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DDW 2022
A Sampling of Lower GI Abstracts

William Karnes, MD
Clinical Professor of Medicine
Director of High-Risk Program and Colonoscopy Quality
Digestive Health Institute, UCIHealth

Disclosures

- Cofounder and CMO Docbot

Impact of Serrated Polyps Detected During 1st Surveillance Exam on Outcomes at 2nd Surveillance Colonoscopy

O. DAIRI[1], J. ANDERSON[2,3,4], C. ROBINSON[3,1], W. HISEY[1], T. MACKENZIE[3], L. BUTTERLY[3,1]

1 Dartmouth-Hitchcock Medical Center, Lebanon, NH 2 White River Junction VA Medical Center, White River Junction, VT
3 Dartmouth College Geisel School of Medicine, Hanover, NH 4 University Of Connecticut School of Medicine, Farmington, CT

Introduction

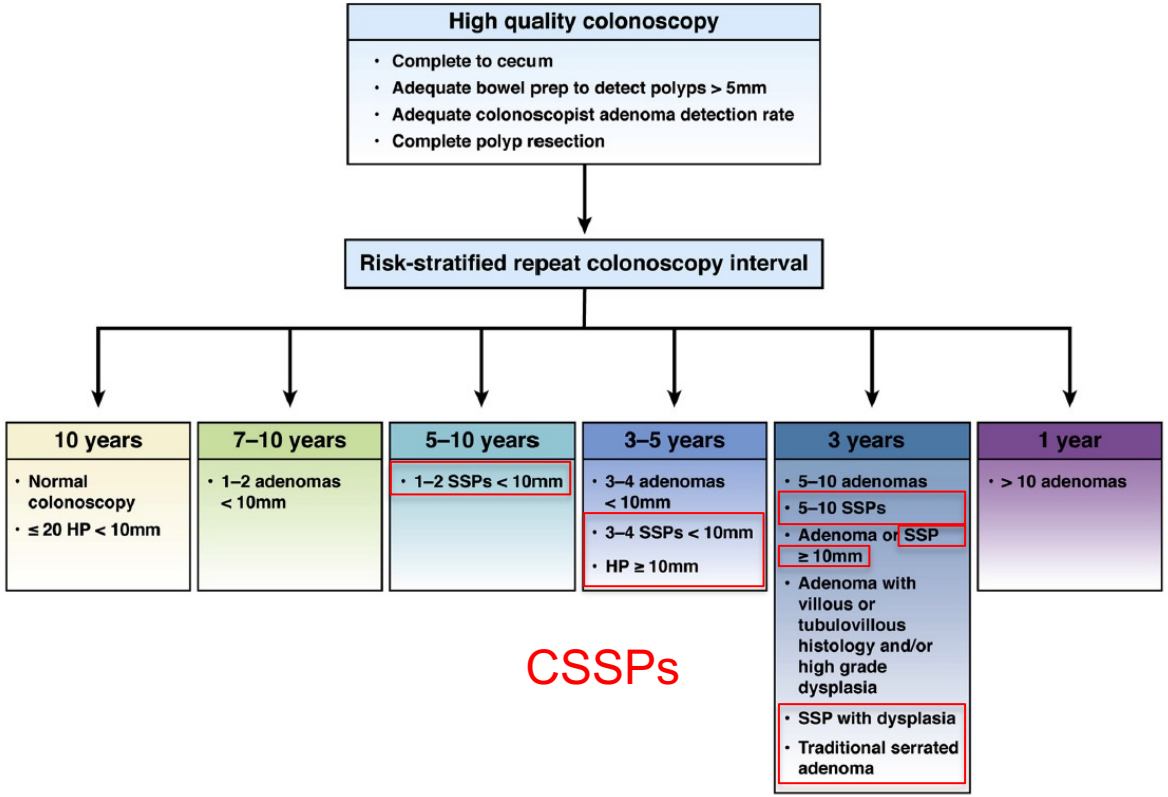
The United States Multi-Society Task Force (USMSTF) provides surveillance interval recommendations for the 2nd surveillance exam (3rd colonoscopy) based on index (1st colonoscopy) and 1st surveillance exam (2nd colonoscopy).

Though, the USMSTF does not provide surveillance interval recommendations for exams with clinically significant serrated polyps (CSSPs) detected on 1st surveillance (2nd colonoscopy).

CSSPs were defined as any sessile serrated polyp (SSP) or traditional serrated adenoma (TSA) or hyperplastic polyp (HP) >/= 1 cm or > 5 mm and proximal to the sigmoid colon.

Background

GASTROINTESTINAL ENDOSCOPY Volume 91, No. 3 : 2020



CSSPs

CSSPs are not considered in recommendations for timing of second surveillance

GASTROINTESTINAL ENDOSCOPY Volume 91, No. 3 : 2020

TABLE 7. Recommendations for Second Surveillance Stratified by Adenoma Findings at Baseline and First Surveillance

Baseline finding	Recommended interval for first surveillance	Finding at first surveillance	Recommended interval for next surveillance
1–2 tubular adenomas <10 mm	7–10 y	Normal colonoscopy[a]	10 y
		1–2 tubular adenomas <10 mm	7–10 y
		3–4 tubular adenomas <10 mm	3–5 y
		Adenoma ≥10 mm in size; or adenoma with tubulovillous/villous histology; or adenoma with high grade dysplasia; or 5–10 adenomas <10 mm	3 y
3–4 tubular adenomas <10 mm	3–5 y	Normal colonoscopy[a]	10 y
		1–2 tubular adenomas <10 mm	7–10 y
		3–4 tubular adenomas <10 mm	3–5 y
		Adenoma ≥10 mm in size; or adenoma with tubulovillous/villous histology; or adenoma with high grade dysplasia; or 5–10 adenomas <10 mm	3 y
Adenoma ≥10 mm in size; or adenoma with tubulovillous/villous histology; or adenoma with high-grade dysplasia; or 5–10 adenomas <10 mm	3 y	Normal colonoscopy[a]	5 y
		1–2 tubular adenomas <10 mm	5 y
		3–4 tubular adenomas <10 mm	3–5 y
		Adenoma ≥10 mm in size; or adenoma with tubulovillous/villous histology; or adenoma with high grade dysplasia; or 5–10 adenomas <10 mm	3 y

[a]Normal colonoscopy is defined as colonoscopy where no adenoma, SSP, or CRC is found.

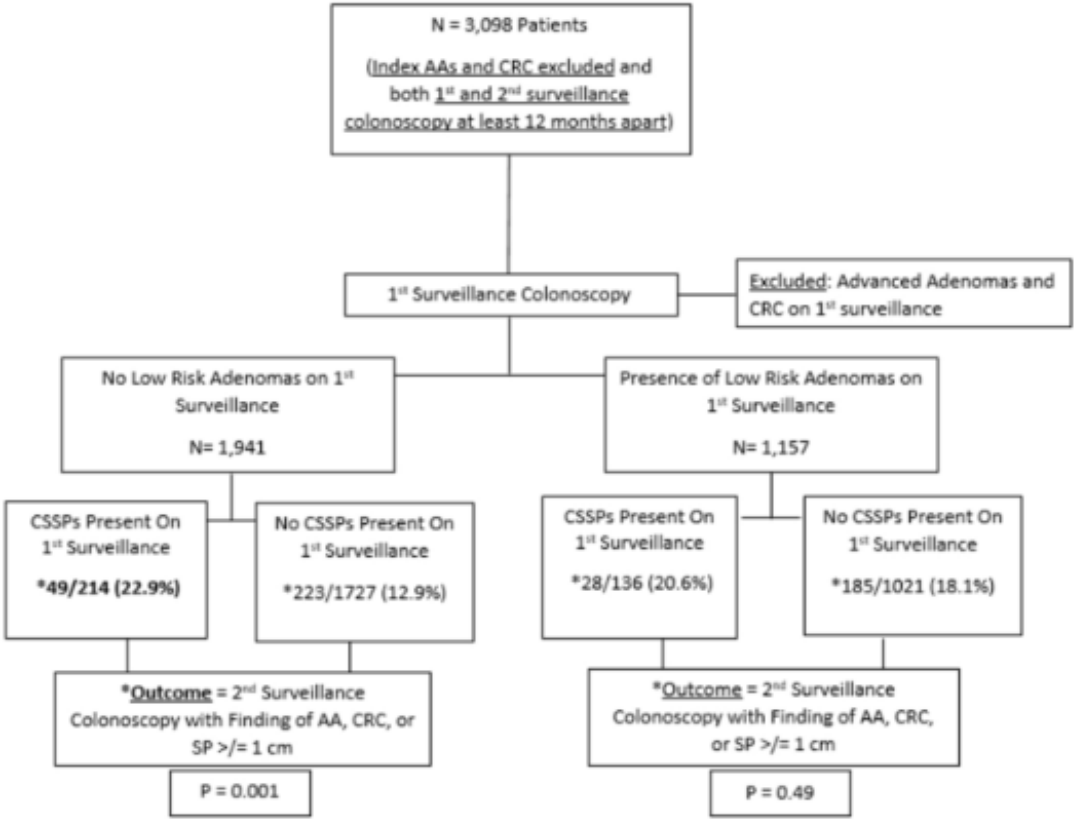
Objective

We sought to assess if there was a statistically significant risk of colorectal cancer (CRC), advanced adenoma (AA), or serrated polyp (SP) >/= 1 cm on 2nd surveillance in those with CSSPs on 1st surveillance exam with no conventional adenomas versus those without CSSP or conventional adenomas on 1st surveillance exam.

Methods

- Our analysis included 3,098 patients from the New Hampshire Colonoscopy Registry (NHCR) who had undergone both 1st and 2nd surveillance colonoscopy at least 12 months apart.
- Examinations that were incomplete, had poor bowel preparation, baseline CRC, inflammatory bowel disease, or polyposis syndrome were excluded.
- Also excluded were patients with a finding of high risk lesions, AAs, or CRC on index or 1st surveillance colonoscopy, since those patients were recommended to return in shorter interval periods.
- CSSPs were defined as any sessile serrated polyp (SSP) or traditional serrated adenoma (TSA) or hyperplastic polyp (HP) >/= 1 cm or > 5 mm and proximal to the sigmoid colon.
- Exposure Variable: CSSPs on 1st surveillance exam vs those without CSSPs as stratified by the presence of conventional low risk adenomas on 1st surveillance exam
- Logistic Regression analysis was performed adjusting for our covariates of age, sex, adenoma on 1st surveillance, and the presence of index CSSPs.
- Outcome: Advanced adenomas, CRC, or any Serrated Polyp >/= 1 cm on 2nd surveillance.

Flow Chart of Methods/Finding



CSSP (Clinically significant sessile serrate polyp)

- Any SSP (Sessile serrated polyp)
- Any TSA (Traditional serrated polyp)
- Any HP (Hyperplastic polyp) > 10cm
- Any HP proximal to sigmoid > 5mm

AA = Advanced adenoma
CRC = Colorectal cancer
SP = Serrated polyp

CONCLUSION

CSSPs found on 1st surveillance exams with no conventional adenomas increases the risk for the finding of CRC, AA, or SP >/= 1 cm on 2nd surveillance compared to those without CSSP or conventional adenomas on 1st surveillance exam.

“Hence, the USMSTF should consider providing interval recommendations for exams with CSSPs detected on 1st surveillance exam”

THE DIFFERENCES IN ADENOMA DETECTION RATES AND OTHER INDICES BETWEEN STANDARD SCREENING COLONOSCOPY VS. COMPUTER-AIDED DETECTION VS. MUCOSAL EXPOSURE DEVICE VS. THE COMBINATION: A RANDOMIZED TRIAL

Satimai Aniwan[1,2], Krittaya Mekritthikrai[1,2], Stephen J. Kerr[1], Kasenee Tiankanon[1,2], Natanong Kongtub[2], Panida Piyachaturawat[1], Santi Kulpatcharapong[1], Nareumon Wisedopas[1], Pinit Kullavanijaya[1,2], Rungsun Rerknimitr[1]

[1]Chulalongkorn University Faculty of Medicine, Bangkok, Thailand; [2]King Chulalongkorn Memorial Hospital, Bangkok, Thailand;

Introduction and Aim

Computer-aided detection (CADe) and mucosal exposure device (Endocuff Vision assisted colonoscopy, EAC) can improve adenoma detection during screening colonoscopy. However, there are no comparative data to support their use individually, or in combination.

This study aimed to compare the differences in adenoma detection rate (ADR) and other secondary indices between the CADe alone, EAC alone, the combination of CADe and EAC (CADe+EAC), with the standard high-definition colonoscopy.

Methods

- Prospective randomized controlled study among 942 screening colonoscopies
- Randomization:
  - CADe alone (Fujifim's CAD EYE) - 237
  - EAC alone (Endocuff VISION) - 235
  - CADe+EAC - 233
  - standard colonoscopy (SC) - 237
- High-definition colonoscope (EC 760ZP-V/L, Fujifilm Co, Japan).
- Primary outcome: ADR.
- Secondary outcomes:
  - proximal adenoma detection rate (pADR)
  - number of adenomas per colonoscopy (APC)
  - number of proximal adenomas per colonoscopy (pAPC).

Demographics

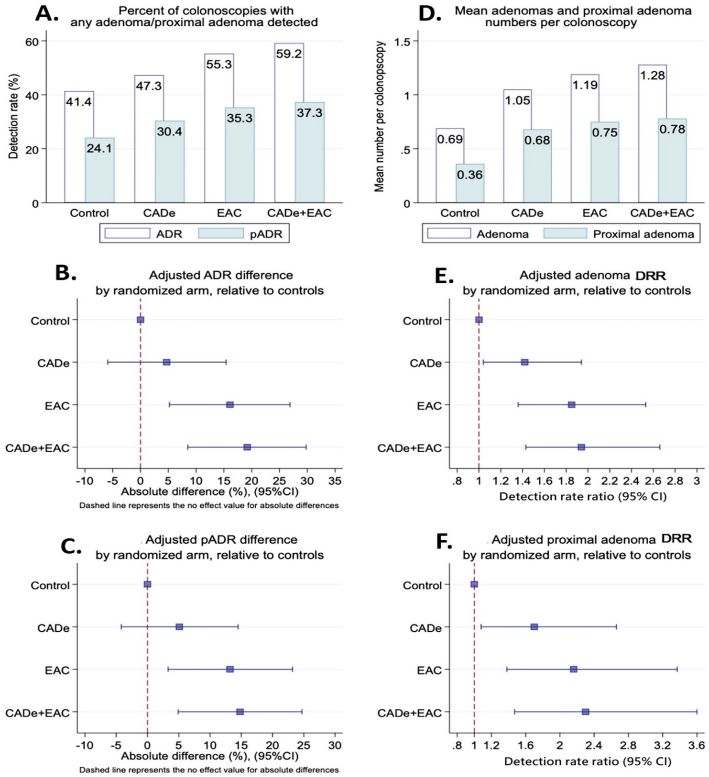
Table 1. Demographic and procedure related characteristics of 942 participants, by randomized arm

Characteristics	Total (n=942)	Control (n=237)	CADe (n=237)	EAC (n=235)	CADe+EAC (n=233)
Patient characteristics					
Age, mean (SD), years	61 (6.8)	61 (7.0)	62 (6.6)	61 (6.8)	61 (6.8)
Male patient, (%)	382 (40.6)	109 (46.0)	99 (41.8)	78 (33.2)	96 (41.2)
Smoker, n (%)	133 (14.1)	26 (11.0)	39 (16.5)	32 (13.6)	36 (15.5)
Present family history of CRC, n (%)	118 (12.5)	24 (10.1)	24 (10.1)	32 (13.6)	38 (16.3)
Body mass index, mean (SD, kg/m^2)	24.0 (4.0)	24.2 (3.9)	23.7 (3.8)	24.0 (4.2)	24.0 (3.9)
Fecal occult blood positive (%)	136 (14.4)	33 (13.9)	37 (15.6)	31 (13.2)	35 (15.0)
Procedure-related characteristics					
Staff performed (n, %)	518 (55.0)	134 (56.5)	128 (54.0)	126 (53.6)	130 (55.8)
Boston bowel preparation score, median (IQR)	8 (7 – 9)	9 (8 – 9)	8 (7 – 9)	8 (6 – 9)	8 (7 – 9)
Withdrawal time, median (IQR), min	7.8 (6.3 – 9.3)	8.1 (6.6-10.0)	7.8 (6.4-9.6)	7.4 (6.1-9.0)	7.5 (6.2-9.0)
Cecal intubation time, median (IQR), min	5.7 (4.0 – 8.0)	6.0 (4.4-8.5)	6.5 (4.1-9.0)	5.3 (3.9-7.4)	5.0 (4.0-6.8)

SD, standard deviation; CRC, colorectal cancer; IQR, interquartile range

Results

Figure 1: Differences in detection rates of adenomas among randomized arms



Conclusions

- EAC alone or in combination with CADe is associated with significantly improved ADR, pADR, APC, and pAPC
- CADe alone is associated with significantly improved APC and pAPC but not ADR or pADR

ARTIFICIAL INTELLIGENCE FOR LEAVING-IN-SITU COLORECTAL POLYPS: RESULTS OF A CLINICAL TRIAL

Cesare Hassan[2], Roberto Lorenzetti[2], Angelo Zullo[2], Giulio Antonelli[2,1]
[1]Sapienza University of Rome, Rome, Italy; [2]Poliambulatorio Nuovo Regina Margherita, Roma, Lazio, Italy;

Background and Aim

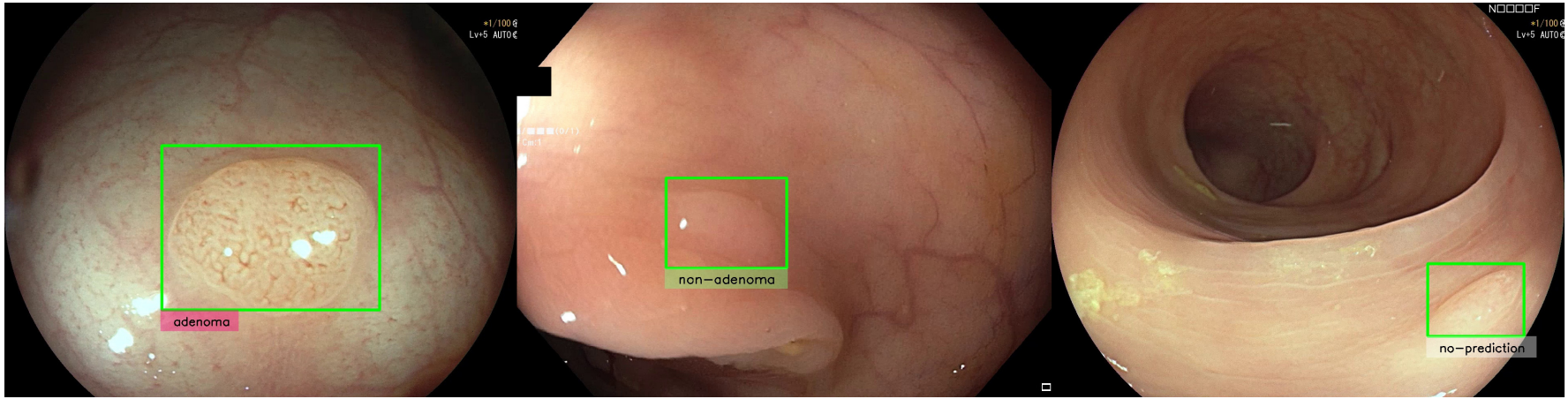
- Hypothesis: Artificial Intelligence (AI) can support cost-saving strategies related to reduced pathology costs due to its accuracy in optical diagnosis using standard white-light endoscopy with no need of advanced imaging
- AI must match predefined criteria to be implemented in clinical setting
  - "Leave *in situ*" applies to < 5 mm rectosigmoid polyps and requires >90% NPV for adenomas <5 mm
  - "Resect and Discard" apples to < 5 mm polyps proximal to the sigmoid and requires > 90% concordance in recommended surveillance interval

Aim: Evaluate the performance of the first AI system capable of predicting polyp histology during real-time colonoscopy using standard-of-care, non-magnified white light images.

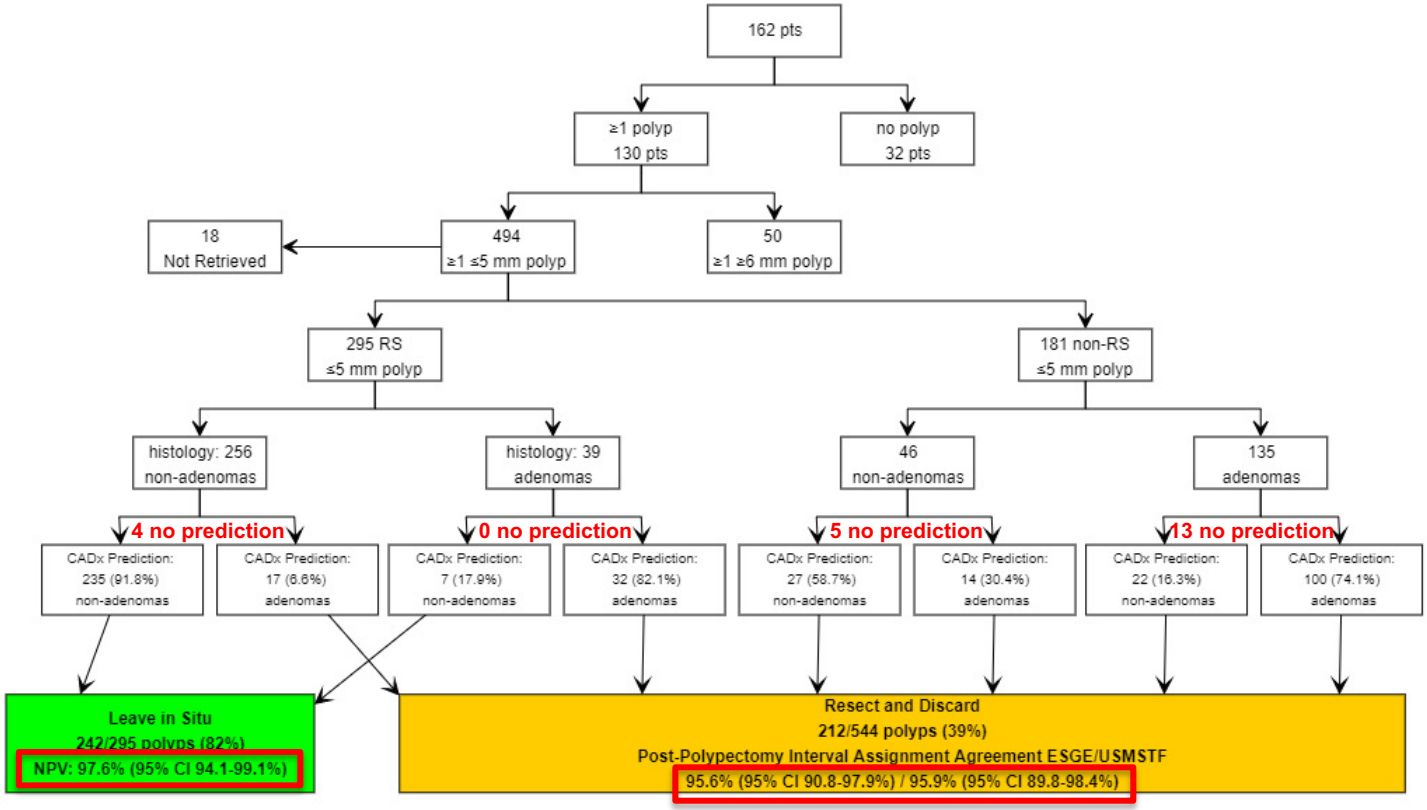
Methods

- Tool being tested: A regulatory approved deep learning (CADe-)CADx module designed to differentiate between adenoma and non-adenoma in unmagnified white-light colonoscopy
- Tool applied to consecutive patients undergoing colonoscopies in a single center participating in the nationwide colorectal cancer screening program
- For each polyp, CADx-output is compared to gold-standard represented by histology
- Measured Outcomes:
    - Negative Predictive Value (NPV) for adenomatous histology for ≤5 mm rectosigmoid lesions by CADx and AI-assisted endoscopist
    - Agreement between CADx- and histology-based post-polypectomy surveillance intervals according to European and American guidelines.

Real-time Readout



Results


162 pts
≥1 polyp
130 pts
no polyp
32 pts
18
Not Retrieved
494
≥1 ≤5 mm polyp
50
≥1 ≥6 mm polyp
295 RS
≤5 mm polyp
181 non-RS
≤5 mm polyp
histology: 256
non-adenomas
histology: 39
adenomas
46
non-adenomas
135
adenomas
4 no prediction
0 no prediction
5 no prediction
13 no prediction
CADx Prediction:
235 (91.8%)
non-adenomas
CADx Prediction:
17 (6.6%)
adenomas
CADx Prediction:
7 (17.9%)
non-adenomas
CADx Prediction:
32 (82.1%)
adenomas
CADx Prediction:
27 (58.7%)
non-adenomas
CADx Prediction:
14 (30.4%)
adenomas
CADx Prediction:
22 (16.3%)
non-adenomas
CADx Prediction:
100 (74.1%)
adenomas
Leave in Situ
242/295 polyps (82%)
NPV: 97.6% (95% CI 94.1-99.1%)
Resect and Discard
212/544 polyps (39%)
Post-Polypectomy Interval Assignment Agreement ESGE/USMSTF
95.6% (95% CI 90.8-97.9%) / 95.9% (95% CI 89.8-98.4%)

Conclusions

- First real-time clinical trial of CADx system that can predict polyp histology using standard-of-care, non-magnified white light images
- CADx exceeded thresholds for required for “Leave *in situ*” and “Resect and Discard”
- Potential huge savings in pathology costs

MULTI-MODAL BLOOD-BASED COLORECTAL CANCER SCREENING IS A VIABLE COLORECTAL CANCER SCREENING OPTION – A PROSPECTIVE STUDY

Paloma Peinado[2,3], Enrique Sanz-Garcia[2], Maria Castro-Henriques[6], Maria Teresa Curiel-Garcia[4], Susana Prados[8], Marcial Garcia-Morillo[2], Rafael Alvarez-Gallego[2,3], Yupeng He[1], William W. Young Greenwald[1], Iris Faull[1], Ariel Jaimovich[1], Victoria M. Raymond[1], Sven Duenwald[1], Darya Chudova[1], Amirali Talasaz[1], Jesus Rodriguez Pascual[5,3], CÉSAR GREGORIO MUÑOZ SÁNCHEZ-MIGUEL[2,3], Lisardo Ugidos[2,3], Enrique de la Fuente[8], Jordi Remon[6], Clara Montagut[6,7], Antonio Cubillo[2,3]

[1]Guardant Health Inc, Redwood City, California, United States; [2]HM Hospitales, Madrid, Spain; [3]Universidad CEU San Pablo, Madrid, Spain; [4]HM Hospitales, Santiago de Compostela, Spain; [5]HM Hospitales, Madrid, Móstoles, Spain; [6]HM Hospitales, Barcelona, Spain; [7]Hospital del Mar-IMIM, CIBERONC, Barcelona, Spain; [8]Department of Gastroenterology, Hospital HM Sanchinarro, Madrid, Spain;

Background and Aim

- Despite the availability of multiple colorectal cancer (CRC) screening options, about one-third of individuals are not up to date with CRC screening.
- A blood-based CRC screening test with optimized sensitivity and specificity may improve screening adherence.
- Retrospective studies of a multimodal blood-based test in individuals with early-stage CRC have yielded promising results
    - 500kb next-generation sequencing based panel and bioinformatic platform that incorporates cell-free DNA (cfDNA) methylation-based partitioning to identify cancer related genomic alterations and epigenomic modifications (methylation and modifications in chromatin state)
- No prospective studies have been completed

AIM: to evaluate the performance of this blood-based colorectal neoplasia test prospectively in individuals presenting for colonoscopy.

Methods

- Prospective observational study of patients (45 – 84 years of age) undergoing colonoscopy at one of four hospitals in Spain
- Whole blood was collected and shipped ambient to a central laboratory for analysis (Guardant Health Redwood City, CA, USA).
- Results were integrated to yield a binary “positive” or “negative” result and reported at 90% and 95% specificity. Primary analysis correlated the blood-based test results with colonoscopy findings: colorectal adenocarcinoma or non-advanced adenoma/negative colonoscopy.

Demographics

- 557 subjects, 52% female, median age 55
- Indication for colonoscopy:
  - Symptoms 49%
  - Average Risk Screening 33%
  - Positive stool-based test 6%
  - FHx CRC 11%
  - Other 1%
- 8 CRCs found (prevalence 2%)

Key Results

Specificity Cutoffs	Stage I	Stage II	Stage III	Stage IV	Overall (Sensitivity)
90%	1/1	3/3	2/2	2/2	8/8 (100%)
95%	1/1	2/3	2/2	2/2	7/8 (88%)

Conclusions

- Sensitivity and specificity of the blood-based test reaches clinically significant thresholds and is consistent with available stool-based non-invasive screening options.
- The reported performance, combined with a more acceptable mode of testing suggests that this blood-based test may be a viable CRC screening option.
- Awaiting results of performance in intended population (average risk screening)

Adenoma detection improves clinical outcomes across adherence scenarios for a CRC screening blood test meeting CMS performance targets: Results from the CRC-MAPS model

Lauren N. Carroll[1], Andrew Piscitello[2], Tarun Chandra[2], and Girish Putcha[1]
[1]Freenome Holdings, Inc. South San Francisco, CA.; [2]EmpiriOA, LLC. Long Grove, IL.

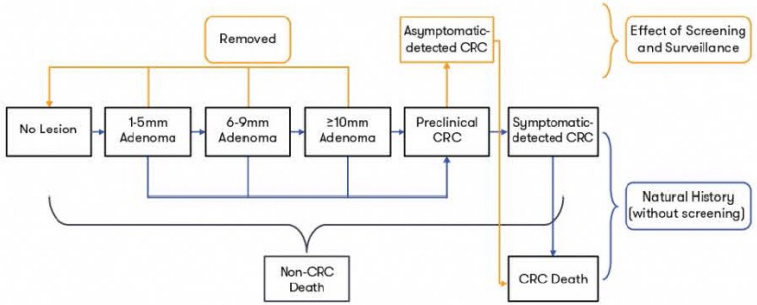
Background and Objective

- In 2021, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) establishing a specificity (~90%) and CRC sensitivity (~74%) required for coverage of an FDA-authorized, triennial, blood based colorectal cancer (CRC) screening test
- CMS did not specify any requirements for adenoma sensitivity

Objective: Examine the impact of different levels of adenoma sensitivity for a hypothetical triennial blood-based CRC screening test benchmarked to the CMS targets across adherence scenarios, screening stop ages, and test intervals

Methods

A semi-Markov microsimulation model of the CRC adenoma-carcinoma pathway was developed in TreeAge and calibrated to autopsy, SEER, and endoscopy data



The model demonstrated good internal validity

The model's cumulative lifetime natural history (no screening) and screening outcomes for a cohort of 65-year-olds free of diagnosed CRC were consistent with validated CISNET models

The model also reproduced mortality reduction (MR) estimates observed in the Minnesota FOBT trial, a randomized controlled trial from 1993 that can be used for external validation

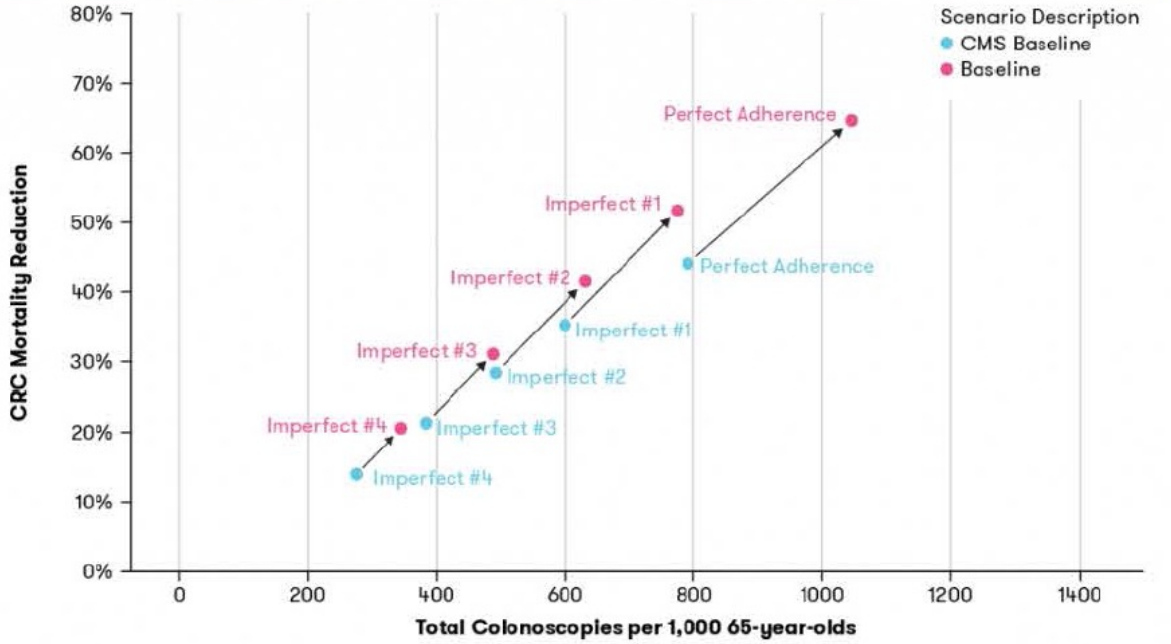
Modeling Scenarios

Table 1. Modeling scenarios

Input Parameters	Baseline	Adenoma
Performance		
Specificity[1]	90%	
Adenoma sensitivity	All-size: 1-Specificity = 10%	1-5mm: 15% 6-9mm: 20% ≥10mm: 30%
CRC sensitivity[1]	74%	
Screening interval[1]	Triennial	
Perfect adherence (initial screen participation, diagnostic, and surveillance colonoscopy)	100%	
Imperfect adherence		
Scenario #1:	100% screening, 80% diagnostic, 80% surveillance	
Scenario #2:	80% screening, 80% diagnostic, 80% surveillance	
Scenario #3:	60% screening, 80% diagnostic, 80% surveillance	
Scenario #4:	40% screening, 80% diagnostic, 80% surveillance	

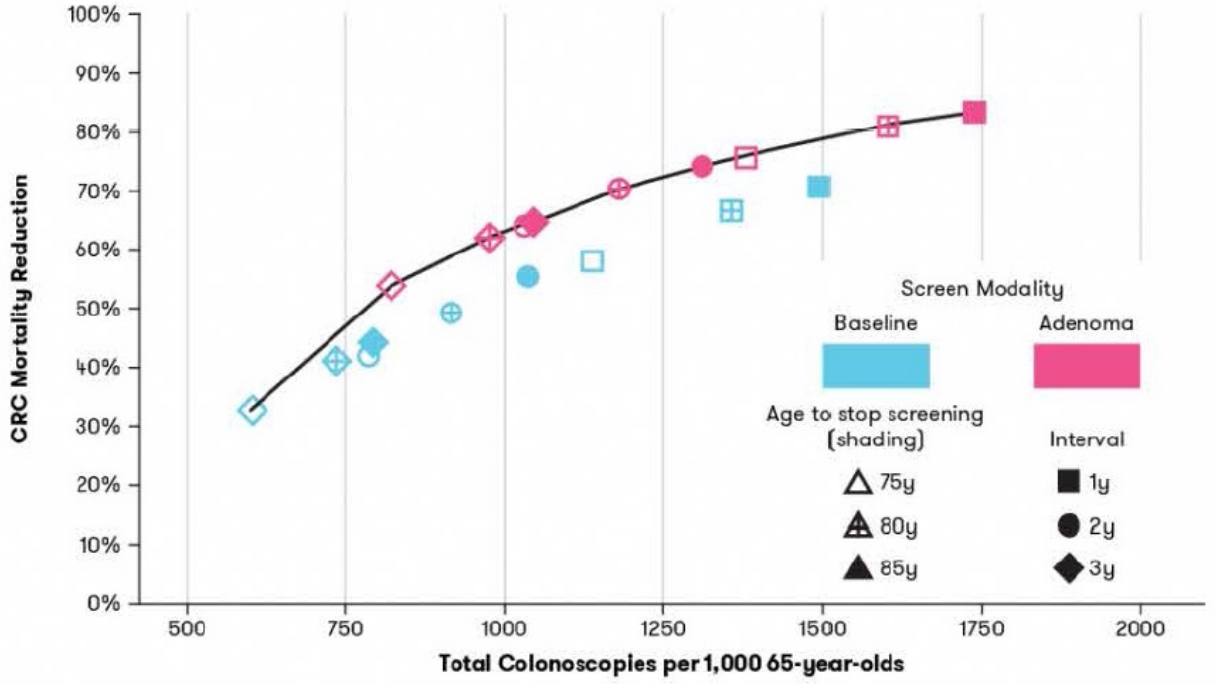
Results

Figure 4. Across adherence scenarios, a CRC screening test with increased adenoma sensitivity yields better outcomes than the CMS benchmark test



Results

Figure 5. All strategies for the CMS benchmark test with increased adenoma sensitivity dominated the CMS benchmark test



Conclusions

- This microsimulation study of hypothetical blood-based CRC screening tests benchmarked to CMS performance indicates that increasing adenoma sensitivity reduces CRC incidence and mortality reduction across all adherence scenarios, test intervals, and screening stop ages
- Higher adherence on clinical outcomes can be further improved by increasing adenoma sensitivity