Evidence Table

Clinical Area: Immunochemical FOBT

Study Type: Randomized controlled trial.

Outcomes
- **Primary**: Compliance with testing.
- **Secondary**: Prevalence of positive tests, proportion of adequate samples.

Design
- **Number of subjects**: N=130 GPs randomized; N=7320 patients: n=3604 guaiac FOBT (gFOBT), n=3716 immunochemical FOBT (iFOBT)
- **Description of study population**: Multicenter study in Italy. gFOBT group: 47% men; 44% age 50-59/ 39% age 60-69; 17% age 70+. iFOBT group: 46% men; 43% age 50-59/ 41% age 60-69; 16% age 70+.
- **Inclusion criteria**: Patients of participating GPs; age 50-74 years old.
- **Exclusion criteria**: None mentioned.
- **Intervention**: A coordinating center contacted patients by mail to pick up test at either their GPs office or a nearby hospital. All letters were signed by the GP. Patients picked up kits for either a gFOBT (Hemo-Fec) or iFOBT (OC-Hemodia). Patients in the gFOBT group were instructed to sample 3 different evacuations and to abstain from meat and anticoagulant drugs for 3 days prior to sampling. Patients in the iFOBT group were instructed to sample a single evacuation and abstain from anticoagulant use. Patients who tested positive were referred for a colonoscopy.
- **Source of outcome data**: FOBT results. All tests were analyzed at a single district GI center.

Validity
- **Blinding?** Assume that FOBT analysis was blinded.
- **Appropriate randomization procedures?** Yes, four-armed factorial design. Randomized providers to gFOBT or iFOBT groups. Then, randomized a sample of the provider’s patients to a GP or a hospital arm.
- **Appropriate comparison intervention?** Yes.
- **Treatment/control groups comparable at baseline?** Yes.
- **Other than intervention, was care/follow-up similar in each group?** Yes.
- **Sufficient statistical power?** Yes. Adequate power to detect an RR of 1.5 for type of test.
- **Intention to treat analysis?** Yes.
- **Industry funding?** None declared.
• **Conclusions regarding validity of methods:** Valid methods. Used a general population sample, and did not exclude individuals who were symptomatic.

**Results**

Primary outcome, GP and hospital groups combined\(^1\) No. (%)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Guaiac</th>
<th>Immunochemical</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests picked up</td>
<td>1236/3604 (34.2)</td>
<td>1422/3716 (38.3)</td>
<td></td>
</tr>
<tr>
<td>Tests returned</td>
<td>1096/3604 (30.4)</td>
<td>1341/3716 (36.1)</td>
<td>1.20 (1.02-1.44)</td>
</tr>
<tr>
<td>Of tests picked up</td>
<td>1096/1236 (88.7)</td>
<td>1341/1422 (94.3)</td>
<td>1.06 (1.02-1.10)</td>
</tr>
</tbody>
</table>

\(^1\)Calculations for the combined group were done by the reviewer.

**Secondary outcomes**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Guaiac</th>
<th>Immunochemical</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of positive tests</td>
<td>10.3%</td>
<td>6.3%</td>
<td>0.60 (0.43-0.84)</td>
</tr>
<tr>
<td>Proportion of inadequate samples</td>
<td>2.1%</td>
<td>1.1%</td>
<td>1.91 (0.80-4.71)</td>
</tr>
</tbody>
</table>

**Absolute difference and number needed to invite to screen (calculated by reviewer)**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Absolute difference in participation(^1)</th>
<th>Number needed to invite to screen to have one additional participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>iFOBT vs. gFOBT</td>
<td>5.7%</td>
<td>18</td>
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</tbody>
</table>

\(^1\)Participation is defined as picking up the test and returning the samples.

**Authors’ Conclusions**

“Compliance is more likely with the immunochemical than the guaiac test, independent of the provider. Guaiac tests show a higher variability of the results among centers…”

**Reviewer’s Conclusions**

In this cluster randomized trial conducted in Italy, the investigators found that patients who received a letter inviting them to conduct an immunochemical test were more likely to return samples than patients who received a letter inviting them to conduct a guaiac test (36.1% vs. 30.4%, absolute difference=5.7%). The guaiac test had dietary and medication restrictions, the immunochemical test only medication restrictions. The study used a general population screening sample with no exclusions e.g. for symptomatic individuals.