A COMPARATIVE STUDY OF

HEMOCCULT & HEMAPROMPT,

A SELF-DEVELOPING FECAL OCCULT BLOOD TEST.

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ABSTRACT

Objectives: This study compared a new, guaiac-based, self-developing, fecal occult blood test (HemaPrompt) with an established fecal occult blood test (Hemoccult). We also determined inter-observer variability in test interpretation.

Methods: Four physicians collected stool samples during rectal examination from 105 male and 95 female inpatient/outpatients at The Johns Hopkins Hospital. Three Hemoccult (HO) and two HemaPrompt (HP) cards were collected per patient, with one HO card (official HO card) being developed immediately for clinical/charting purposes. The other cards were developed by a single physician in a blinded fashion.

Results: The subsequently developed HO and HP cards disagreed with official HO result in 3.8% and 4.5% of card comparisons, respectively. The sensitivity and specificity of subsequently developed HO cards were 84% and 99%, respectively. The sensitivity and specificity of subsequently developed HP cards were 90% and 99%, respectively. Inter-observer variability was 2%.

Conclusions: HemaPrompt and Hemoccult cards are comparable tests of fecal occult blood. The self-developing quality of HemaPrompt is convenient and may facilitate patient self-testing and interpretation. Inter-observer variability in fecal occult blood testing is low and should not be a factor in evaluating the patient referred for heme positive stools.

MATERIALS AND METHODS

Four Physicians prospectively collected stool samples from 200 patients (105 males, 95 females) seen as inpatients who had a rectal examination performed and had stool in the rectal vault qualified for inclusion into the study. There were no exclusion criteria. Three Hemoccult (HO) and 2 HemaPrompt (HP) cards were collected per patient. Stool was applied to both windows on each card. One of the three HO cards was developed immediately by the physician who obtained the sample. This interpretation was used for clinical purposes (official HO result). The remaining four cards were coded and developed by one of us (sp). All cards from each day were batched and developed simultaneously. The cards were read 60 seconds after developer application. The card reader was blinded in two ways. First, the official Hemoccult result was not known to this person. Second, the cards were developed and read before the codes were recorded or any attempt was made to match cards with the same codes.

A positive result was a blue color that matched the hue of the positive control on the card. A negative result was recorded otherwise.

The relative test agreement of HP and HO was determined by comparing the remaining four cards (two HO and two HP) per patient to the official HO result. No disagreement was seen between the two windows in any card. Therefore, both windows were counted as a single observation. Sensitivity and specificity as test negatives/true negatives.

Inter-observer variation was calculated using only those patients who were not examined by the FOB test reader (sp). The result of each card (two per patient) was compared to the official HO result.

RESULTS

Twenty percent (40/200) of the patients were positive for FOB on the official Hemoccult card. Comparison between HO and HP cards is seen in table 1. Analysis of the test agreement with the official HO card show 3.8% disagreement in 400 HP card comparisons. Sensitivity and specificity of the subsequently developed HO cards were 84% and 99%, respectively. Sensitivity and Specificity of the HP cards were 90% and 97%, respectively. Inter-observer variation with the official HO card interpretation was 2% (disagreement in 4/198 card comparisons).

DISCUSSION

This study was undertaken for two reasons. First, the performance of a new, FDA-approved fecal occult blood (FOB) card called HemaPrompt was tested against an accepted card (Hemoccult). Second, inter-observer variability in FOB testing was evaluated. The latter issue is relevant because patient referrals are made between physicians for evaluation of "heme positive" stools. In our experience, a subsequent rectal exam is often negative for FOB. This discrepancy could result from interpretation variability. [1,2] Consequently, the consultant must judge whether to proceed with evaluation because of a history of FOB or make decisions based on his/her own examination.

While the performance of the HemaPrompt test in detecting specific gastrointestinal pathology was comparable (97% vs. 99%).To our knowledge, no prior studies have introduced a new fecal occult blood test by comparing it to an established test. Most recent studies [3,4] have compared tests in relation to the ability to detect gastrointestinal lesions. The alternative approach of comparing HemaPrompt to an established FOB test was utilized because it best answers questions of test performance and inter-observer variability. By extension, two tests, which perform comparably, should be equally efficacious in detecting occult gastrointestinal bleeding.

No particular pattern in the positive or negative discrepancies for either test was observed. Of note, our study had a high (20%) fecal occult blood positive rate compared to other recent investigation [5,6] (range 4.4%-11.8%). These studies were screening programs for FOB, while our patients were referred for suspected gastrointestinal disease.

To our knowledge, this investigation is the first to analyze inter-observer variability in fecal occult blood testing. If FOB testing results are not reproducible between physicians, the validity of this diagnostic approach can be questioned. Our results reveal about 2% inter-observer variability between gastroenterologists. Thus, the common approach of using any reported FOB positive test as the basis to initiate work-up for gastrointestinal pathology seems appropriate.

Although many FOB tests are available, HemaPrompt offers several potential advantages. First, it is comparably priced to other guaiac-based cards. Second, the developer is readily available. Third, the up card standardizes the amount of developer applied per test and removes user variation in developer application. Finally, the HP card may be more applicable to outpatient colorectal cancer screening is to provide patients with FOB cards, have the patient apply stool from several days to the window(s), and mail the cards to the physician for development. Patient compliance with this approach is often poor (34.6% in one study [8] and 46% in another). [9]

Furthermore, because of the time delay, mailed-in cards are often rehydrated before application of developer. In one large study, [10] card rehydration increased sensitivity by 11.4% but decreased specificity by 7.3%. The positive predictive value decreased from 5.6 to 2.2 percent. Consequently, card rehydration made screening more expensive since false positive patients underwent diagnostic test. While the use of HemaPrompt may not increase compliance, it could eliminate the need for rehydration of cars.

Although some authors [1,2] feel that experienced and formally instructed professionals should interpret FOB test, the current mood in health-care policy is increasing patient empowerment and responsibility for disease prevention and management. While validation of patient interpretation is essential, the design of the HP card could allow patient home use.

In conclusion, this study shows that the new, self-developing fecal occult blood test HemaPrompt is comparable to the established test Hemoccult. With attached developer and low cost per card, the HemaPrompt card is convenient and may allow patient home use and interpretation. This may alleviate problems with rehydration and low patient compliance by increasing patient involvement in their health maintenance.

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PARAMETER	HEMOCCULT (# CARDS) CARDS)	HEMAPROMPT (#
Disagreement with official Hemoccult	1.8% (15/400)	4.5% (18/400)
Sensitivity (test card positive/official HO positive)	84% (69/82)	90% (74/82)
Specificity (test card negative/official HO negative)	99% (316/318)	97% (308/318)