

Prospective clinical study of circulating tumor cells for colorectal cancer screening.

Presented Saturday, January 20, 2018

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Abstract Disclosures

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Background:

Colorectal cancer (CRC) is among the most preventable cancers when precancerous lesions are detected at an early stage. Current screening methods for CRC require bowel prep or stool-based testing that are inconvenient, resulting in low compliance. Stool based tests have limited sensitivity for the detection of precancerous lesions. We have conducted a prospective clinical study over a period of > 3 years to assess a novel assay to detect and enumerate circulating tumor cells (CTCs) in a blood sample for early CRC detection.

Methods:

A single-center, IRB-approved, prospective and blinded clinical study was conducted in 620 subjects including 438 with adenoma, polyps or stage I-IV CRC and 182 healthy controls. For each subject, 2mL peripheral whole blood collected through a routine blood draw was processed using the CellMax biomimetic platform (CMx). The CMx test is a proprietary microfluidic biochip that minimizes non-specific binding and accurately enumerates CTCs. A multivariate analysis was performed to assess the clinical performance characteristics of the CMx test.

Results:

Disease status was evaluated by a standard clinical protocol which included colonoscopy and biopsy results. Probability of CRC risk was assessed by an age-adjusted regression model which correlated CTCs to clinical status. The CMx test's overall accuracy was 88% for all stages of colorectal illness, including precancerous lesions.

Conclusions:

The study has demonstrated high accuracy for the detection of CRC using a novel CTC assay. It is the first study to show high sensitivity in the detection of precancerous colorectal lesions. The simple blood draw required can be easily integrated into a patient's routine physical, increasing test compliance.

Subject (size)	Subgroup (size, percent)	Sensitivity (95% CI)	Specificity (95% CI)	AUC
All (620)	Healthy (182, 29%)	84.0 (80.3 - 87.2)	97.3 (93.7 - 98.8)	0.87
	Diseased (438, 71%)			
Diseased (438)	Precancerous lesions (111, 25%)	76.6 (67.9 - 83.5)	97.3 (93.7 - 98.8)	0.84
	Cancer (327, 75%)	86.9 (82.8 - 90.1)	97.3 (93.7 - 98.8)	0.88

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