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Evaluation of an automated immunochemical fecal occult blood test for colorectal neoplasia detection in a Chinese population.

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BACKGROUND: Most commercial fecal occult blood tests (FOBT) used for colorectal carcinoma screening of Western populations are guaiac-based, manually developed, subjective, and sensitive to dietary components. Preliminary studies demonstrated the unsuitability of these tests for screening a Chinese population. The goal of the current study was to evaluate the performance characteristics of a human hemoglobin-specific automated immunochemical FOBT, the Magstream 1000/Hem SP (Fujirebio, Inc., Tokyo, Japan), in a Chinese population referred for colonoscopy. **METHODS:** Two hundred fifty consecutive patients who were referred for colonoscopy and met the study inclusion criteria provided samples for the immunochemical FOBT (without dietary restrictions) from two successive stool specimens. Tests were developed with an automated instrument that had an adjustable sensitivity threshold. The sensitivity, specificity, and positive predictive value for detecting colorectal adenomas and carcinomas were calculated according to the manufacturer's instructions over a range of sensitivity levels. **RESULTS:** At the optimal threshold level, the sensitivity, specificity, and positive predictive value for detection of significant colorectal neoplasia (adenomas \geq 1.0 cm and carcinomas) were 62%, 93%, and 44%, respectively. The test was easy to use, and results did not depend on operator experience. **CONCLUSIONS:** The automated immunochemical FOBT used in the current study was a robust, convenient, and useful tool for colorectal carcinoma screening in the study population. Copyright 2003 American Cancer Society. DOI 10.1002/cncr.11369

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