Preliminary Results of a Study of Four Fecal Immunochemical Tests

Barcey Levy, MD, PhD[1]; Jeanette Daly, PhD[1]; Yinghui Xu, MS[1]; Seth Crockett, MD[2]; Richard Hoffman, MD[1] ; Navkiran Shokar, MA, MD, MPH[3]; Jeffrey Dawson, ScD[1]; Daniel Reuland, MD, MPH[2]; Marc Zuckerman, MD[3]; Avraham Levin, MD[1]

[1]University of Iowa, Department of Family Medicine, Iowa City, IA; [2]University of North Carolina, Chapel Hill, NC; [3]Texas Tech University Health Sciences Center, El Paso, TX

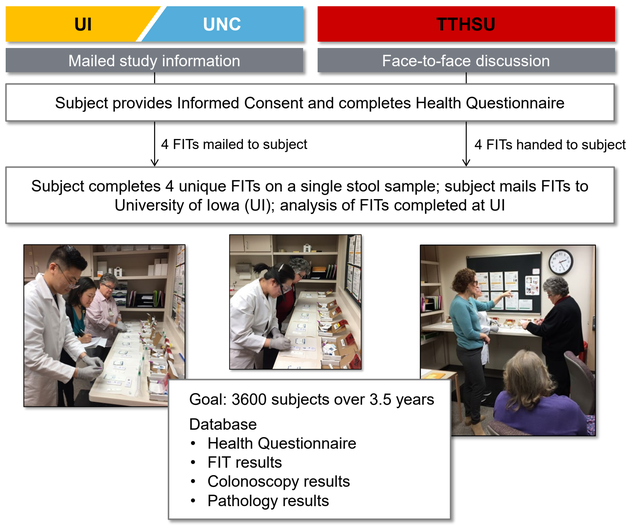
Introduction

- Colorectal cancer (CRC) is the 2nd leading cause of cancer death in the U.S.[1]
- CRC develops from adenomatous and other types of polyps.[2]
- As these polyps grow, they like most CRCs, tend to bleed, which is the rationale for the use of fecal occult blood tests (FOBT).[3]
- Fecal immunochemical tests (FITs) are a type of FOBT that can be a sensitive, specific, and low-cost alternative to colonoscopy for CRC screening.[3]
- FITs can be collected in the home, require no dietary or medication restrictions, and are often preferred by patients compared with colonoscopy.[4]
- Colonoscopy is very expensive screening, has potential complications, and requires time off work and a driver.[5]
- Modeling studies comparing a CRC screening strategy of annual FIT vs. colonoscopy every 10 years show no difference in life-years gained.[6]
- In order to reach the “80% by 2018” CRC screening goal set by several organizations, FITs will likely need to be used.
- There are about 16 unique FITs on the market in the U.S. (sold under 24 brand names), with minimal to no data on how well these work for detecting advanced colorectal neoplasia.[7]

Purpose

To compare the test characteristics of four of the most commonly used FITs for detecting advanced colorectal neoplasia in a head-to-head study, using colonoscopy as the gold standard.

Methods

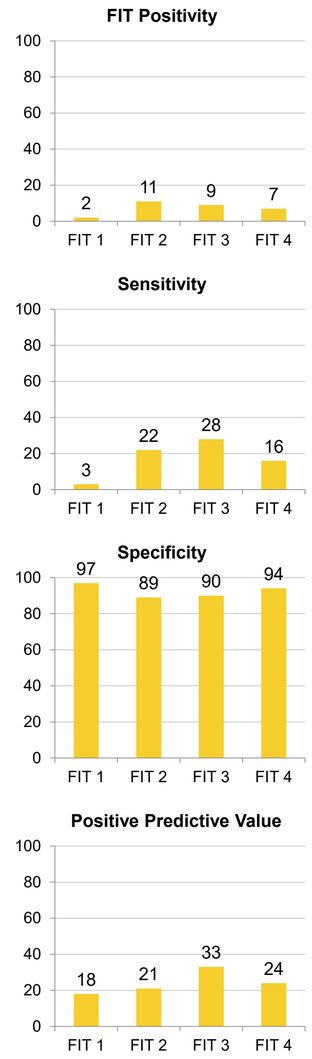


Results (n=641)

Participant Characteristics	n (%)
Age, mean (SD), y	61.2 (7.5)
Gender (Female)	400 (62.5)
Race	
White	594 (92.7)
Black	20 (3.1)
Asian	11 (1.7)
Latino	197 (31.0)
Education	
8th grade or less	71 (11.2)
High school	153 (24.0)
College or higher	413 (64.8)
Income	
< $40,000	251 (40.4)
$40,000 - < $80,000	140 (22.5)
≥ $80,000	230 (37.4)
Medications	
Daily aspirin	222 (35.1)
NSAID use > 3 times per week	55 (8.6)
Any blood thinner use	31 (4.8)
Colonoscopy type	
Screening	468 (73.0)
Surveillance	173 (27.0)

Colonoscopy Results	n (%)
Adenoma	
Tubular	267 (41.7)
Tubulovillous	8 (1.3)
Villous	1 (0.2)
Sessile serrated	33 (5.2)
Traditional serrated	1 (0.2)
Hyperplastic polyp	121 (18.9)
Colorectal cancer	5 (0.8)
Advanced adenoma or cancer	68 (14.8)

Test Characteristics (%)



Discussion

- There is little data on how well specific FITs work for detection of advanced colorectal neoplasia.
- Preliminary results have been presented on 4 FITs collected from a diverse sample of 641 subjects recruited from 3 academic health centers.
- FIT positivity, sensitivity, and PPV varied widely across the 4 FITs.
  - FIT positivity: 2 to 11%
  - Sensitivity: 3 to 28%
  - Positive predictive value: 18 to 33%
- Specificity was high at about 90%, regardless of FIT.

Strengths and Limitations

- This study will allow head-to-head comparisons across 4 of the most commonly used FITs.
- FITs are analyzed the day they are delivered by U.S. mail.
- We already have a fairly large, ethnically diverse sample.
- Our data will not provide information on how well these FITs work for population-based CRC screening where FIT is recommended every year to two years, depending on the country. However, programmatic sensitivity will always be higher than singe-sample sensitivity.

Conclusion

Preliminary data indicate that these four FIT products have significant variation in test characteristics, which if confirmed in a larger sample, has implications for CRC screening programs choosing and using FITs.

References

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