

The Use of a New Stool Test M2-PK in the Diagnosis of Colorectal Cancer: A Case-Control Study

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Background. Fecal levels of tumor M2-PK, an isoform of a glycolytic enzyme pyruvate kinase (PK), are found to be significantly higher in patients with colorectal cancer than healthy subject (Koss et al. Colorectal Dis 2007). There is also evidence of suggest M2-PK is elevated in large polyps and correlated with tumor staging. Aim. This is a case-control study to evaluate the efficacy of M2-PK stool test in diagnosing colorectal cancer. Method. Patients diagnosed to have colorectal cancer (CRC) and asymptomatic (Control) subjects (1:2 ratio) were enrolled in this study. Single stool samples were collected prior to surgery for CRC or colonoscopy for controls and stored at -20°C. M2-PK stool test (Alere Inc, San Diego, USA) were performed in a blinded manner and correlated with diagnosis or colonoscopy findings. If M2-PK test result is positive but colonoscopy showed no abnormality in control subjects, M2-PK were repeated and gastroscopy plus colonoscopy were offered to detect gastrointestinal malignancy. Result. 70 CRC and 161 Controls were recruited in this interim analysis. The mean age (SD) and male gender (%) of the CRC and Control groups were 65.5 (10.7) years vs 58.2 (5.2) years respectively and 64.3% vs 47.2% respectively. The CRC staging of CRC are shown in Table 1. The sensitivity of M2-PK in detecting CRC is 78.6% (95%CI: 66.8-87.1%), specificity is 96.3% (95%CI: 91.7-98.5%), positive predictive value is 90.2% (95%CI: 79.1-95.9%) and negative predictive value is 91.2% (95%CI: 85.6-94.8%). The sensitivity of M2-PK stool test in detecting CRC in proximal colon is 64.3% (95%CI: 35.6-86%) and in distal colon is 82.1% (69.2-90.7%). Conclusion. M2-PK stool test is a promising test for detection of colorectal cancers. A population-based test is warranted.

Table 1. M2-PK Test Results according to CRC Staging

	No. of Patients	% of CRC	M2-PK Test Positive	Sensitivity (95% CI)
Stage 1	8	11.4%	4	50% (17.4-82.6%)
Stage 2	25	35.7%	22	88% (67.7-96.8%)
Stage 3	24	34.3%	19	79.2% (57.3-92.1%)
Stage 4	10	14.3%	8	80% (44.2-96.5%)
Staging Pending	3	4.3%	2	-
Total	70	100%	55	78.6% (66.8-87.1%)

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