Evidence Table

Clinical Area: Immunochemical FOBT

Study Type: Non-randomized controlled trial.

Outcomes
- **Primary:** Not specified. Evaluated several outcomes including compliance with testing, number of inadequate tests and prevalence of positive tests.

Design
- **Number of subjects:** n=5929: n=2965 immunochemical-based tests (iFOBT); n=2964 guaiac-based tests (gFOBT).
- **Description of study population:** Conducted at the Seattle VA. Mean age=63 years; 86% White; 98% male.
- **Inclusion criteria:** Patients who received CRC testing; included both screening population and patients being evaluated for GI tract symptoms.
- **Exclusion criteria:** None reported.
- **Intervention:** Patients received screening with either), Hemoccult SENSA or immunochemical FOBT, FlexSure. All patients received manufacturers’ written instructions for conducting the tests. The gFOBT involved collecting two samples smeared on separate areas of the test card. The instructions for the iFOBT were more complex; patients were asked to collect two samples from separate areas and to smear them together on a small area of the test card. Patients who tested positive were referred for further evaluation.
- **Source of outcome data:** FOBT results.

Validity
- **Blinding?** Assume that FOBT analysis was blinded.
- **Method of assigning patients to intervention group?** The clinic is divided into two firms. One firm was arbitrarily chosen to use iFOBT and the other to use gFOBT.
- **Appropriate comparison intervention?** Yes.
- **Treatment/control groups comparable at baseline?** Similar on measured characteristics.
- **Sufficient statistical power?** Not reported.
- **Intention to treat analysis?** Appeared to be.
- **Industry funding?** None declared.
- **Conclusions regarding validity of methods:** Although group assignment was not random, there was a relatively large sample and patients in the two groups were similar on measured demographic characteristics. Used a general population sample, and did not exclude individuals who were symptomatic.
Results

Comparison of gFOBT and iFOBT, No. (%)

<table>
<thead>
<tr>
<th></th>
<th>iFOBT (n=2965 ordered)</th>
<th>gFOBT (n=2964 ordered)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests returned</td>
<td>1410 (48)</td>
<td>1396 (47)</td>
<td>0.26</td>
</tr>
<tr>
<td>Inadequate tests</td>
<td>136 (10)</td>
<td>77 (5)</td>
<td>0.001</td>
</tr>
<tr>
<td>Positive result</td>
<td>128 (9)</td>
<td>122 (9)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

Authors’ Conclusions

“Overall, immunochemical-based and guaiac-based fecal occult blood tests had comparable performance. However, although immunochemical-based testing is reported to be easier for patients than guaiac-based testing, we found that patients were no more likely to return cards for analysis…”

Reviewer’s Conclusions

The investigators did not find a significant difference between the proportion of tests returned for patients assigned to iFOBT (FlexSure) or gFOBT (Hemoccult SENSA). This lack of difference may be explained in part by the instructions patients received. Unlike other similar studies, the instructions for collecting samples did not appear to be simpler for the iFOBT tests. The authors did not discuss diet or medication restrictions. An advantage of the study was that it was conducted in Seattle and reflects local dietary habits. Disadvantages included that it was a VA sample that was 98% male, and it combined screening and symptomatic populations.