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**Week 11: Non-Alcoholic Steatohepatitis: Disease Burden, Diagnosis, and Treatment**
Zobair M. Younossi, MD, MPH, FACP
*June 4, 2020 at Noon EDT*

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Henry P. Parkman, MD, FACP
*June 11, 2020 at Noon EDT*

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COVID-19: RESUMING ENDOSCOPY: UNANSWERED QUESTIONS AND ONGOING CONTROVERSIES
Current guidance and best practices for the difficult issues of reopening, including personal and environmental safety

MONDAY, JUNE 1st, 8 to 9:30 PM EDT
Introduction:
ACG President Mark B. Pochapin, MD, FACG

Hosted by:
ACG Trustee Costas H. Kefalas, MD, MMM, FACG
ACG Chair of the Board of Governors Neil H. Stollman, MD, FACG
ACG Endoscopy Resumption Task Force

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BOLSTERING RESILIENCY & WELL-BEING:
Strategies to Reactivate Your Staff & Your Practice During COVID-19

MONDAY, JUNE 8th, 8 to 9:30 pm EDT

Presenters
• Mark B. Pochapin, MD, FACG
• Renee L. Williams, MD, MHPE, FACG
• Cynthia M. Stonnington, MD
• Patrick E. Young, MD, FACG
• Dona E. Locke, PhD
• Jonathan A. Leighton, MD, FACG

Moderator
• Caroll D. Koscheski, MD, FACG

Visit gi.org/ACGVGR to Register
Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.

How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR
ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2020 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2021 for this activity.

ACG will submit MOC points on the first of each month. Please allow 3-5 business days for your MOC credit to appear on your ABIM account.
MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement. THESE ANSWERS WILL BE REVIEWED.

Disclosures:

Moderator:
Brooks D. Cash, MD, FACG
Consultant: Allergan, QOL Medical, Salix, Takeda
Speakers Bureau: Allergan, QOL Medical, Salix, Takeda

Speaker:
Renee Williams, MD, MHPE, FACG
Stockholder: Boston Scientific Corporation

Off Label Use:
None
Colorectal Cancer Screening in a Post-COVID World

Renee Williams, MD, MHPE, FACP
Associate Professor of Medicine
Program Director, Gastroenterology Fellowship
NYU Grossman School of Medicine

Outline

• Review current screening guidelines
• Screening during a pandemic
• Review non-invasive screening options
• Future considerations

American College of Physicians Clinical Guideline

- Average risk individuals between the ages of 50-75
- High sensitivity FOBT or FIT (yearly)
- Sigmoidoscopy (q5 years)
- Combined sigmoidoscopy (q5 years) plus HS FOBT/FIT (q3 years)
- Colonoscopy (q10 years)
There are numerous screening tests to detect early-stage colorectal cancer, including stool-based tests (gFOBT, FIT, and FIT-DNA), direct visualization tests (flexible sigmoidoscopy, alone or combined with FIT; colonoscopy; and CT colonography), and serology tests (SEPT9 DNA test). The USPSTF found no head-to-head studies demonstrating that any of these screening strategies are more effective than others, although they have varying levels of evidence supporting their effectiveness, as well as different strengths and limitations.
TABLE 1. American Cancer Society Guideline for CRC Screening, 2018

Recommendations

The ACS recommends that adults aged 45 y and older with an average risk5 of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on noncolonoscopy screening tests should be followed up with timely colonoscopy.

The recommendation to begin screening at age 45 y is a qualified recommendation.

The recommendation for regular screening in adults aged 50 y and older is a strong recommendation.

The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 y continue CRC screening through the age of 75 y (qualified recommendation).

The ACS recommends that clinicians individualize CRC screening decisions for individuals aged 76 through 85 y based on patient preferences, life expectancy, health status, and prior screening history (qualified recommendation).

The ACS recommends that clinicians discourage individuals over age 85 y from continuing CRC screening (qualified recommendation).

Options for CRC screening

Stool-based tests
- Fecal immunochemical test every y
- High-sensitivity, guaiac-based fecal occult blood test every y
- Multitarget stool DNA test every 3 y

Structural examinations
- Colonoscopy every 10 y
- CT colonography every 5 y
- Flexible sigmoidoscopy every 5 y

Conclusions:
The effect of screening with fecal occult blood testing on colorectal cancer mortality persists after 30 years but does not influence all-cause mortality. The sustained reduction in colorectal cancer mortality supports the effect of polypectomy.
Polypectomy and Long-Term Prevention of CRC Deaths

**Abstract**

**BACKGROUND**
In the National Polyp Study (NPS), colorectal cancer was prevented by colonoscopic removal of adenomatous polyps. We evaluated the long-term effect of colonoscopic polypectomy in a study on mortality from colorectal cancer.

**METHODS**
We included in this analysis all patients prospectively referred for initial colonoscopy (between 1980 and 1990) at NPS clinical centers who had polyps (adenomas and nonadenomas). The National Death Index was used to identify deaths and to determine the cause of death; follow-up time was as long as 25 years. Mortality from colorectal cancer among patients with adenomas removed was compared with the expected incidence-based mortality from colorectal cancer in the general population, as estimated from the Surveillance Epidemiology and End Results (SEER) Program, and with the observed mortality from colorectal cancer among patients with non-adenomatous polyps (internal control group).

**RESULTS**
Among 2962 patients who had adenomas removed during participation in the study, after a median of 15.8 years, 1246 patients had died from any cause and 12 had died from colorectal cancer. Given an estimated 25.4 expected deaths from colorectal cancer in the general population, the standardized incidence-based mortality ratio was 0.47 (95% confidence interval [CI] 0.32 to 0.68) with colonoscopic polypectomy; suggesting a 53% reduction in mortality. Mortality from colorectal cancer was similar among patients with adenomas and those with nonadenomatous polyps during the first 10 years after polypectomy (relative risk 1.2, 95% CI 0.9 to 1.6).

**CONCLUSIONS**
These findings support the hypothesis that colonoscopic removal of adenomatous polyps prevents death from colorectal cancer. (Funded by the National Cancer Institute and others.)

---

Professional Society Guidelines (COVID)

- **GI Multi-society Guidelines**
  - Recommend that elective procedures should be delayed
    - Screening and surveillance colonoscopy in asymptomatic patients
    - Screening and surveillance for upper GI diseases in asymptomatic patients

- **European Society for Gastrointestinal Endoscopy Guidelines (ESGE)**
  - Procedures that should be postponed
    - GI endoscopy units should strongly consider temporarily postponing elective, non-urgent endoscopy procedures
    - Screening in high risk patients for esophageal cancer, gastric cancer, colon cancer (primary screening endoscopy) or pancreatic cancer

Colorectal Cancer Stat Facts

<table>
<thead>
<tr>
<th>AGE, YEARS</th>
<th>COLORECTUM</th>
<th>PERCENT</th>
<th>COLON</th>
<th>PERCENT</th>
<th>RECTUM</th>
<th>PERCENT</th>
<th>DEATHS</th>
<th>COLORECTUM*</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 49</td>
<td>17,930</td>
<td>12%</td>
<td>11,540</td>
<td>11%</td>
<td>6,390</td>
<td>15%</td>
<td>3,640</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>50 to 64</td>
<td>50,010</td>
<td>34%</td>
<td>32,290</td>
<td>31%</td>
<td>17,720</td>
<td>41%</td>
<td>13,380</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>≥65</td>
<td>80,010</td>
<td>54%</td>
<td>60,780</td>
<td>58%</td>
<td>19,230</td>
<td>44%</td>
<td>36,180</td>
<td>68%</td>
<td></td>
</tr>
<tr>
<td>All ages</td>
<td>147,950</td>
<td>100%</td>
<td>104,610</td>
<td>100%</td>
<td>43,340</td>
<td>100%</td>
<td>53,200</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Note: Estimates are rounded to the nearest 10 and exclude in situ carcinoma.
*Deaths for colon and rectal cancers are combined because a large number of rectal cancer deaths are misclassified as colon.

CA Cancer J Clin (2020); 0: 1-20.

How coronavirus is impacting cancer services in the UK

How is this pandemic affecting those who are yet to be diagnosed?


Cancer Screening During Pandemic

- Many countries advocate for CRC screening
- Australia and the United Kingdom have shut down their screening programs
  - Estimated 2,200 missed cancer cases/week in UK
- Screenings have been deferred by millions worldwide
- Unknown timeline of pandemic
- Patients may be unwilling to undergo screening during and after?
Questions to Consider

- What are the potential consequences of no primary screening?
- Decreased mortality with implementation of screening programs
  - What effect will this have on mortality?
  - Australian National Bowel Cancer Screening program
    - Estimated 2,519 CRC deaths prevented annually
- Economic impact
  - Later stage diagnosis of CRC increases lifetime costs exponentially
  - Earlier diagnosis is cost-saving


Decrease or Absence of Primary CRC Screening

Unknown short term effects
- Most likely not significant

Potential long term effects
- Average and high risk patients
- Survival data?

Decrease or Absence of Primary CRC Screening

Diagnostic delay
- Early stage malignancies
- Advanced neoplasia

What is the burden?
- Cancer progression from delaying screening colonoscopies due to the pandemic

Resuming CRC Screening

High and Low Incidence States

- High
  - New York
  - New Jersey
  - Illinois
  - California
  - Massachusetts
  - Pennsylvania

- Low (<1000 cases)
  - Alaska
  - Montana
  - Hawaii
  - Wyoming
  - Vermont
Screening Colonoscopies

- Where do screening colonoscopies fit into the “new normal”?
  - First tier test in our guidelines
  - First choice for a significant portion of patients
- Risk of COVID-19
  - Joint society guidelines discuss generation of aerosols and droplets during endoscopy
- Should there be an emphasis on non-invasive testing?
  - ESGE recommends FIT test as first line

Resource Allocation

- Larger population with earlier screening age
- Case backlog
- Diminished capacity for endoscopy centers
  - Social distancing for patients
  - Decreased procedural numbers
  - Diagnostic procedures take precedence
Characteristics of a Good Screening Test

- Safe
- Precise
- Validated
- Offers risk stratification
- Good sensitivity and specificity

CT Colonography

- CT Colonography may be of limited use due to concern for COVID-19 transmission
  - Early guidance from radiology societies CTC was put on hold
  - Now recommends restarting on a local level at reduced capacity
- Estimated pooled sensitivity and specificity per patient for polyp detection in asymptomatic patients per one meta-analysis
  - 66.8% and 80.3%
- Accuracy to detect polyps in 1,177 patients by radiologists
  - 3.6% were average risk, 38.7% at elevated risk and 57.7% were FIT+
  - Sensitivity 86% and specificity 90% (polyps ≥6mm)
  - Sensitivity 91% and specificity 98% (polyps>10mm)

Guaiac Based Tests

- **gFOBT**
  - Detection of occult blood in stool
  - Relies on pseudoperoxidase activity of heme
  - Needed 3 separate samples due to low sensitivity
  - Results can be altered by certain foods and drugs
- **HS-gFOBT** (high-sensitivity)
  - Allows detection at lower peroxidase activity
  - Greater analytical sensitivity

*Gut 64.8 (2015): 1327-1337*

Fecal Immunochemical Test

- Immunoassay specific to human hemoglobin
  - Antibody-antigen complex formation
- No dietary restriction
- Qualitative FIT
  - Endpoint that is +/-
  - Each manufacturer sets their own endpoint
- Quantitative FIT
  - Measures the concentration of fecal heme
  - Low sensitivity for serrated lesions

*Gut 64.8 (2015): 1327-1337*

Comparison of 6 Qualitative FIT Tests

Table 2. Positivity Rates, Sensitivities, and Specificities of FOBTs

<table>
<thead>
<tr>
<th>Performance Characteristics</th>
<th>Immunochemical FOBT*</th>
<th>HemOccu/Gaslite-based FOBT*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bioclinica FOBplus</td>
<td>Bioclinica Hb Complex</td>
</tr>
<tr>
<td></td>
<td>Bioclinica FOBplus</td>
<td>PreventID CC</td>
</tr>
<tr>
<td></td>
<td>Bioclinica FOBplus</td>
<td>InnovCare-C</td>
</tr>
<tr>
<td></td>
<td>Bioclinica FOBplus</td>
<td>FOB advanced</td>
</tr>
<tr>
<td></td>
<td>Bioclinica FOBplus</td>
<td>QuickVue FOI</td>
</tr>
<tr>
<td>Overall positivity rate</td>
<td>210/1319</td>
<td>612/1319</td>
</tr>
<tr>
<td>Patients, n/m</td>
<td>286/1319</td>
<td>76/1319</td>
</tr>
<tr>
<td>Percentage (95% CI)</td>
<td>23.5 (21.2-25.9)</td>
<td>46.4 (43.7-49.1)</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>21.7 (19.5-24.6)</td>
<td>5.8 (4.6-7.2)</td>
</tr>
<tr>
<td>Patients, n/m</td>
<td>128/1319</td>
<td>10.5 (9.9-12.2)</td>
</tr>
<tr>
<td>Percentage (95% CI)</td>
<td>34.5 (31.9-37.1)</td>
<td>4.5 (4.4-5.8)</td>
</tr>
</tbody>
</table>

Specificity

- None or hyperplastic polyps

| Patients, n/m               | 127/1319             | 21/388                       |
| Percentage (95% CI)         | 88.1 (85.6-90.6)     | 45.2 (40.3-50.2)             |
| Sensitivity                 | 13.2 (10.0-16.5)     | 5.4 (4.8-6.2)                |

FOBT = fecal occult blood test.
* For manufacturer information, see the figures.
Effects may vary.
** Patients with a positive test are all patients.
*** Patients with a positive test are all patients with this finding.
**** Patients with a negative test on all patients with negative findings on colonoscopy.

Table 1. Overview of the 9 Qualitative FITs

<table>
<thead>
<tr>
<th>Quantitative FIT brand</th>
<th>Manufacturer</th>
<th>FSD (fecal mass/buffer volume)</th>
<th>Analytical instrument</th>
<th>Analytical range (µg Hb/g feces)</th>
<th>Preset threshold (µg Hb/g feces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory-based</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAREPrime Hb</td>
<td>Alfares Pharma, Osaka, Japan</td>
<td>Specimen collection container A (18 mg/1.9 mL)</td>
<td>CAREPrime</td>
<td>0.78-228.0</td>
<td>6.30</td>
</tr>
<tr>
<td>HB ELISA</td>
<td>Immunodiagnostics, Bensheim, Germany</td>
<td>IDK extract (15 mg/1.5 mL)</td>
<td>Dynex System X</td>
<td>0.08-50.0</td>
<td>2.00</td>
</tr>
<tr>
<td>OC Sensor</td>
<td>Eiken Chemical, Tokyo, Japan</td>
<td>OC auto-sampling bottle 3 (10 mg/2.0 mL)</td>
<td>OC Sensor X</td>
<td>10-200</td>
<td>10.00</td>
</tr>
<tr>
<td>RIDASCREEN Hb</td>
<td>R-Biopharm, Darmstadt, Germany</td>
<td>RIDA TUBE Hb (10 mg/2.5 mL)</td>
<td>Dynex System X</td>
<td>0.85-50.0</td>
<td>8.00</td>
</tr>
<tr>
<td>SENTFIT-FOBT Gold</td>
<td>Sentential Diagnostics, Milan, Italy</td>
<td>SENTFIT pieceTube (10 mg/1.7 mL)</td>
<td>SENTFIT 270 analyzer</td>
<td>1.70-129.86</td>
<td>17.00</td>
</tr>
<tr>
<td>Point of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eurolyser FOC test</td>
<td>Eurolyser Diagnostica, Salzburg, Austria</td>
<td>Eurolyser FOC sample collector (19.9 mg/1.6 mL)</td>
<td>Eurolyser CUBE</td>
<td>2.01-80.4</td>
<td>6.04</td>
</tr>
<tr>
<td>ImmOCARE-C</td>
<td>CARE Diagnostica, Voerde, Germany</td>
<td>Sample collection tube (30 mg/2.5 mL)</td>
<td>CAREcube</td>
<td>3.75-250.0</td>
<td>6.25</td>
</tr>
<tr>
<td>QuantiOn Hem</td>
<td>Immunodiagnostics, Bensheim, Germany</td>
<td>QuantiOn Hem TUBE (15 mg/1.5 mL)</td>
<td>Smartphone with ApisIOS</td>
<td>0.30-100.0</td>
<td>3.70</td>
</tr>
<tr>
<td>QuickRead go FOBT</td>
<td>Orion Diagnostics, Espoo, Finland</td>
<td>QuickRead FOC sampling set (10 mg/2.0 mL)</td>
<td>QuickRead go</td>
<td>15-200</td>
<td>15.00</td>
</tr>
</tbody>
</table>

App, mobile application software; FIT, fecal immunochemical test; FSD, fecal sampling device; Hb, hemoglobin; IOS, iPhone operating system.
* iPhone 6s was used for this study.
**Table 3.** Comparison of Sensitivity and Specificity of Quantitative FITs at Preset Thresholds and at a Uniform Threshold

<table>
<thead>
<tr>
<th>Quantitative FIT brand</th>
<th>Threshold (µg hgb/g feces)</th>
<th>Participants of screening colonoscopy (main study)</th>
<th>Clinical setting (auxiliary study)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CRC (n = 16)</td>
<td>AA (n = 200)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sensitivity [%] (95% CI)</td>
<td>Specificity [%] (95% CI)</td>
</tr>
<tr>
<td>Thresholds preset by the manufacturers</td>
<td></td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>Hb ELISA</td>
<td>2.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>QuantDX Hem</td>
<td>3.70</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>ImmoCARE C'</td>
<td>6.25</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>CAPEprime Hb</td>
<td>6.30</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>RIBOSCREEN Hb</td>
<td>8.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>Eurolyser FOI test</td>
<td>8.04</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>OC Sensor</td>
<td>10.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>QuickRead go FOBT</td>
<td>15.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>SENTRIT-FOX Gold</td>
<td>17.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>Thresholds adjusted to 15 µg Hgb/g feces</td>
<td></td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
<tr>
<td>RIBOSCREEN Hb</td>
<td>15.00</td>
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<td>ImmoCARE C'</td>
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<td>QuantDX Hem</td>
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<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
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<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
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<tr>
<td>OC Sensor</td>
<td>15.00</td>
<td>81.3 (94-99)</td>
<td>43.5 (37-51)</td>
</tr>
</tbody>
</table>

AA, advanced adenoma; AN, advanced neoplasia; CI, confidence interval; CRC, colorectal cancer; FIT, fecal immunochemical test; Hb, hemoglobin.

*Calculation is based on 199 AA and 215 AN.

**Difference in Performance of FIT Testing**

- Compared 2 quantitative FITs with the same cutoff concentration of fecal heme for identifying patients with CRC
  - 956,005 patients in Taiwanese screening program
- Cutoff for a positive finding was 20 ug hgb/g feces
- OC-sensor and HM Jack FIT tests
  - 80% sensitivity and PPV of 6.8% in OC-sensor
  - 68% sensitivity and PPV of 5.2% in HM Jack
Performance Characteristics of FIT

- 2019 systematic review and meta-analysis
- 120,255 patients and 18 FIT tests
- Threshold of 10ug/g for CRC
  - 91% sensitivity (95% CI, 0.84 to 0.95)
  - 90% specificity (95% CI, 0.81 to 0.95)
- Threshold of 20ug/g for CRC
  - 71% sensitivity (95% CI, 0.56 to 0.83)
  - 95% specificity (95% CI, 0.94 to 0.96)
- Low sensitivity for advanced adenomas regardless of threshold (<50%)

Patient Participation FIT vs FOBT

<table>
<thead>
<tr>
<th>Trial</th>
<th>FIT kit</th>
<th>FOBT kit</th>
<th>Country</th>
<th>Absolute difference in participation (FIT—FOBT %)</th>
<th>Number of collected samples</th>
<th>Dietary/medication restrictions?</th>
<th>Method of invitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cole* et al**</td>
<td>FlexSure OBT, InSure/Hemoccult Sensa</td>
<td></td>
<td>Australia</td>
<td>7.4% (FlexSure OBT), 16.2% (InSure)</td>
<td>FlexSure OBT (5), InSure (1)</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
</tr>
<tr>
<td>Federici et al**</td>
<td>DC-Hemoccult/ Hemo-Fec**</td>
<td></td>
<td>Italy</td>
<td>5.4%</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
<td>FOBT only</td>
</tr>
<tr>
<td>Van Rossum et al**</td>
<td>DC-Sensor/ Hemoccult 88</td>
<td></td>
<td>The Netherlands</td>
<td>12.7%</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
<td>FOBT only</td>
</tr>
<tr>
<td>Ho et al**</td>
<td>DC-Sensor/ Hemoccult</td>
<td></td>
<td>The Netherlands</td>
<td>12%</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
<td>FOBT only</td>
</tr>
<tr>
<td>Hoffman et al**</td>
<td>DC-Sensor/ Hemoccult</td>
<td>USA</td>
<td>10.9%</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
<td>FOBT only</td>
<td>Mailed invitation only</td>
</tr>
<tr>
<td>Lee et al**</td>
<td>DC-Sensor/ Hemoccult Sensa</td>
<td></td>
<td>Israel</td>
<td>-2.9%</td>
<td>FIT (1), FOBT (3)</td>
<td>FOBT only</td>
<td>FOBT only</td>
</tr>
</tbody>
</table>

*This study compared two FIT, FlexSure OBT and InSure, with a FOBT, Hemoccult Sensa.
**Hemoccult Co Ltd, Viro. Hawaii, Portland, Maine, USA.
**Significant difference.
**Biolan Chemical, Japan.
**Medische Diagnos GmbH, Germany.
FIT, fecal immunochemical test; FOBT, guaiac-based fecal occult blood test.
Patient Participation FIT vs FOBT

Uptake of fecal occult blood test (FOBT) and fecal immunochemical test (FIT) by sex, age and socioeconomic deprivation (with 95%CI). SIMD, Scottish Index of Multiple Deprivation.

Uptake = the percentage of participants with a final definitive screening test result out of those invited

Clark, Gavin, et al. Gut; 2020;0:1–8

Delaying Colonoscopies in FIT+ Patients

- Evaluated the prevalence of any CRC and advanced-stage CRC associated with delays in follow-up colonoscopies for patients with positive results from a FIT
- Participants were part of the Taiwanese nationwide screening program aged 50-69

Clinical Gastroenterology and Hepatology 17.7 (2019): 1332-1340.
Prevalence of CRC with Delays in FIT+ Colonoscopies

- Risks were significantly higher when colonoscopy was delayed >6 months
- >6 months
  - Any CRC (aOR, 1.31; 95% CI, 1.04–1.64; 68 cases per 1000 patients)
  - Advanced-stage disease (aOR, 2.09; 95% CI, 1.43–3.06; 24 cases per 1000 patients).
- >12 months
  - Any CRC (aOR, 2.17; 95% CI, 1.44–3.26; 98 cases per 1000 patients)
  - Advanced-stage disease (aOR, 2.84; 95% CI, 1.43–5.64; 31 cases per 1000 patients).
- 3-6 months
  - Any CRC (aOR, 0.98; 95% CI, 0.86–1.12; 49 cases per 1000 patients)
  - Advanced-stage disease (aOR, 0.95; 95% CI, 0.72–1.25; 10 cases per 1000 patients).

Fecal Testing with Limited Colonoscopy Capacity

- Used the validated MISCAN-Colon microsimulation model to estimate the number of colonoscopies, costs, and health effects of different screening strategies using guaiac FOBT or FIT
  - Hemoglobin cutoff levels between 50 and 200 ng hemoglobin per mL
  - Different surveillance strategies
  - Various age ranges
- Optimized the allocation of a limited number of colonoscopies on the basis of incremental cost-effectiveness
- Need to increase cutoff levels for FIT and narrow the age range to 50-75
  - More effective in terms of health outcomes and cost than gFOBT
Multitarget Stool DNA

- Molecular assay for aberrantly methylated
  - BMP<sub>3</sub> and NDRG<sub>4</sub> promoter regions
  - Mutant KRAS and β–actin
- Immunochemical assay for human hemoglobin
- Clinically validated in stool samples from 10,000 average risk individuals


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Multitarget Stool DNA Testing for Colorectal Cancer Screening

<table>
<thead>
<tr>
<th></th>
<th>Colonoscopy (N: 9989)</th>
<th>Multitarget DNA Test (N: 9989)</th>
<th>FIT (N: 9989)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>65</td>
<td>60</td>
<td>92.3 (83.0-97.5)</td>
</tr>
<tr>
<td>Stage I to III*</td>
<td>60</td>
<td>56</td>
<td>91.3 (83.8-98.2)</td>
</tr>
<tr>
<td>Colorectal cancer and high-grade dysplasia</td>
<td>104</td>
<td>87</td>
<td>81.7 (75.1-90.2)</td>
</tr>
<tr>
<td>Advanced precancerous lesions†</td>
<td>757</td>
<td>321</td>
<td>42.4 (38.9-46.0)</td>
</tr>
<tr>
<td>Nonadvanced adenoma</td>
<td>2850</td>
<td>498</td>
<td>17.2 (15.0-18.6)</td>
</tr>
<tr>
<td>All nonadvanced adenomas, non-epithelial findings, and negative results on colonoscopy</td>
<td>9167</td>
<td>1211</td>
<td>86.6 (85.9-87.2)</td>
</tr>
<tr>
<td>Negative results on colonoscopy</td>
<td>4417</td>
<td>455</td>
<td>89.8 (88.9-90.7)</td>
</tr>
</tbody>
</table>

* These stages of colorectal cancer, as defined by the system recommended by the American Joint Committee on Cancer, are associated with an increased rate of cure.
† Advanced precancerous lesions include advanced adenomas and sessile serrated polyps measuring 1 cm or more.

Mt-sDNA in an Average Risk Population

<table>
<thead>
<tr>
<th></th>
<th>MT-sDNA</th>
<th>FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>CRC</td>
<td>85.7%</td>
<td>100%</td>
</tr>
<tr>
<td>Advanced precancerous lesions</td>
<td>*35.3%</td>
<td>25.2%</td>
</tr>
<tr>
<td>Advanced adenoma</td>
<td>*39.1%</td>
<td>30.4%</td>
</tr>
<tr>
<td>Advanced serrated polyp</td>
<td>*22.2%</td>
<td>7.4%</td>
</tr>
<tr>
<td>High-grade dysplasia</td>
<td>22.7%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Controls, including non-neoplastic and non-advanced polyps</td>
<td>94.9%</td>
<td>94.9%</td>
</tr>
<tr>
<td>Negative Colonoscopy</td>
<td>97.2%</td>
<td>96.4%</td>
</tr>
</tbody>
</table>

- MT-sDNA results against FIT for detection of different lesions
- 1,047 stool samples tested with MT-sDNA

Colon Capsule Endoscopy

- Colonoscopy for positive CRC screening results are on hold
  - Timely diagnosis of CRC
  - Tumor location and histopathology
- Colon capsule can be done in the community
- Safe procedure with low rate of adverse events
- Has the potential to reduce colonoscopy demand
  - High demand due to backlog of cases
- One study reported a cost of $1,120

Colon Capsule & Detection of Colorectal Polyps

- Systematic review and meta-analysis on accuracy of first and second generation colon capsule
- 14 studies with 2420 patients → CCE-1 (1128) & CCE-2 (1292)
- Detection of polyps
  - CCE-2
    - 86% sensitivity and 88.1% specificity (≥6mm)
    - 87% sensitivity and 95.3% specificity (≥10mm)
    - Identified all invasive cancers detected by colonoscopy
  - CCE-1
    - 58% sensitivity and 85.7% specificity (≥6mm)
    - 54% sensitivity and 97.4% specificity (≥10mm)


Colon Capsule Endoscopy for Surveillance

- Investigated CCE as a possible filter in colonic surveillance
  - Primary outcome of reducing the number of colonoscopies
- 180 patients
  - 77 had no significant findings
  - 103 underwent endoscopy
  - 59 (57%) with no adenomas
- 43% reduction in colonoscopic surveillance

Looking into our Future....

Incidence and mortality

What happens if there's a second surge?

What are the consequences of not screening?

If we put off screening for a year, what are the long-term consequences?

Looking into our Future....

Now it's screening at age 45, implications of adding more patients?

Do we now rely more on noninvasive testing?

Do states with low COVID-19 infection ramp up screening programs?

Can we re-introduce screening without overloading the system?
There is a need for clear and thoughtful policies regarding restarting CRC screening programs and direction for prioritization of patients in need of subsequent colonoscopies


Thank you
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Questions?

Moderator:
Brooks D. Cash, MD, FACG

Speaker:
Renee Williams, MD, MHPE, FACG
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