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**Evaluation of diagnostic accuracy of screening by fecal occult blood testing (FOBT). Comparison of FOB Gold and OC Sensor assays in a consecutive prospective screening series**

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**ABSTRACT**

We evaluated a new immunological fecal occult blood testing assay (FOB Gold, Sentinel = SENT) compared to the assay currently employed in the Florence screening program (OC-Hemodia, Eiken = OC). A total of 4,133 subjects were screened with both tests and underwent colonoscopy if positive (100 ng/mL Hb cutoff) to either test: 190 (4.59%) were positive (OC =140 (3.4%); SENT = 131 (3.2%)). The relative sensitivity for 7 cancers was 100% with OC and 67.9% with SENT, and for 48 high-risk adenomas (HRAs) it was 77.0% with OC and 66.6% with SENT. The positive predictive value (PPV) for cancer+HRA was 31.4% for OC and 28.2% for SENT and the specificity was 97.7 for both. The differences were not statistically significant. Adding SENT to OC increased the positivity rate by 32% and the cancer+HRA detection rate by 25%, and decreased the PPV by 10%. Both tests were performed on the same tubes in 1,601 cases, and in 18 of 47 cases they differed on different tubes but not on the same tube, suggesting inhomogeneous Hb content or varying fecal matrix influence in different samples. SENT has practical advantages for screening (fully automated, high output, requires no dedicated instrument), a comparable specificity and a lower sensitivity, though the latter difference may be partially ascribed to differences in sampling and not to the assay itself. Because of the statistical insignificance of the differences, further studies are needed for confirmation.

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