

OMEC COLORECTAL CANCER SCREENING COMMITTEE MEETING

Saturday, May 30, DDW Chicago, 2009

Presenter: P. Rozen

OMED 2009

1. Immunochemical FOBT stability
2. Comparison with HemoccultSENSA

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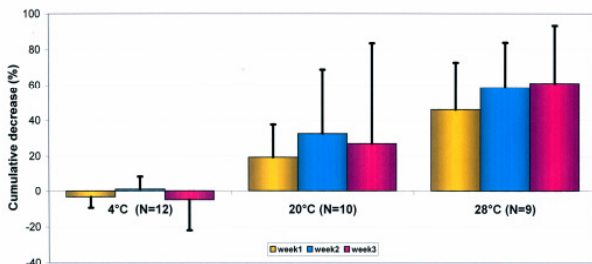
Rozen P et al. Med Sci Monitor 2006; 12: MT27-32

Rozen P et al. Aliment Pharmacol Ther 2009; 29: 450-7

OC-MICRO (I- FOBT) Reproducibility in Laboratory

5 prepared I-FOBTs quantified & each
examined 5 more times during 1 day,
showed no significant variations in
measurements, $F(5,20) = 0.24$, $P=0.66$.

OC-MICRO (I- FOBT) stability: in Laboratory



Changes at end of 1st, 2nd & 3rd week at 4°C, 20°C, or 28°C
Cumulative decay at 28°C was significant ($P<0.05$)

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OC-MICRO (I-FOBT) Stability: In Clinical Practice (N=1682)

I-FOBT positivity for each test prepared over range of thresholds; analyzed <3wks.
Cochran test for significance between tests

Threshold (ngHb/mL buffer)	1 st I-FOBT %	2 nd I-FOBT %	3 rd I-FOBT %	P
50 ngHb/mL	9.74	9.49	8.76	0.368
75 ngHb/mL	7.59	7.53	7.53	0.994
100 ngHb/mL	6.12	6.12	6.43	0.833
125 ngHb/mL	5.45	5.08	5.51	0.701
150 ngHb/mL	4.84	4.65	5.21	0.597
200 ngHb/mL	4.41	4.04	4.35	0.754

No decay of samples over time

No decay of samples having high levels of fecal Hb

HOS Comparison with Quantitative I-FOBT Background

Screening for **significant** neoplasms:
cancer (CRC), advanced adenomas (AAP),
aims for **maximal sensitivity** with **minimal**
unrewarding colonoscopies for positive tests.

Aims

1. Evaluate I-FOBT:
 - a) fecal Hb threshold to use for analysis
 - b) No. of tests neededfor **optimal** sensitivity & specificity
as compared to HOS.
2. Compare **relative efficiencies** of
I-FOBT & HOS for identifying patients
with significant neoplasms by
least No. of colonoscopy examinations
needed for positive tests.

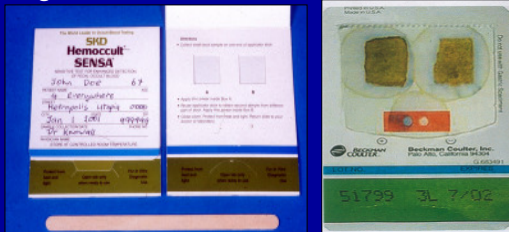
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Methods

Prospective cross-sectional study on 330 ambulatory **colonoscopy patients**, without rectal bleeding, some above average risk, having 3-day I-FOBTs & positive or negative annual HOS tests



Results: Colonoscopy

32 patients had significant neoplasms.

- CRC in 6 patients
- AAP in another 26

Results: FOBT

- HOS detected all 6 CRC & 11/26 AAPs
- I-FOBT detected all 6 CRC & 18/26 AAPs
 - by using highest result of 3 I-FOBTs examined at 50ngHb/mL of buffer threshold

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I-FOBT Comparison with HOS						
I-FOBT						
Threshold	1 st I-FOBT		1 st 2 I-FOBTs		All 3 I-FOBTs	
ngHb/mL	Sens.	Spec.	Sens.	Spec.	Sens.	Spec.
50	53.1	94.0	68.8	91.9	75.0*	86.9 [†]
75	50.0	95.6	59.4	94.3	68.8	90.6
100	46.9	97.3	56.3	96.0	68.8	93.3
HOS	Sensitivity		Specificity		I-FOBT vs. HOS	
	53.1*		59.4 [†]		*P=0.065 [†] P=<0.001	

Relating efficacy of G-FOBT to I-FOBT by No. colonoscopies/neoplasm for positive FOBT

- 3 x HOS had 53.1% sensitivity & required 8.1 colonoscopies.
- 1 I-FOBT at 50ng had 53.1% sensitivity & required 2.1 colonoscopies.

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- 2 I-FOBTs at 50ng had 68.8% sensitivity (29.5% more) & required 2.1 colonoscopies.
- 3 I-FOBTs at 50ng had 75.0% sensitivity (9.1% more) & required 2.6 colonoscopies.

Analysis of I-FOBT sensitivity by:

*No. tests collected

*development threshold

*No. colonoscopies/neoplasm for positive I-FOBT

Threshold ngHb/mL	1 I-FOBT		2 I-FOBTs		3 I-FOBTs	
	Sens.	No. colo.	Sens.	No. colo.	Sens	No. colo.
50	53.1	2.1	68.8*	2.1	75.0†	2.6
75	50.0	1.8	59.4	1.9	68.8	2.3
100	46.9*	1.5	56.3	1.7	68.8	1.9

*P<0.016, †P<0.01

Conclusions

- I-FOBT is more **specific** than HOS
- I-FOBT is more **sensitive** for **AAPs** than HOS
- 1 I-FOBT analyzed at 50ngHb/mL, has **sensitivity = 3 HOS**, which requires **4x** more colonoscopies /significant neoplasm.
- 1 I-FOBT, at 100ngHb/mL, is being used instead of **G-FOBT**:
 - would reduce colonoscopies from 8.1 to 1.5 /significant neoplasm
 - but, would be **less sensitive than HOS**

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2 or 3 I-FOBTs analyzed at 50ngHb/mL,
further **improves** sensitivity:

- 17 - 22% more than 1 test, with similar
No. colonoscopies /neoplasm
- 22-28% more than 1 I-FOBT, at
100ngHb/mL (P <0.01) . But would:
 - ❖ require compliance of screenee
 - ❖ require refrigeration of samples
 - ❖ increase costs
