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**CADTH RAPID RESPONSE REPORT:**
**SUMMARY WITH CRITICAL APPRAISAL**

# Fecal Occult Blood Testing in Acute Care Settings: A Review of Clinical Utility


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## Abbreviations

| | |
|---|---|
| GIB | gastrointestinal bleeding |
| FOBT | fecal occult blood testing |
| gFOBT | guaiac fecal occult blood testing |
| VTE | venous thromboembolism |

## Context and Policy Issues

Gastrointestinal bleeding (GIB) can be a substantial clinical and economic burden to the patient and the healthcare system.[1] GIB can be classified as obscure, occult, or overt.[2] Overt GIB presents with visible bleeding with bloody vomit or stool; occult GIB is not visible to the physician or the patient; and obscure GIB refers to recurrent bleeding after a negative initial evaluation using tests such as upper endoscopy, small bowel radiography, or colonoscopy.[2] Occult bleeding is often associated with a colorectal source.[2] Fecal occult blood test (FOBT) is a lab test used to check stool samples for occult blood and is often used to screen for colorectal cancer.[3] FOBT is indicated for use in the general population for colorectal cancer screening programs.[4] However, it is often not validated for use in the hospital setting.[4] Two hospitals in Canada and the United States have moved to disinvest in the use of FOBT in the non-screening acute care population in 2017 and 2018 respectively.[4,5] This review seeks to determine the updated clinical utility evidence since the 2017 CADTH Rapid Response Report[6] regarding fecal occult blood tests for the identification of gastrointestinal bleeding in acute care settings outside of screening for colorectal cancer.

## Research Question

What is the clinical utility of fecal occult blood tests for the identification of gastrointestinal bleeding in acute care settings outside of screening for colorectal cancer?

## Key Findings

One non-randomized study was identified regarding the clinical utility of fecal occult blood testing in acute care settings, outside of screening for colorectal cancer. Evidence of limited quality from the non-randomized retrospective chart review study suggested that there is a lack of evidence to support the clinical utility of guaiac fecal occult blood testing performed before initiating anticoagulation in patients with venous thromboembolism. The evidence presented in this report should be interpreted with caution based on the limitations and paucity of prospective comparative data for general patients in acute care settings outside of screening for colorectal cancer.

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including Ovid Medline All, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH

(Medical Subject Headings), and keywords. The main search concepts were fecal occult blood test, gastrointestinal bleeding, and acute care. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01, 2014 and August 07, 2019.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

## Table 1: Selection Criteria

| | |
|---|---|
| **Population** | Patient of all ages with suspected gastrointestinal bleeding in acute care settings, outside of screening for colorectal cancer |
| **Intervention** | Fecal occult blood test, including Guaiac Fecal Occult Blood Test (gFOBT) and Fecal Immunoassay Test (FIT) |
| **Comparator** | No testing |
| **Outcomes** | Clinical utility (e.g., time to diagnosis, diagnosis/misdiagnosis, subsequent testing such as endoscopy) |
| **Study Designs** | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized trials |

### Exclusion Criteria

Articles were not eligible for inclusion if they did not meet the selection criteria outlined in Table 1 or were published prior to 2017, as the previous CADTH report on the same topic was published in January 2017.[6]

### Critical Appraisal of Individual Studies

The included non-randomized study were critically appraised using the Downs and Black checklist.[7] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

## Summary of Evidence

### Quantity of Research Available

A total of 466 citations were identified in the literature search. Following screening of titles and abstracts, 465 citations were excluded and one potentially relevant report from the electronic search was retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full-text review. Of these potentially relevant articles, one publication was excluded due to intervention not meeting the inclusion criteria, and one non-randomized study met the inclusion criteria and was included in this report. Appendix 1 presents the PRISMA[8] flowchart of the study selection. Additional references of potential interest are provided in Appendix 5.

## Summary of Study Characteristics

Additional details regarding the characteristics of the included publication are provided in Appendix 2

### *Study Design*

The non-randomized retrospective chart review study included in this review was published in 2017.[9]

### *Country of Origin*

The non-randomized study included in this review was conducted in the United States.[9]

### *Patient Population*

The non-randomized study screened 718 patients and enrolled 422 patients 18 years old and older who were admitted to a hospital in Paoli, Pennsylvania between January 2010 and December 2012 with a new diagnosis of venous thromboembolism (VTE).[9] Of the 422 patients, 375 patients initiated anticoagulant therapy(enoxaparin, unfractionated heparin, or warfarin in combination with enoxaparin or unfractionated heparin) and were tested to determine whether they had GIB.[9] Of these 375 patients, the study participants were 56.8% females and 43.2% males.[9] The length of follow-up was not reported.[9] Patients were excluded if they had already received anticoagulation therapy, overt GIB, or other known risk factors that automatically excluded them from being considered for anticoagulation at admission.[9]

### *Interventions and Comparators*

In the non-randomized retrospective chart review of the utility of gFOBT to predict GIB, patients were analyzed by the group that had documented gFOBT or the group that had no documented gFOBT.[9]

### *Outcomes*

In the included study, the outcomes of interest were GIB events, and gFOBT sensitivity and specificity.[9] Other outcomes including negative and positive gFOBT tests, and relative risk, positive predictive value, and negative predictive value were also reported. [9]

## Summary of Critical Appraisal

The objectives of the included study, the characteristics of the patients included, and the interventions of interest were reported clearly.[9] The main outcomes to be measured and the main findings of the study were well reported.[9] The study evaluated outcomes with standard, widely used measures (e.g., GIB, sensitivity, specificity).[9] The authors declared that they had no potential conflict of interest and or financial relationships.[9]

In the included study, study sample size calculations were not performed a priori to determine the power of the study to detect significant differences in outcomes between the treatment arms.[9] It was unclear whether the participants in the included study were representative of the source population.[9] The baseline characteristics of patients with documented and no documented gFOBT were not reported, while the baseline charateristers were reported by the outcome groups of GIB and no GIB.[9] This and the lack of randomization may lead to selection bias.[9] There were no comparative statistically analyses between the GIB outcome and no GIB groups for some demographic features,

such as gender, age, race, diagnosis and social/past medical history.[9] The description of adverse effects or consequences that may have resulted from the intervention was not reported.[9] Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

### Summary of Findings

*Clinical Utility of Fecal Occult Blood Testing in Acute Care Settings*

One non-randomized study[9] provided evidence on the clinical utility of fecal occult blood testing in acute care settings, outside of screening for colorectal cancer. In the included study, the sensitivity and specificity of positive gFOBT pre-anticoagulation for predicting GIB were low at approximately 86% and 88%, respectively.[9] The positive predictive value of pre-anticoagulation gFOBT was low at 30.77% even though the relative risk of a GIB event with a positive gFOBT when initiating anticoagulation therapy was 31.54.[9] The negative predictive value of pre-anticoagulation gFOBT was reported to be 99.02%.[9] GIB was reported in 3.73% of patients with documented gFOBT, including 3.2% with positive gFOBT and 0.5% with negative gFOBT.[9] No patients had GIB among those with no documented gFOBT.[9]

Appendix 4 presents a table of the main study findings and authors' conclusions.

### Limitations

The non-randomized study was conducted in a single medical center in the United States.[9] It was unclear whether the participants from this medical center were representative of the general patients in acute care outside of the colorectal cancer screening program.[9] It is unknown if the results are generalizable to patients in Canada given the different demographics and health technology utilization There was a paucity of the comparative evidence regarding the clinical utility of FOBT versus no testing with respect to hospital length of stay, mortality, severity and location of bleeding, subsequent therapy by treatment group, or further testing.[9]

## Conclusions and Implications for Decision or Policy Making

One non-randomized study[9] was identified regarding the clinical utility of fecal occult blood testing in acute care settings, outside screening program for colorectal cancer. The study reported low sensitivity, specificity and positive predictive value of pre-anticoagulation gFOBT and the utility of checking for occult blood in the pre-anticoagulation VTE patient population remains uncertain.[9] The authors concluded that gFOBT should not be performed before initiating anticoagulation in patients newly diagnosed with VTE.[9] The evidence presented in this report should be interpreted with caution based on the limitations and paucity of comparative data. Specifically, there were limitations related to the quality of the included primary study.[9] Due to the limited number of studies and the retrospective nature of the data, the clinical utility of FOBT for patients in acute care with suspected GIB outside of the colorectal screening program remains uncertain.

## References


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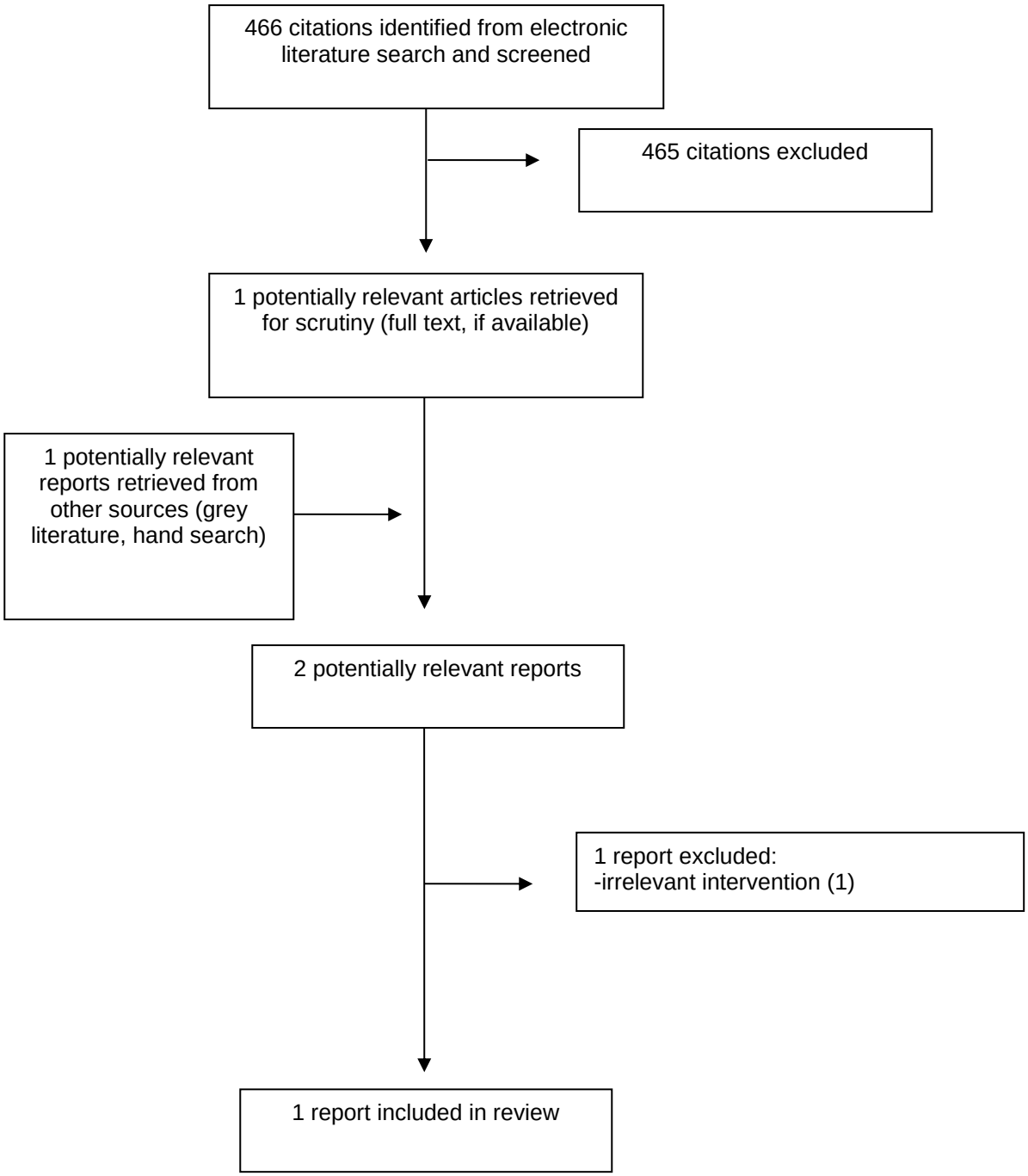
8. 8Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1-e34.
9. Urbas R, Badri M, Albert NE, Prince C, Mayilvaganan B. Utility of hemoccult testing before therapeutic anticoagulation in venous thromboembolism. *South Med J.* 2017;110(5):375-380.

## Appendix 1: Selection of Included Studies



# Appendix 2: Characteristics of Included Publications

## Table 2: Characteristics of Included Non-Randomized Clinical Study

| First Author, Publication Year, Country | Study Design | Population Characteristics | Intervention and Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|---|---|---|---|
| **Urbas, 2017**[9]<br><br>**United States** | Single center, retrospective chart review | Patients ≥18 years old who were admitted to the hospital with a new diagnosis of VTE<br><br>N = 422<br>n = 375 initiated anticoagulant therapy and statistically analyzed for gFOBT and GIB<br>n = 47 patients not statistically analyzed due to no initiation of anticoagulant therapy<br><br>Initiation of anticoagulant therapy (% out of N = 422):<br>Enoxaparin initiation 31.8%<br>Unfractionated heparin initiation 55.7%<br>Warfarin initiated concurrently with one of enoxaparin or unfractionated heparin in 1.2%<br>Not prescribed anticoagulation therapy 11.2%<br><br>Female 56.80%<br>Male 43.20% | Documented gFOBT versus no documented gFOBT | GIB, gFOBT sensitivity and specificity<br><br>Length of follow-up not reported |

GIB = gastrointestinal bleeding; gFOBT = guaiac fecal occult blood testing; VTE = venous thromboembolism

# Appendix 3: Critical Appraisal of Included Publications

## Table 3: Strengths and Limitations of Non-Randomized Clinical Study Using Downs and Black Checklist[7]

| Strengths | Limitations |
|---|---|
| Urbas, 2017[9] | |
| • The objective of the study, the characteristics of the patients included, the interventions of interest, main outcomes to be measured, and the main findings of the study were described clearly<br>• Study participants were recruited from the same population, using the same inclusion criteria, and over the same period<br>• The statistical analyses used to assess the main outcomes were appropriate<br>• The main findings were evaluated with standard widely used measures (e.g., GIB, sensitivity, specificity)<br>• The authors declared that they had no potential conflicts of interest and or financial relationship for the study | • There is a potential for selection bias because of no randomization<br>• There was no blinding of participants or investigators<br>• The baseline characteristics of patients with documented and no documented gFOBT were not reported. Baseline characteristics were reported by the outcome group patients with GIB outcome and patients no GIB.<br>• There were no comparative statistical analyses between the GIB outcome and no GIB groups in terms of some demographic features, such as gender, age, race, diagnosis and social/past medical history.<br>• It was unclear whether the participants were representative of the source population<br>• Sample size calculations were not performed a priori to determine the power of the study to detect significant differences in outcomes between the treatment arms<br>• A description of adverse effects or consequences that may resulted from the intervention was not reported |

GIB = gastrointestinal bleeding; gFOBT = guaiac fecal occult blood testing.

# Appendix 4: Main Study Findings and Authors' Conclusions

## Table 4: Summary of Findings of Included Non-Randomized Clinical Study

| Main Study Findings | Authors' Conclusion |
|---|---|
| Urbas, 2017[9] | |
| **Documented gFOBT (% out of n = 375):**<br>Documented gFOBT, n(%): 244(65.07):<br>• Negative gFOBT result, n(%): 205(84.02% out of 244)<br>• Positive gFOBT result, n(%): 39(15.98% out of 244)<br>No documented gFOBT, n(%):131 (34.93)<br><br>**GIB (% out of n = 375):**<br>Documented gFOBT with GIB, n(%): 14(3.73):<br>• Positive gFOBT, n(%): 12 (3.2)<br>• Negative gFOBT, n(%): 2(0.5)<br>No documented gFOBT with GIB, n(%): 0(0)<br><br>**Sensitivity of positive gFOBT pre-anticoagulation for predicting GIB**: 85.71%<br>**Specificity of positive gFOBT pre-anticoagulation for predicting GIB:** 88.26%<br>**Negative predictive value of pre-anticoagulation gFOBT:** 99.02%,<br>**Positive predictive value of pre-anticoagulation gFOBT:** 30.77%<br>**Relative risk of a GIB event with a positive gFOBT when initiating anticoagulation therapy**: 31.54 (95% confidence interval 7.34–135.44, P < 0.0001) | "gFOBT should not be performed before initiating anticoagulation in patients with VTE. The question remains, however, whether there is utility in further workup of the occult positivity (ie, endoscopic evaluation or whether prophylactic acid-suppressing medication should be used). Further prospective studies may determine any other utility of gFOBT in this setting, but it only appears marginally helpful and is unlikely to change patient management. A future study investigating its usefulness in morbidity and mortality may be beneficial." (p.379) |

GIB = gastrointestinal bleeding; gFOBT = guaiac fecal occult blood testing; VTE = venous thromboembolism

# Appendix 5: Additional References of Potential Interest

## Previous CADTH Reports

Occult blood detection testing for non-colorectal cancer related medical conditions: clinical effectiveness. *(CADTH rapid response report: reference list)*. Ottawa (ON): CADTH; 2019: https://www.cadth.ca/sites/default/files/pdf/htis/2019/RA1026%20Occult%20Blood%20Detection%20Testing%20Final.pdf. Accessed 2019 Sep 04.

Urgent, non-screening fecal occult blood testing for patients with suspected gastrointestinal bleeding: a review of clinical effectiveness and guidelines. *(CADTH rapid response report: summary with critical appraisal)*. Ottawa (ON): CADTH; 2017: https://www.cadth.ca/sites/default/files/pdf/htis/2017/RC0839%20FOBT%20in%20Hospitals%20Final.pdf. Accessed 2019 Sep 04.

## Non-Randomized Studies – Alternative Intervention

Gupta A, Tang Z, Agrawal D. Eliminating in-hospital fecal occult blood testing: our experience with disinvestment. *Am J Med.* 2018;131(7):760-763. PubMed: PM29601803