


Diagnostic yield for advanced colorectal neoplasia using FIT with one or two samples.

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- Aim

- To assess the diagnostic yield for advanced colorectal neoplasia* using FIT with one sample (FIT1) v the highest concentration of two samples (FITmax) in symptomatic individuals.

* Advanced colorectal neoplasia (ACRN) includes colorectal cancer (CRC) and high risk adenoma (HRA). High risk adenoma include any advanced adenoma (i.e., lesions ≥ 10 mm in size or with a villous component or high grade dysplasia) or three or more non-advanced adenomas.




- Patients and Methods

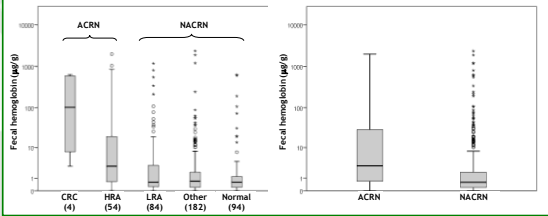
- The study involved 209 consecutive patients (117 women, mean age 60.7 years (range: 22-86)) who required colonoscopy for the investigation of gastrointestinal symptoms or for colonic polyp surveillance.

- Patients were asked to collect faecal samples from two consecutive bowel motions using the collection device provided by the manufacturer (Kyowa Medex Co., Ltd., Tokyo, Japan).

- Samples were analyzed using the fully automated analyzer - HM-JACKarc (Kyowa Medex Co., Ltd.).




- Results

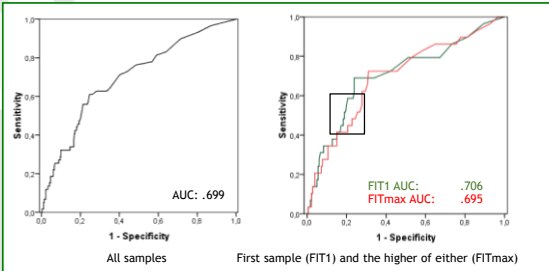


Faecal haemoglobin concentration in relation to colonoscopy findings


- Advanced colorectal neoplasia (ACRN) includes colorectal cancer (CRC) and high risk adenoma (HRA). High risk adenoma includes any advanced adenoma (i.e., lesions ≥ 10 mm in size or with villous component or high grade dysplasia) or three or more non-advanced adenomas.
- Low risk adenoma (LRA).
- Other findings includes individuals with inflammatory and hyperplastic polyps, inflammatory bowel disease and angiodysplasia.
- Normal includes individuals with minor findings (i.e., hemorrhoids and diverticulosis).
- Non-advanced colorectal neoplasia (NACRN) includes the remaining results not included in ACRN.



- Results




ROC curve (ACRN) of all samples and FIT1 v FITmax.



- Results

- FIT and FITmax diagnostic yield for ACRN at different faecal haemoglobin cut-off concentrations.

Cut-off	n° tests	Sensitivity	Specificity	PPV	NPV	Positivity	Detection rate	NNS	NNSC
10 µg/g	FIT	34.6%	87.2%	30.3%	89.2%	15.8%	4.8%	20.9	3.3
10 µg/g	FIT max	41.4%	79.4%	24.5%	89.4%	23.4%	5.7%	17.4	4.1
15 µg/g	FIT	34.6%	93.6%	37.0%	89.6%	12.9%	4.8%	20.9	2.7
15 µg/g	FIT max	41.4%	83.9%	29.3%	89.9%	19.6%	5.7%	17.4	3.4
20 µg/g	FIT	31.0%	92.8%	40.9%	89.3%	10.5%	4.3%	23.2	2.4
20 µg/g	FIT max	34.6%	85.6%	27.8%	89.0%	17.2%	4.8%	20.9	3.6
25 µg/g	FIT	31.0%	93.3%	42.9%	89.4%	10.0%	4.3%	23.2	2.3
25 µg/g	FIT max	34.6%	86.1%	28.6%	89.1%	16.7%	4.8%	20.9	3.5
30 µg/g	FIT	31.0%	93.3%	42.9%	89.4%	10.0%	4.3%	23.2	2.3
30 µg/g	FIT max	34.6%	86.1%	28.6%	89.1%	16.7%	4.8%	20.9	3.5
35 µg/g	FIT	31.0%	93.3%	42.9%	89.4%	10.0%	4.3%	23.2	2.3
35 µg/g	FIT max	34.6%	87.2%	30.3%	89.2%	15.8%	4.8%	20.9	3.3
40 µg/g	FIT	27.6%	93.9%	42.1%	88.9%	9.1%	3.8%	26.1	2.4
40 µg/g	FIT max	34.6%	88.3%	32.3%	88.3%	14.6%	4.8%	20.9	3.1
45 µg/g	FIT	24.1%	94.4%	41.2%	88.5%	8.1%	3.3%	29.8	2.4
45 µg/g	FIT max	34.6%	89.4%	34.6%	89.4%	13.9%	4.8%	20.9	2.9
50 µg/g	FIT	20.7%	94.4%	37.5%	88.1%	7.7%	2.9%	34.8	2.6
50 µg/g	FIT max	31.0%	89.4%	32.1%	89.0%	13.4%	4.3%	23.2	3.1



- Results

- FIT and FITmax diagnostic yield for ACRN at different faecal haemoglobin cut-off concentrations.

- At the same cut-off, two samples v one sample represents:
 - Sensitivity \blacktriangle 6.2% \pm 2.9
 - Specificity \blacktriangledown 6.4% \pm 1.0
 - PPV \blacktriangledown 10% \pm 3.7
 - NPV \blacklozenge 0.2% \pm 0.5
 - Positivity rate \blacktriangle 6.4% \pm 0.7
 - Detection rate \blacktriangle 0.9% \pm 0.4
 - Number needed to be screened \blacktriangledown 17.4% \pm 8.9
 - Number needed to be scoped \blacktriangle 25.4% \pm 7.6

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- Conclusions

- These results are consistent with previous studies*
- Using two samples increases the sensitivity and detection rate for ACRN, but increases the positivity rate and number of individuals needed to scope.
- One sample with a lower cut-off faecal haemoglobin equals or increases the performance of two samples with higher cut-off.
- There is evidence to support the use of one only sample for each individual in FIT-based CRC screening programmes.

* Cost-effectiveness of one versus two sample faecal immunochemical testing for colorectal cancer screening. Goede SL, van Roon AH, Reijnen JC, et al. Gut. 2013 May;62(5):727-34.
Diagnostic yield improves with collection of 2 samples in fecal immunochemical test screening without affecting attendance. van Roon AH, Wischnal JA, Hal L, et al. Clin Gastroenterol Hepatol. 2011 Apr;9(4):333-9
Fecal immunochemical test accuracy in average-risk colorectal cancer screening. Hernandez V, Cubiella J, Gonzalez-Mao MC, et al. World J Gastroenterol. 2014 Jan 28;20(4):1038-47.

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