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Title

Comparative Performance of Five Single-Sample Fecal Immunochemical Tests for Detecting Colorectal Neoplasia

Priority 1 (Research Category)

Screening, prevention, and health promotion

Presenters

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Abstract

Context: Colorectal cancer (CRC) is the second leading cause of cancer death worldwide; it is largely preventable with appropriate screening. Fecal immunochemical tests (FIT) followed by colonoscopy, if positive, is a cost-effective option for CRC screening. There are limited data on the performance of various FITs for detecting advanced colorectal neoplasia (ACN). Objective: To compare the performance of five commonly used FITs for detecting ACN, using colonoscopy as the gold standard. Methods: Patients aged 50-85 years undergoing screening or surveillance colonoscopy were recruited from three academic medical centers in the United States. Each patient completed five FITs on a single stool sample prior to colonoscopy. FITs were analyzed according to manufacturer instructions and the subsequent colonoscopy and pathology reports were abstracted. ACN was defined as any advanced pre-cancerous lesion (adenomatous or sessile serrated polyps 10 mm or greater); villous, tubulovillous, or traditional serrated adenoma of any size, any lesion with high-grade dysplasia, or any stage adenocarcinoma. Based on histology, we calculated the test characteristics for each FIT for ACN. We used PROC GLIMMIX models in SAS to compare sensitivity and specificity across the different brands, accounting for within-patient correlation. Results: For the 3759 participants enrolled, the mean (SD) age was 62 (7.8) years, 63% were women, 86% white, and 29% Hispanic. Based on colonoscopy, 319 patients (8.5%) had ACN, including 9 participants (0.2%) with CRC and 310 (8.2%) with advanced adenomas. The positivity rates for each test were 4%, 13%, 16%, 11%, and 6%. The sensitivity for detecting ACN was 10%, 27%, 37%, 30%, and 19%; and the corresponding specificities were 97%, 89%, 85%, 91%, and 96%. Positive predictive values were 21%, 18%, 20%, 23%, and 29%; and the corresponding negative predictive values were 92%, 93%, 93%, 93%, and 93%. We found statistically significant differences in sensitivity (p<.0001) and specificity (p<.0001) across FITs. Conclusion: There were substantial variations in test performance among different FITs when used for single-sample stool testing. The ideal test for population-based screening should have a high sensitivity without a substantial loss of specificity and depends on

resources for colonoscopy. These differences could impact regulatory policy and FIT selection by healthcare providers.