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Diagnostic Yield of One-Time Colonoscopy vs One-Time Flexible Sigmoidoscopy vs Multiple Rounds of Mailed Fecal Immunohistochemical Tests in Colorectal Cancer Screening

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Abstract

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Background & Aims

We compared the diagnostic yields of colonoscopy, flexible sigmoidoscopy, and fecal immunochemical tests (FITs) in colorectal cancer (CRC) screening.

Methods

A total of 30,007 asymptomatic persons, 50–74 years old, were invited for CRC screening in the Netherlands. Participants were assigned to groups that received 4 rounds of FIT (mailed to 15,046 participants), once-only flexible sigmoidoscopy (n=8407), or once-only colonoscopy (n=6600). Patients with positive results from the FIT (≥10 μg Hb/g feces) were referred for colonoscopies. Patients who underwent flexible sigmoidoscopy were referred for colonoscopy if they had a polyp of ≥10 mm; adenoma with ≥25% villous histology or high-grade dysplasia; sessile serrated adenoma; ≥3 adenomas; ≥20 hyperplastic polyps; or invasive CRC.

The primary outcome was number of advanced neoplasias detected (diagnostic yield) by each test. Secondary outcomes were number of colonoscopies needed to detect advanced neoplasia and number of interval CRCs found during each primary screening test. Patients with interval CRCs (detected between a negative result from a screening colonoscopy and next scheduled colonoscopy) were found through linkage with Netherlands Cancer Registry. Advanced neoplasias were defined as CRC, adenomas ≥ 10 mm, adenomas with high-grade dysplasia, or adenomas with a villous component of at least 25%.

Results

The cumulative participation rate was significantly higher for FIT screening (77%) than for flexible sigmoidoscopy (31%; $P<.001$) or colonoscopy (24%; $P<.001$). The percentage of colonoscopies among invitees was higher for colonoscopy (24%) compared to FIT (13%; $P<.001$) or flexible sigmoidoscopy (3%; $P<.001$). In the intention to screen analysis, the cumulative diagnostic yield of advanced neoplasia was higher with FIT screening (4.5%; 95% CI 4.2–4.9) than with colonoscopy (2.2%; 95% CI, 1.8–2.6) or flexible sigmoidoscopy (2.3%; 95% CI, 2.0–2.7). In the as-screened analysis, the cumulative yield of advanced neoplasia was higher for endoscopic screening with colonoscopy (9.1%; 95% CI, 7.7–10.7) or flexible sigmoidoscopy (7.4%; 95% CI, 6.5–8.5) than with the FIT (6.1%; 95% CI, 5.7–6.6). All 3 screening strategies detected a similar proportion of patients with CRC. Follow-up times differed for each test (median 8.3 years for FIT and flexible sigmoidoscopy and 5.8 years for colonoscopy). Proportions of patients that developed interval CRC were 0.13% for persons with a negative result from the FIT, 0.09% for persons with a negative result from flexible sigmoidoscopy, and 0.01% for persons with a negative result from colonoscopy.

Conclusions

Mailed multiple-round FITs detect significantly more advanced neoplasias, on a population level, compared with once-only flexible sigmoidoscopy or colonoscopy screening. Significantly fewer colonoscopies are required by individuals screened by multiple FITs.

Key Words:
colon cancer, early detection, non-invasive, compliance

Abbreviations:
advanced neoplasia (AN), clinical record form (CRF), colorectal cancer (CRC), computed tomographic colonography (CTC), confidence interval (CI), diagnostic yield (DY), faecal immunochemical testing FIT (flexible sigmoidoscopy), FS (inter quartile range), IQR (number needed to invite, NNI)

Conflicts of interests: the authors disclose no conflict of interests

Author contributions: conceived idea for the study: M.C.W. Spaander and E.Dekker; E.J. Grobbee, M. van der Vlugt, M.C.W. Spaander and E.Dekker designed and conceptualized the study; Supervised execution of the study was done by M.C.W. Spaander, E. Dekker and E.J. Kuipers; Responsible for data entry was E.J. Grobbee and M. van der Vlugt; Analysis and interpretation of data was done by E.J. Grobbee, M. van der Vlugt, I. Lansdorp-Vogelaar and P.M.M. Bossuyt. E.J. Grobbee and M. van der Vlugt drafted the manuscript. M. van der Vlugt, I. Lansdorp-Vogelaar, P.M.M. Bossuyt, R.C. Mallant-Hent, A.K. Stroobants, E. Dekker, M.C.W. Spaander and E.J. Kuipers provided critical revision of the manuscript for important intellectual content.

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