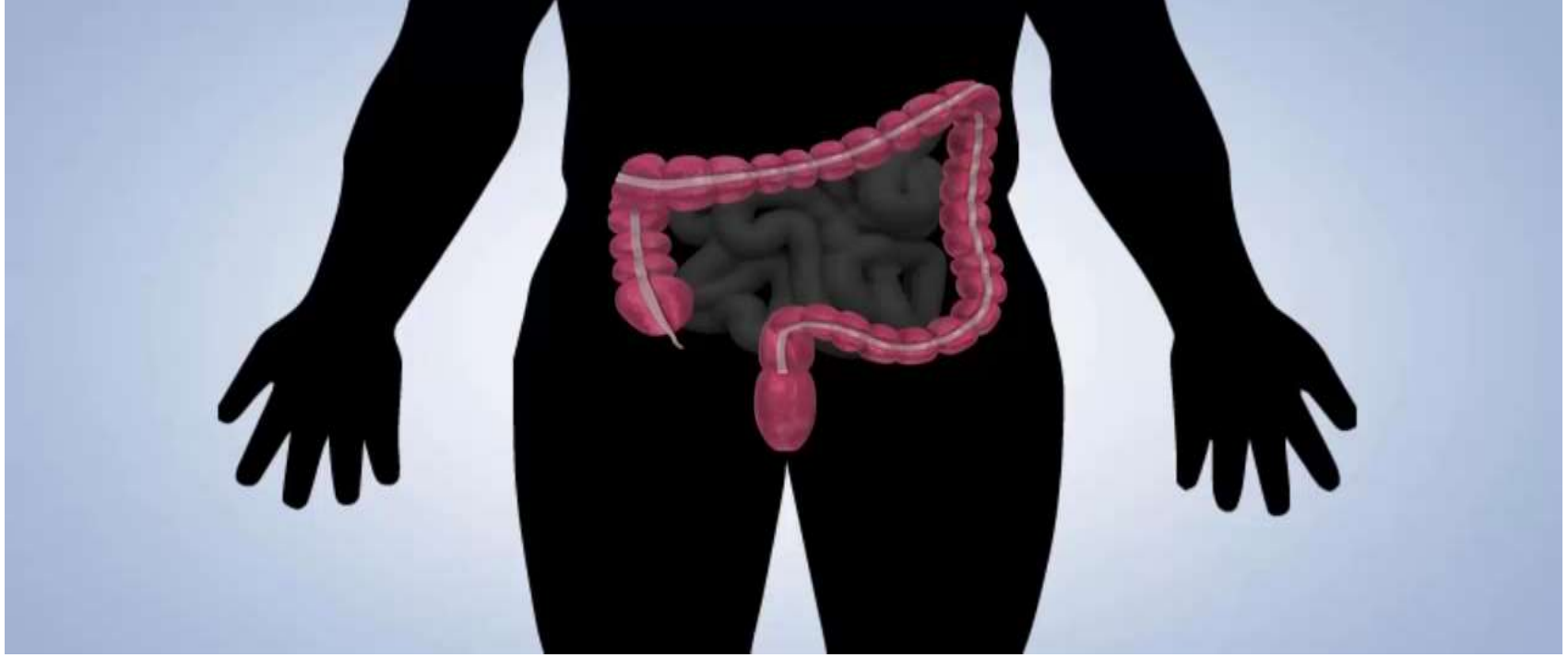
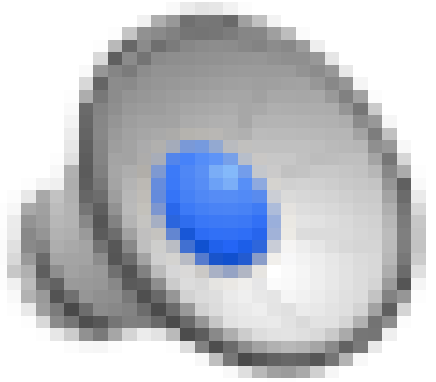
Inspection of polyp base for normal surrounding pits after cold resection





Devices for low detectors, patients at high risk for polyps, or all?





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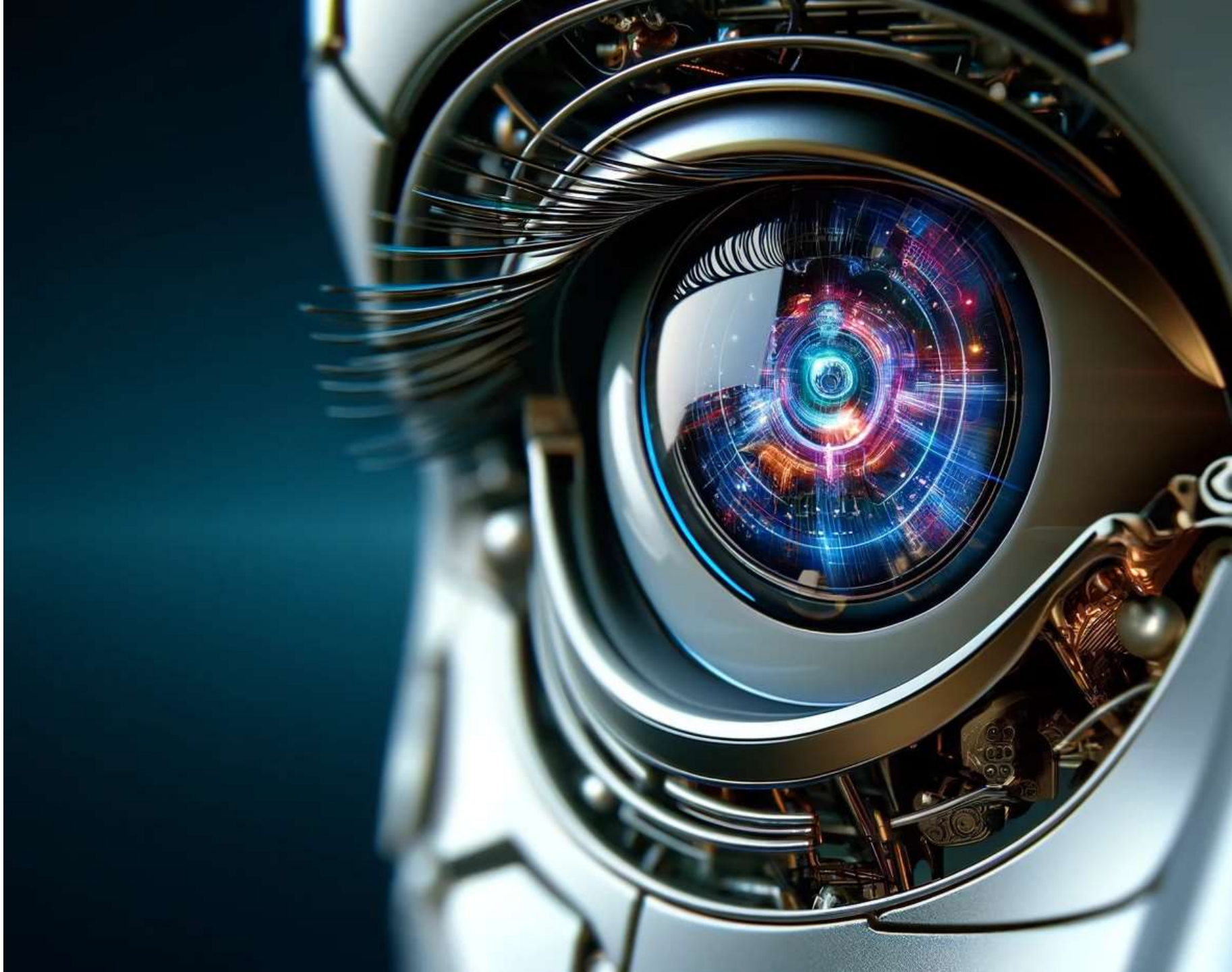
- Randomized prospective trial.
- 498 patients [249 males]; median age 67
- EC group, the number of polyps detected per patient was 63% higher [2.00 (IQR, 1.00-4.00) vs. 1.00 (IQR, 1.00-2.25), P<0.0001].

- Polyp detection rate in patients increased by 14% with the use of EC (56% vs. 42%, P=0.001).
- In the EC group, the number of adenomas detected per patient significantly increased by 86% (P=0.002).

Biecker et al. J Clin Gastroenterol. 2014

Computer Vision:



Current status of FDA Cleared AI Computer Vision

- [alphabetically]

Fujifilm	CAD-Eye
Iterative Health	SKOUT
Magentiq	ME-APDS
Medtronic	GI Genius*
Microtech	Endoscreener
Olympus/Odin	CADDIE

*Predicate device De Novo approval

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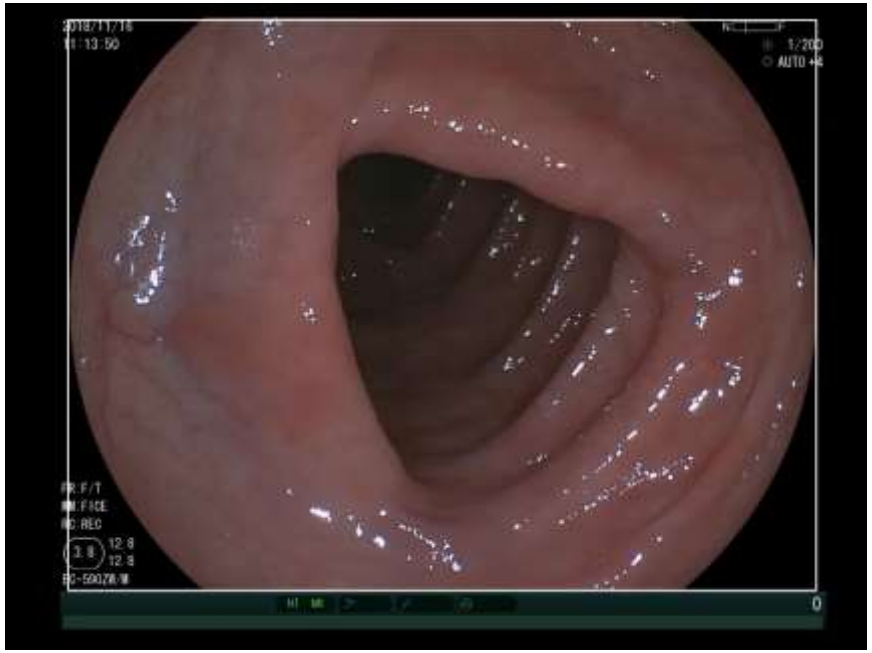
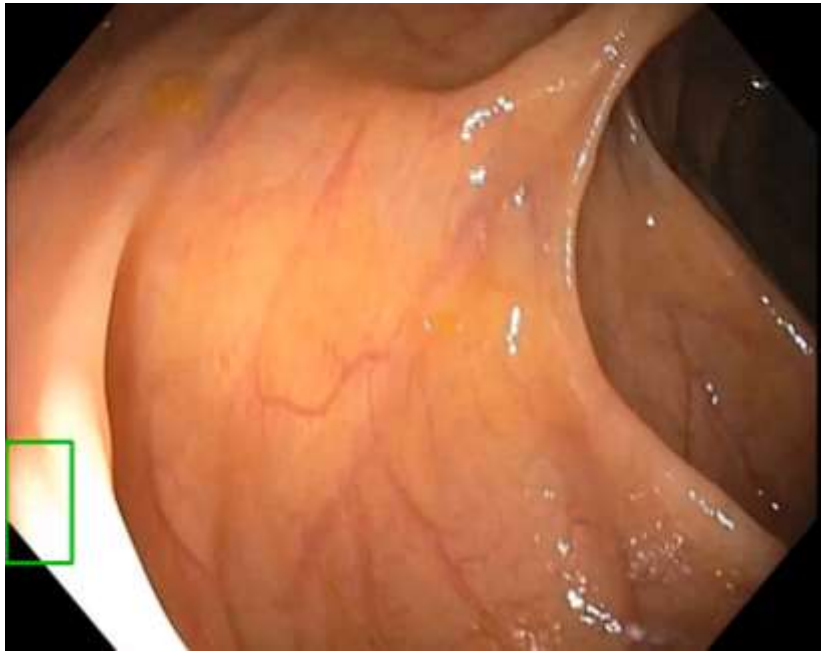
Approved Applications in the EU

- LGI Polyp Detection--CADe
- **LGI Polyp Characterization--CADx**
- **LGI Polyp Size Estimation**
- **BBPS Scoring**
- **Barrett's Dysplasia Detection**
- **Mayo scoring for IBD patients**

POLYP DETECTION DURING COLONOSCOPY





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Discovery AI CADe

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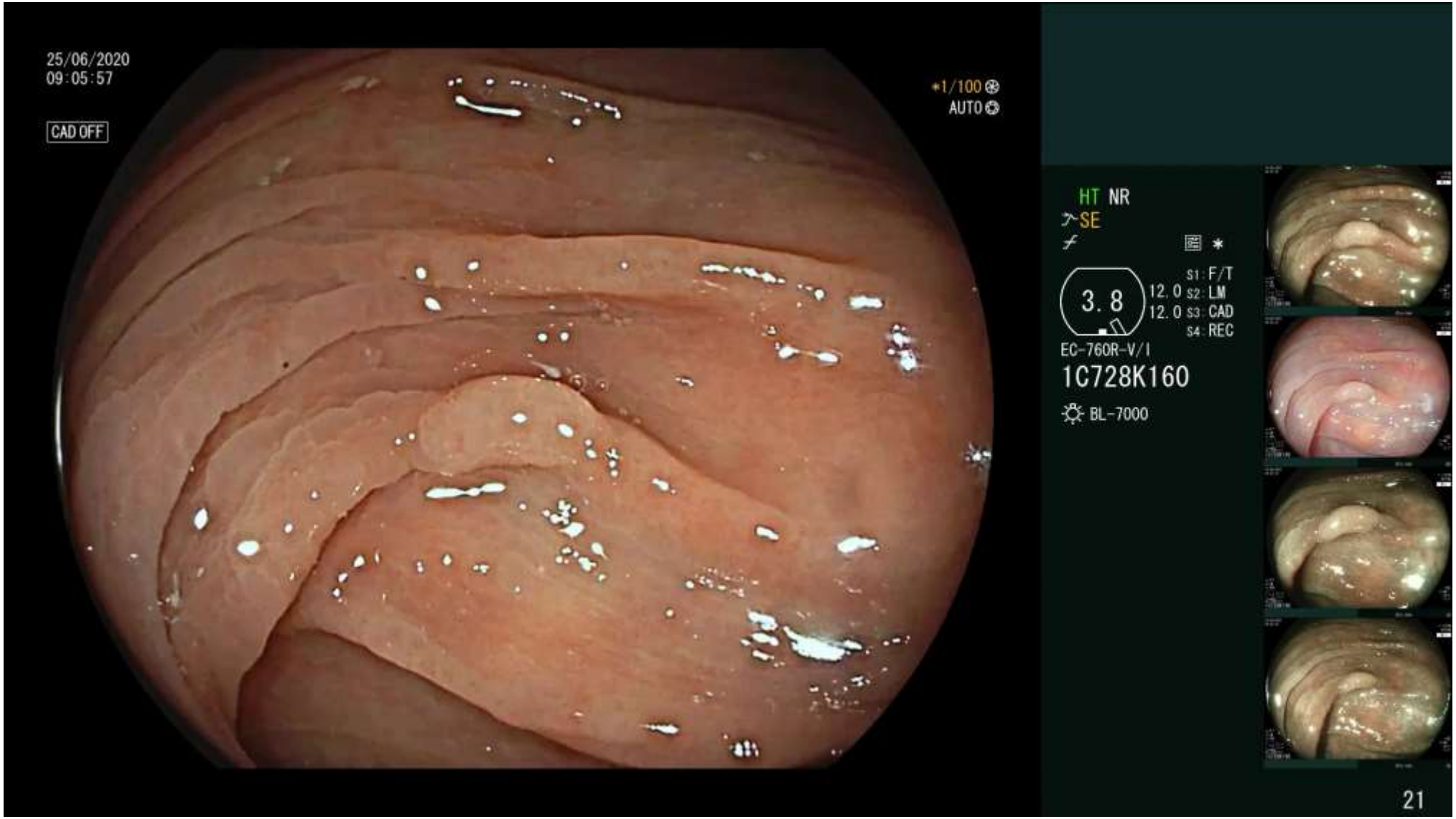
CADx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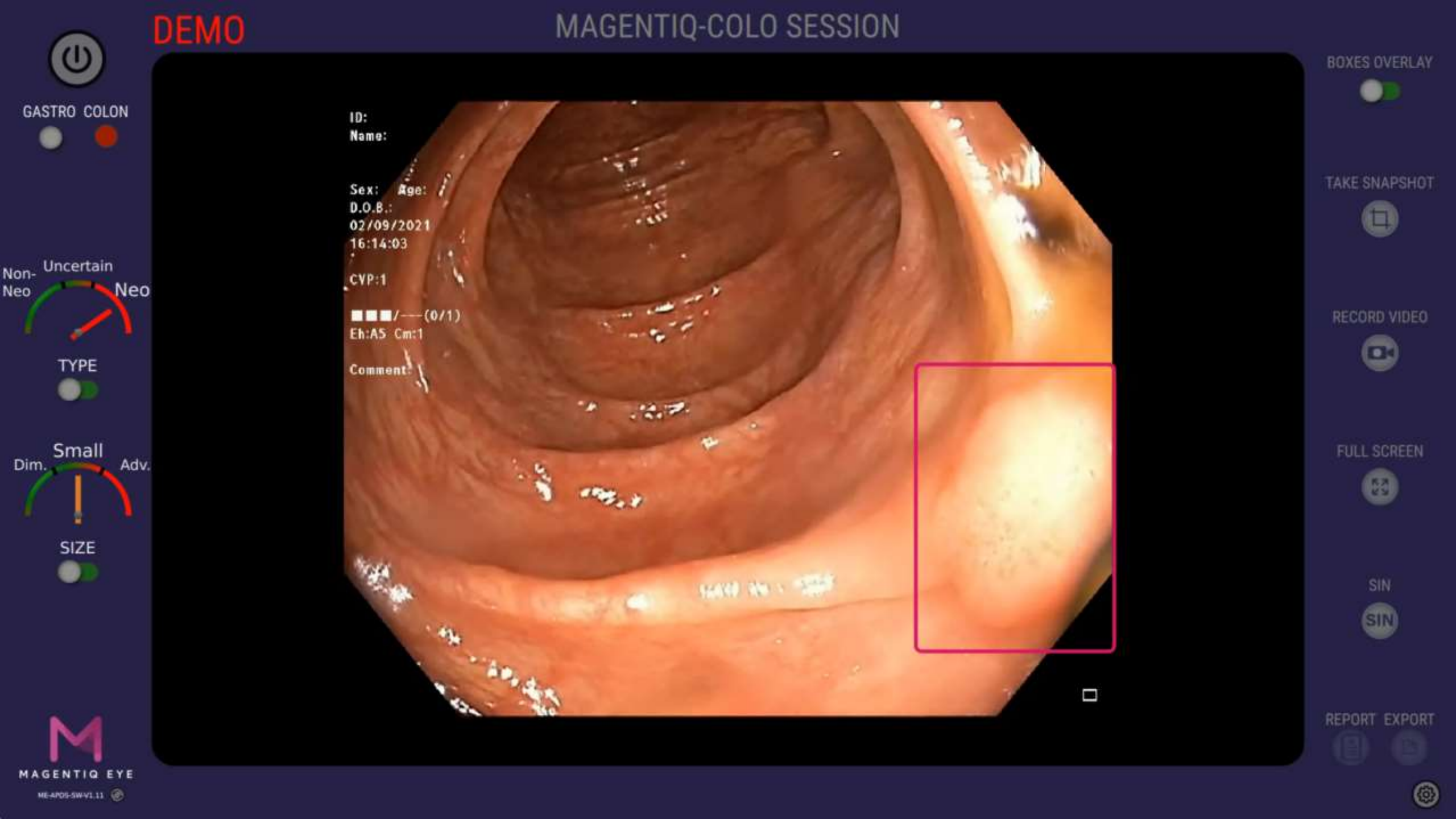
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REPORT EXPORT

REAL TIME CAD OF COLORECTAL NEOPLASIA: RCT

- 685 patients (screening/surveillance)
- Mean age - 61 years; 51% males
- HD-colonoscopy (n= 344) vs CADe (n= 341)
- CNN – GI-Genius

	Standard	CADe	RR
ADR	40%	55%	1.30 (1.14-1.45)
Adenoma per patient	0.71	1.07	1.46 (1.15-1.86)
Diminutive polyp	27%	34%	1.26 (1.01-1.52)
Large adenoma	6%	11%	1.78 (1.09-2.86)

Repici et al, Gastroenterology 2020

IMPACT OF AI ON MISS RATE OF COLORECTAL NEOPLASIA

- 230 patients
- Tandem study
  - 116 AI first
  - 114 non-AI first
- Mean age - 64 years; 68% males

	Standard	CADe	OR
AMR	32%	15%	0.38 (0.23-0.62)
Diminutive polyp	36%	16%	0.34 (0.21-0.55)
Non-polypoid	46%	17%	0.24 (0.13-0.43)
Proximal colon	33%	18%	0.46 (0.26-0.78)
Distal colon	32%	11%	0.25 (0.11-0.57)

Wallace et al, Gastroenterology 2022

AI FOR POLYP DETECTION: SYSTEMATIC REVIEW AND META-ANALYSIS

- 18 RCTs
- 13,276 patients
- With AI– 6610
  - Mean age: 57y, Males: 53%
- Without AI – 6666
  - Mean age: 57y, Males: 52%

	With AI	Without AI	RR
ADR	41%	33%	**1.26** (1.19-1.34)
PDR	54%	42%	1.28 (1.18-1.38)
AMR	16%	29%	0.57 (0.47-0.70)

Significant difference for ADR, PDR and AMR in sub group analysis of studies with screening or surveillance colonoscopy only

Patel et al, DDW, 2023

2024 Meta-analysis of CADe results

- 28 RCTs involving 23861 participants.
- Random-effects meta-analysis demonstrated a 20% increase in ADR (RR 1.20, 95% CI 1.14-1.27, p<0.01) and 55% decrease in AMR (RR 0.45, 95% CI 0.37-0.54, p<0.01) with AI-assisted colonoscopy.
- Similar magnitude effects by experts, across different systems and practice settings
- Significant increase in APC primarily due to increased diminutive lesion detection
- No difference in advance adenoma detection or SSLDR
- CADe led to average 9 second longer WT
- CADe resulted in 39% increase in the non-neoplastic resection (RR 1.39, 95% CI 1.23-1.57, p<0.001).

Makar J, Abdelmalak J, Con D, Hafeez B, Garg M, Use of Artificial Intelligence Improves Colonoscopy Performance in Adenoma Detection: A Systematic Review and Meta-Analysis, Gastrointestinal Endoscopy (2024), doi: https://doi.org/10.1016/j.gie.2024.08.033.

CADe Plus Endocuff: A Logical Combo

- Pilot single center retrospective sudy of 90 patients getting screening colonoscopy
- ADR was higher in the CADe + ECV group compared to the CADe and colonoscopy groups: (p = 0.03).
- CADe + ECV ADR 60%
- CADe ADR 40%
- Colonoscopy alone ADR 30%,

Caillo L, et al. COLODETECT 1: comparative evaluation of endocuff with computer-aided detection versus computer-aided detection alone versus standard colonoscopy for enhancing adenoma detection rates during screening colonoscopy-a pilot study. Therap Adv Gastroenterol. 2024; 27;17:1756284824129043 3.

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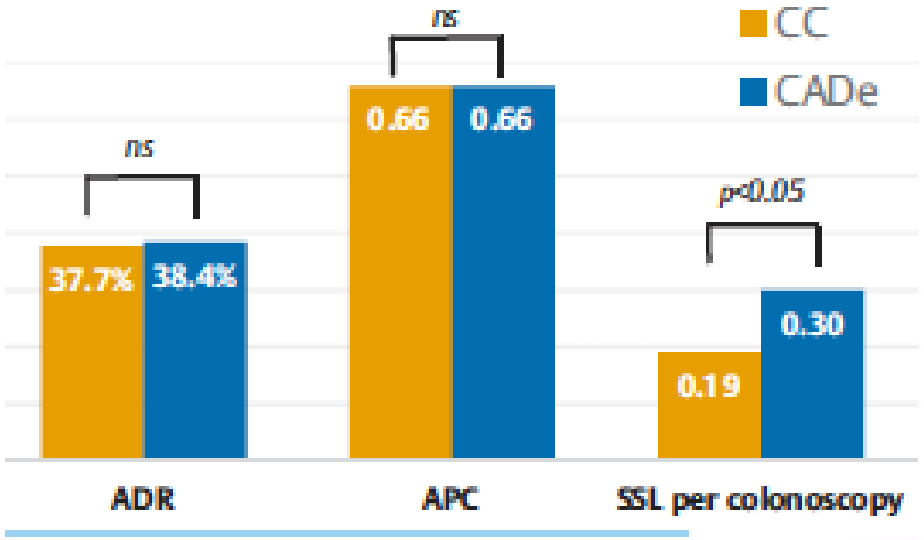
Efficacy ≠ Effectiveness

A number of abstracts and uncontrolled trails in real-world settings have not reproduced the degree of increased ADR from CADe validated by multiple RCTs

This underscores key area of effort to better define and address human-AI interaction

Real world data on CADe—a more complicated story

- RCT 7 hospitals in Europe and Canada with Discovery AI CADe
- 250 in the CADe arm and 247 in Conventional colonoscopy arm
- ADR (38.4% vs. 37.7%; P = 0.43) and APC(0.66 vs. 0.66; P = 0.97)
- SSLs per colonoscopy was increased using CADe:
  (0.30 vs. 0.19; P = 0.049)
- All expert colonoscopists with good ADRs



Mass, MHJ, et al. A computer-aided detection system in the everyday setting of diagnostic, screening, and surveillance colonoscopy: an international, randomized trial. Endoscopy 2024.

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Panel Discussion: HUMAN-AI Interaction: What is the experience with CADe in your units?

How many of you have a system in place now?

Do all the doctors use the AI?

Do the doctors that use it use in on every case?

What do you see as the barriers to adoption or real world problems you have encountered with its use?

Conclusion:

- **If you want to find more polyps and leave less behind . . .**
- Ensure a clean field of vision
- Inspect behind folds, retroflex, re-examine
- Consider new tools to help see more polyps
- Go slowly enough to take advantage of any detection benefits of advanced imaging and CADe when available
- Know what mucosal & vascular patterns to look for and note where they abruptly change
- Use optical contrast for accurate margin assessment
- Involve nurses and techs in the inspection and listen!

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. . . consider efforts to reduce access and barriers to high quality colonoscopy, and measure how well you are doing!

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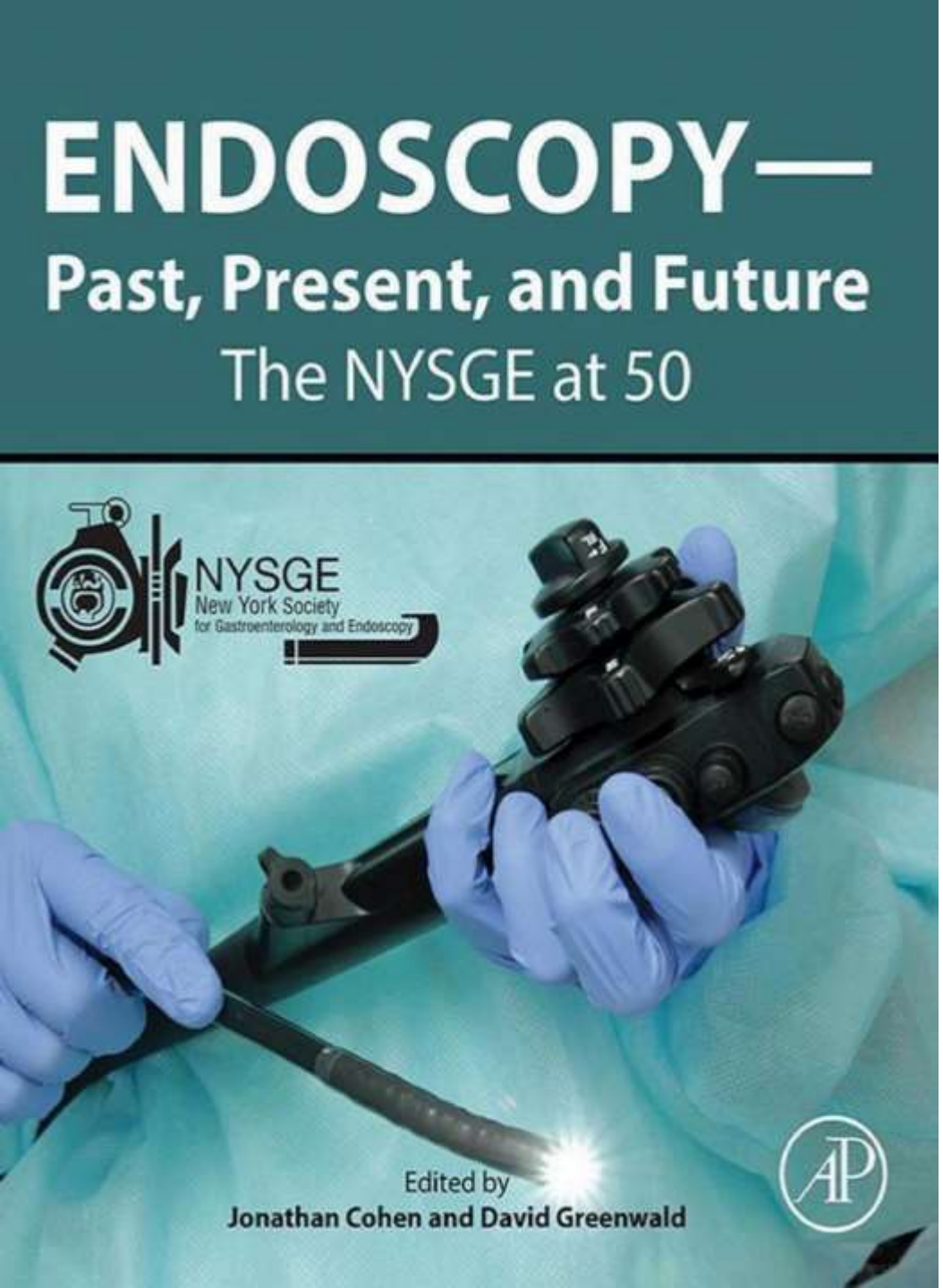

Thank you!

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