**The Accuracy of Fecal Immunochemical Test in Colorectal Cancer Screening: A Meta-Analysis**

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**Abstract**

**Objective:** To investigate the accuracy of OC-Sensor and colorectal cancer screening in a population-based randomized controlled trial at Khon Kaen province, Thailand. **Methods:** The MOOSE Guidelines for Systematic Reviews and Meta-Analyses of Observational Studies was applied. Eligibility criteria were English language, hand searching was conducted using Medline databases from 2010 to 2021 for identify literatures reviews of OC-Sensor and colorectal cancer screening. The initial screen based on the research titles and abstracts, final screenings based on full-text reports. Synthesis the results with meta-analysis using fixed effect model, random effect model, determined statistically significant with p-value < 0.05. Confirmed the pooled effect sizes of high heterogeneity by meta-regression including tested precision of each estimates by bubble plot using STATA version 14. **Results:** Meta-regression showed sensitivity of OC-sensor = 72.54% (95% CI: 65.82-79.25), and specificity of OC-sensor = 89.59% (95% CI: 87.23-91.95). **Conclusions:** Sample size and cut-off of fecal hemoglobin concentration in each study were differed but sub-group analysis and sensitivity analysis were not considered for this analysis because population, setting and location for detected cancer of included study are not differences.

**Keywords:** FIT- advance neoplasia- colorectal cancer

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**Introduction**

In terms of measurements, accuracy is a set of the measurements to a specific value which low accuracy causes a difference between a result and a true value. As more than 80% of colorectal cancers arise from adenomatous polyps, screening for this cancer is effective not only for early detection but also for prevention. Diagnosis of cases of colorectal cancer through screening tends to occur 2-3 years before diagnosis of cases with symptoms (Cunningham et al., 2010). American Cancer Society (2018) recommended methods for colorectal cancer screening such as Flexible sigmoidoscopy, Colonoscopy, Double-contrast barium enema (DCBE), CT colonography (virtual colonoscopy), Guaiac-based fecal occult blood test (gFOBT), Stool DNA test including Fecal immunochemical test (FIT). Fecal immunochemical test or FIT for colorectal cancer screening were used to measure human hemoglobin in stool. However, most of FITs are qualitative tests can indicate when hemoglobin is detected in the sample that is higher than a specific reference standard. A few FITs are quantitative tests, the amount of hemoglobin is measured numerical and then reported as positive if greater than a reference count (Songster et al., 1980, Robertson et al., 2017) moreover, immunochemical tests are accurate and do not require dietary or medication changes before testing (Lee et al., 2014). However, the study of Silva-Illanes and Espinoza (2018) were conducted a systematic review to critical analysis of Markov models used for the economic evaluation of colorectal cancer screening, found that parameterization of adenoma dwell time, sojourn time, and surveillance differed between studies, and there was a lack of validation and statistical calibration against local epidemiological data. Colorectal cancer screening using FIT in a population-based randomized controlled trial at Khon Kaen province, Thailand, procedures for collecting FIT, all participants in study arm receive a sampling bottle and instructions for collecting a stool sample, and sending to the laboratory at hospital. The quantitative human hemoglobin content of each the collected stool specimens is measured in the laboratory using OC-Sensor (Sarakarn et al., 2017). The authors conducted a systematic reviews and meta-analysis to investigate the accuracy which refer to sensitivity and specificity of OC-Sensor and colorectal cancer screening (Table1)
Materials and Methods

Sources
The procedures followed the MOOSE Guidelines for Systematic Reviews and Meta-Analyses of Observational Studies. The eligibility criteria for the studies were English language, hand searching was conducted using the Medline databases, from 2010 to 2021 from wording “sensitivity” and or “specificity” “fecal immunochemical test” or FIT and colorectal cancer screening or “CRC” for identify literatures reviews of OC-Sensor and colorectal cancer screening. Colorectal cancer defined as advance neoplasia and colorectal cancer in adults. The selection of each study in the initials screening were based on the research titles and abstracts. Final screenings based on full-text reports excepted results from systematic reviews and meta-analysis double checked from abstracts.

Study Selection
The authors considered selected articles for investigate the accuracy of FIT such as cohort study, observation study including excluded results from systematic reviews and articles from meta-analysis. Each studies presents percentage and 95%CI of sensitivity and specificity of clinical testing for OC-Sensor and advance neoplasia or colorectal cancer. Assessment study quality and estimates precision of each study by considerate sample size and 95%CI in the studies including comparable characteristic of participants in each studies between FIT and colonoscopy.

Statistical analysis
The authors summarizing the effects size of sensitivity, specificity and confidence interval of each selected articles, synthesis the results with meta-analysis using fixed effect model, random effect model, by considered heterogeneity from Tau², Chi², I², and determined statistically significant with p-value < 0.05. However, the selected articles are not differences between population, setting and location for sub-group analysis, finally calculated standard error from 95%CI, and confirmed the pooled effect sizes of high heterogeneity by meta-regression including tested precision of each estimates by bubble plot using STATA program version 14.

Results
Meta regression is useful when there is substantial heterogeneity, a guide for the interpretation of the amount of heterogeneity is considered as I² from 0% to 40% might not be important, I² from 30% to 60% is represent moderate heterogeneity, I² from 50% to 90% is represent substantial heterogeneity, and I² from 75% to 100% considered as high heterogeneity (Higgins and Green, 2011). Result from meta-regression showed Knapp-Hartung modification I² = 96.80% for sensitivity of OC-sensor effect sized = 72.54 (95% CI: 65.82-79.25), and Knapp-Hartung modification I² = 99.10% for specificity of OC- sensor effect sized = 89.59% (95% CI: 87.23-91.95). The way to present the fitted model, sometimes refer to a bubble plot that is a graph for the fitted regression line together with circles representing the estimates from each study, sized according to the precision of each estimate (The Stata Journal Science Citation Index Expanded and CompuMath Citation Index, 2008). (Table 2, Table 3, Figure 1, Table 4, Table 5, Figure 2, Table 6, and Figure 3).

Discussion
This meta-regression showed high accuracy which is sensitivity and specificity of OC-Sensor for detecting fecal hemoglobin concentration and colorectal cancer screening. Interval FIT testing is capable of detecting neoplasia in the high-risk adult population undergoing colonoscopy.

Table 1. Quantitative FIT Brand for Using Colorectal Cancer Screening (Robertson et al., 2017)

| Authors           | Year | FIT brand     | FIT samples | Cut-off fHb (µg/g) | Reference standard |
|-------------------|------|---------------|-------------|------------------|-------------------|
| Nakama et al.     | 1999 | Monohaem      | 1           | 20               | Colonoscopy       |
| Morikawa et al.   | 2005 | Magstream     | 1           | 67               | Colonoscopy       |
| Hundt et al.      | 2009 | ImmoCARE-C    | 1           | 30               | Colonoscopy       |
| Haug et al        | 2010 | Ridascreen    | 1           | 14               | Colonoscopy       |
| Brenner and Tao   | 2013 | Ridascreen    | 1           | 24.5             | Colonoscopy       |
| Itoh              | 1996 | OC-Hemodia    | 1           | 10               | 2-year follow up  |
| Sohn et al.       | 2005 | OC-Hemodia    | 1           | 20               | Colonoscopy       |
| Nakazato et al.   | 2006 | OC-Hemodia    | 2           | 16               | Colonoscopy       |
| Levi et al.       | 2007 | OC-Micro      | 3           | 15               | Colonoscopy       |
| Park et al.       | 2010 | OC-Micro      | 1           | 20               | Colonoscopy       |
| Parra-Blanco et al.| 2010 | OC-Ligh      | 1           | 10               | 2-year follow up  |
| Chiang et al.     | 2011 | OC-Light      | 1           | 10               | Colonoscopy       |
| Levi et al.       | 2011 | OC-Micro      | 3           | 14               | 2-year follow up  |
| Brenner and Tao   | 2013 | OC-Sensor     | 1           | 6.1              | Colonoscopy       |
| Kapidzic et al.   | 2014 | OC-Sensor     | 1           | 10               | Colonoscopy       |
| Hernandez et al.  | 2014 | OC-Sensor     | 1           | 20               | Colonoscopy       |
| Imperiale et al.  | 2014 | OC-FIT CHEK   | 1           | 20               | Colonoscopy       |
surveillance and a first time FIT can detected significant neoplasia in 1.8% of subjects who were enrolled in a colonoscopy-based surveillance program for either a personal or family history of colonic neoplasia (Robertson et al., 2017, Bampton et al., 2005) including interval FIT in patients who had at least 2 prior colonoscopy

Table 3. Summarizing the Sensitivity and 95% CI of OC-Sensor and CRC Screening

| Model | Heterogeneity test | Sensitivity (%) | 95% CI (%) |
|-------|-------------------|----------------|------------|
| Fixed effect | 95.80% | 81.33 | 80.21-82.44 |
| Random effect weight with inverse variance | 319.48 | 95.80% | 71.94 | 65.69-78.19 |

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Figure 1. Forest Plot showed random effect of sensitivity, 95% CI of OC-sensor and CRC screening.

Figure 2. Forest Plot showed random effect of specificity, 95% CI of OC-sensor and CRC screening.
Table 4. Summarizing Specificity of OC-Sensor and CRC Screening

| No. | Authors | Years | Population | n   | Location | Cut-off fHb (µg/g) | Specificity (%) | 95% CI (%) |
|-----|---------|-------|------------|-----|----------|-------------------|----------------|-----------|
| 1   | Terhaar sive Droste | 2011 | Netherlands | 2,145 | CRC | $\geq 50$ | 86 | 85 - 88 |
| 2   | Terhaar sive Droste | 2011 | Netherlands | 2,145 | CRC | $\geq 75$ | 89 | 87 - 90 |
| 3   | Terhaar sive Droste | 2011 | Netherlands | 2,145 | CRC | $\geq 100$ | 90 | 88 - 91 |
| 4   | Gimeno-Garcia    | 2011 | Spain | 346 | AN | $\geq 50$ | 87 | 83 - 90 |
| 5   | Wijkerslooth et al. | 2012 | Netherlands | 1,256 | CRC | $\geq 50$ | 91 | 89 - 92 |
| 6   | Wijkerslooth et al. | 2012 | Netherlands | 1,256 | CRC | $\geq 75$ | 93 | 92 - 95 |
| 7   | Wijkerslooth et al. | 2012 | Netherlands | 1,256 | CRC | $\geq 100$ | 95 | 93 - 96 |
| 8   | Terhaar sive Droste | 2012 | Netherlands | 1,041 | CRC | 50 | 89 | 87 - 91 |
| 9   | Castro et al.    | 2013 | Spain | 595 | CRC | 50 | 92 | 89 - 94 |
| 10  | Castro et al.    | 2013 | Spain | 595 | CRC | 100 | 95 | 93 - 96 |
| 11  | Hernandez et al. | 2014 | Spain | 779 | CRC | 50 | 92 | 90 - 94 |
| 12  | Hernandez et al. | 2014 | Spain | 779 | CRC | 75 | 93 | 91 - 95 |
| 13  | Hernandez et al. | 2014 | Spain | 779 | CRC | 100 | 94 | 92 - 95 |
| 14  | Cubiella       | 2014 | Spain | 787 | AN | $\geq 20$ | 97 | 95 - 98 |
| 15  | Quintero et al. | 2014 | Spain | 638 | AN + CRC | $\geq 10$ | 91 | 88 - 93 |
| 16  | Rodriguez-Alonso | 2015 | Spain | 1,003 | CRC | $\geq 10$ | 80 | 77 - 82 |
| 17  | Rodriguez-Alonso | 2015 | Spain | 1,003 | CRC | $\geq 15$ | 83 | 81 - 85 |
| 18  | Rodriguez-Alonso | 2015 | Spain | 1,003 | CRC | $\geq 20$ | 86 | 83 - 88 |
| 19  | Otero-Estevez et al. | 2015 | Spain | 516 | AN | $\geq 100$ | 98 | 97 - 99 |
| 20  | Vleugels et al. | 2015 | Netherlands | 173 | AN | 20 | 93 | 88 - 97 |
| 21  | Aniwan et al. | 2017 | Thailand | 1,580 | CRC | 25 | 82 | 80 - 84 |
| 22  | Aniwan et al. | 2017 | Thailand | 1,580 | CRC | 50 | 89 | 87 - 90 |
| 23  | Aniwan et al. | 2017 | Thailand | 1,580 | CRC | 100 | 93 | 92 - 95 |
| 24  | Digby et al. | 2020 | Scotland | 593 | CRC+HRA | $<2$ LoD | 63 | 58-67 |
| 25  | Digby et al. | 2020 | Scotland | 593 | CRC+HRA | $<4$ LoQ | 76 | 72-79 |
| 26  | Digby et al. | 2020 | Scotland | 593 | CRC+HRA | $<10$ | 86 | 83-89 |
| 27  | Mattar et al. | 2020 | Brazil | 289 | CRC, FIT1 | 10 | 87 | 77-93 |
| 28  | Mattar et al. | 2020 | Brazil | 289 | CRC, FIT2 | 10 | 93 | 82-98 |
| 29  | Ykema et al. | 2020 | Netherlands | 73 | AN | 10 | 91 | 80-97 |
| 30  | Ykema et al. | 2020 | Netherlands | 73 | AN | 15 | 93 | 82-98 |
| 31  | Ykema et al. | 2020 | Netherlands | 73 | AN | 20 | 94 | 85-99 |
| 32  | Vieito et al. | 2021 | Spain | 38,675 | CRC, FIT1 | $\geq 10$ | 82 | 81-82 |
| 33  | Vieito et al. | 2021 | Spain | 38,675 | CRC, FIT2 | $\geq 20$ | 87 | 86-87 |
| 34  | Lu et al | 2021 | China | 3144 | CRC, FIT1 | 8 | 97 | 96.5-97.6 |
| 35  | Lu et al | 2021 | China | 3144 | CRC, FIT2 | 14.4 | 98 | 97.6-98.5 |
| 36  | Lu et al | 2021 | China | 3144 | CRC, FIT3 | 20.8 | 98 | 98-99 |

Table 5. Summarizing the Specificity and 95% CI of OC-Sensor and CRC Screening

| Model                                      | Heterogeneity test | Specificity (%) | 95% CI (%) |
|--------------------------------------------|--------------------|----------------|-----------|
| Fixed effect                               | $\tau^2$           | $I^2$          | Chi$^2$   |
| $-$                                        | 98.80%             | $p < 0.0001$   | 92.98     |
| Random effect weight with inverse variance | $38.54$            | 98.80%         | $p < 0.0001$ | 89.58     | 87.48-91.68 |

Examinations and with personal or family history of colonic neoplasia that detected 86% sensitivity and 63% sensitivity for advanced adenomas during follow-up evaluation (Robertson et al., 2017, Lane et al., 2010). In addition few data are available to guide the development of quality benchmarks for FIT processes given the similarities to FOBT-based programs, examining results from these programs may be informative (Robertson et al., 2017) and 29.8% of those eligible participated in screening, and when FOBT was positive, 74.6% proceeded to colonoscopy in 6 months (Rabeneck et al., 2014). Higher participation rates were reported from England.
Table 6. Meta-Regression of OC-Sensor and CRC Screening

| Accuracy                                      | I²  | Percentage | SE | 95%CI       |
|-----------------------------------------------|-----|------------|----|-------------|
| Heterogeneity with Knapp-Hartung modification | 96.80% | 72.54       | 3.32 | 65.82-79.25 |
| Over-all effect of sensitivity from 39 result |     | 99.10%     |     |             |
| Heterogeneity with Knapp-Hartung modification |     | 89.59       | 1.16 | 87.23-91.95 |
| Over-all effect of specificity from 36 result |     |             |     |             |

52% (Logan et al., 2012) and Finland 70% (Malila et al., 2008). The follow-up colonoscopy rate in Ontario also was lower than that reported in England 83% (Logan et al., 2012). Yen, et al., (2014) assessed how much of the variation in incidence of colorectal neoplasia is explained by baseline fecal hemoglobin concentration (FHbC) and also to assess the additional predictive value of conventional risk factors. The result showed the predictive model between FHbC and risk of developing colorectal neoplasia area under curve (AUC) = 83.5% (95% CI: 82.1%–84.9%). Liao Chao - Sheng, et al. (2013) evaluate fecal hemoglobin concentration, in the prediction of histological grade and risk of colorectal tumors. The results showed a significant log-linear relationship
between the concentration and positive predictive value of the FIT for predicting colorectal tumors (R^2 > 0.95, P < 0.001), and conclude that higher FIT concentrations are associated with more advanced histological grades. Risk prediction for colorectal neoplasia based on individual FIT concentrations is significant and may help to improve the performance of screening programs. Although this study found high accuracy which is sensitivity and specificity of OC-Sensor for detecting fecal hemoglobin concentration and colorectal cancer screening but The American Cancer Society (2018) described the benefit of FIT that no direct risk to the colon, no bowel prep, no pre-test diet changes, sampling done at home and fairly inexpensive but the limitation of FIT that can miss many polyps and some cancers, can produce false-positive test results, needs to be done every year including Colonoscopy will be needed if abnormal. However, in this trial participants who receive positive results are contacted by health officers, who work in their village, and are prepared for a confirmatory colonoscopy examination at a subsequent date. Participants who receive negative results will be examined for FIT every two years which is the optimal timing for a subsequent FIT (Sarakarn et al., 2017). The limitation of this meta-analysis found that although sample size and cut-off of fecal hemoglobin concentration of each study were differed but sub-group analysis and sensitivity analysis were not considered for this analysis because population, setting and location for detected cancer of included study are not differences.

Author Contribution Statement
None declared.

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Conflict of interest
The author declares that is no conflict of interest

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