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Diagnostic Performance of Immunochemical versus Guaiac Fecal Occult Blood Tests in Symptomatic Cameroonian Patients Undergoing Colonoscopy: A Cross-Sectional Diagnostic Accuracy Study

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Abstract

Background: Fecal occult blood testing (FOBT) stands as a fundamental, non-invasive diagnostic tool for detecting subtle gastrointestinal bleeding, a common indicator of colorectal cancer (CRC). CRC remains the second leading cause of cancer-related mortality globally. In Cameroon, despite CRC being the second most common digestive cancer, a national screening strategy is yet to be established. Among the available FOBT methods, the traditional guaiac-based fecal occult blood test (gFOBT) and the immunochemical fecal occult blood test (iFOBT) are predominant, with iFOBTs generally demonstrating superior diagnostic performance. **Objective:** This study aimed to compare the diagnostic performance of Hemoccult® (gFOBT) and SD BIOLINE FOB® (iFOBT) for the detection of colorectal abnormalities, utilizing colonoscopy as the reference standard, in symptomatic adult patients referred for colonoscopy in healthcare facilities across Yaoundé and Douala, Cameroon.

Methods: A cross-sectional diagnostic accuracy study was conducted from November 2, 2021, to August 20, 2022, in four distinct health facilities. We enrolled adult patients, aged 21 years and older, presenting symptomatic indications for colonoscopy. Key diagnostic accuracy indicators—namely sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Youden's Index—were meticulously assessed for both index tests against the definitive colonoscopy results concerning colorectal abnormalities.

Results: Out of 323 initially screened patients, 108 met the inclusion criteria and were included in the final analysis. SD BIOLINE FOB® identified occult blood in 45.37% of cases, while

Hemoccult® yielded positive results in 31.48%. SD BIOLINE FOB® unequivocally demonstrated superior sensitivity (67.9%; 95% CI: 54.1–80.1%) compared to Hemoccult® (41.1%; 95% CI: 28.0–55.2%). Notably, both tests exhibited comparable specificity (78.8%; 95% CI: 66.0–88.7%). Furthermore, SD BIOLINE FOB® successfully identified a higher number of various colorectal abnormalities, including polyps and exophytic lesions. **Conclusion:** The SD BIOLINE FOB® test exhibited better diagnostic performance than Hemoccult® in detecting colorectal abnormalities within this symptomatic Cameroonian patient cohort. While these findings underscore its promising utility as a diagnostic aid in resource-limited contexts, its broader role in population-based CRC screening necessitates further rigorous evaluation in asymptomatic cohorts, given the inherent spectrum bias in our study design.

Keywords: Fecal occult blood test, Colorectal cancer, Diagnostic accuracy, Sensitivity, Specificity, Colonoscopy, Cameroon

Introduction

The fecal occult blood test (FOBT) is recognized as a non-invasive diagnostic tool designed to detect occult blood within stool samples. Typically, quantities exceeding 50 µg of hemoglobin per gram of stool, far above the normal physiological range of 2 to 3 µg/g in a healthy adult, can indicate various gastrointestinal conditions, both benign and malignant, including colonic neoplasms [1].

Colorectal cancer (CRC) constitutes a significant global health burden, ranking as the second leading cause of cancer-related mortality worldwide and accounting for approximately 12% of all cancer deaths, predominantly affecting individuals over 65 years of age. While the 5-year overall survival rate for all stages is estimated at 63% [2], early detection is crucial for improved outcomes. Consequently, numerous countries have implemented systematic screening programs, primarily relying on immunochemical fecal occult blood tests (iFOBT).

In Cameroon, CRC is the second most diagnosed digestive cancer [3]. Despite this prevalence, a structured national screening strategy has not yet been established. The primary diagnostic modalities for colorectal disease currently available include FOBT and lower digestive endoscopy (rectosigmoidoscopy or colonoscopy) [4]. A recent study by Jovanka et al., conducted in Cameroon, investigating the predictive value of an immunochemical fecal occult blood test (iFOBT) for colorectal cancer (CRC) diagnosis in symptomatic patients undergoing colonoscopy showed a good negative predictive value and a poor positive predictive value of this test for CRC diagnosis [5]. This highlights the local relevance and ongoing research interest in effective colorectal diagnostic tools. Building on this context, our study provides a direct head-to-head comparison of two fecal occult blood test (FOBT) methods, thereby offering valuable insights into their applicability within resource-limited settings.

FOBTs broadly fall into two main categories: guaiac-based tests (gFOBT) and immunochemical tests (iFOBT). Guaiac-based tests, though historically prevalent, exhibit limited sensitivity and are susceptible to dietary interferences. In contrast, iFOBTs detect human hemoglobin specifically using monoclonal antibodies. Since their introduction in 2008, iFOBTs have consistently demonstrated superior diagnostic performance, with studies reporting significantly higher detection rates for cancers and precancerous lesions compared to gFOBT in various populations [6,7].

Among the array of iFOBTs, SD BIOLINE FOB® (Abbott, formerly Standard Diagnostics, Korea), identified by product codes 25FK10 and 25FK12, is widely adopted in several

European public health campaigns. Its defining characteristics – simplicity, relatively low cost, and accessibility – position it as a promising option for integration into diagnostic algorithms within resource-limited countries.

Sub-Saharan Africa, and particularly its Black populations, exhibits a unique epidemiological profile for CRC, characterized by a younger age of onset; nearly 40% of cases are diagnosed before the age of 40, a trend documented in several regional studies [8,9]. This challenging situation is similarly observed in Cameroon [10], further compounded by the absence of an organized prevention program and restricted access to high-performance diagnostic tools like iFOBT.

With these various considerations in mind, we conducted a cross-sectional diagnostic accuracy study to compare the performance of two FOBT methods – the guaiac-based Hemoccult® test and the immunochemical SD BIOLINE FOB® test. Colonoscopy findings in symptomatic patients presenting at healthcare facilities in Yaoundé and Douala served as the reference standard. The goal was to generate evidence that can inform the development of effective and accessible diagnostic strategies for colorectal abnormalities within this region.

Methods

Study Design and Setting This investigation was designed as a cross-sectional analytical study to evaluate diagnostic accuracy. It was conducted in two major Cameroonian cities, Yaoundé and Douala, both of which possess relatively well-developed healthcare infrastructures, particularly in digestive endoscopy. The study involved endoscopy units from four institutions: Yaoundé General Hospital (a public tertiary hospital), La Cathédrale Medical Center, the Promoters of Good Health Center, and the Poitiers Polyclinic in Douala (the latter three being private facilities). At the time of the study, most public hospitals lacked endoscopy equipment, resulting in a predominance of patients being managed in private facilities. Data was collected from November 2, 2021, to August 20, 2022. This study was reported following the STARD (Standards for Reporting Diagnostic Accuracy Studies) guidelines.

Participants and Eligibility Criteria Participants were adults aged 21 years and older who had been referred for colonoscopy due to a range of symptomatic indications, including but not limited to abdominal pain, chronic constipation, altered general status, or unexplained anemia and who provided fully informed consent. The minimum age criterion of 21 years was chosen to ensure ethical consistency and homogeneity within the study population, aligning with the legal age of majority in Cameroon. This age selection also acknowledges the established observation of a younger onset of CRC in African populations. Exclusion criteria were strictly applied to patients exhibiting overt rectal bleeding or melena (defined as visually apparent blood in stool), those with a history of prior FOBT or colonoscopy within the preceding year, or individuals with incomplete data. To exclude potential interference with gFOBT results, patients who reported using non-steroidal anti-inflammatory drugs (NSAIDs) or anticoagulants within 72 hours of stool collection, or who had consumed red meat or vitamin C supplements within 48 hours, were also systematically excluded.

Variables Data were collected on various domains including sociodemographic characteristics (age, sex), clinical variables (specific indications for endoscopy), and paraclinical variables (results derived from fecal occult blood tests and comprehensive endoscopic examinations, histopathological results where biopsies were performed). The primary outcome measure was the detection of "colorectal abnormalities" via colonoscopy. This composite outcome encompassed a spectrum of conditions: polyps, diverticula, ulcers, exophytic lesions, ulcerated exophytic lesions, and hemorrhoidal protrusions. "Exophytic lesions" refer to abnormal tissue growths that protrude from a surface, potentially including adenomas or cancerous lesions.

"Ulcerated exophytic lesions" denote such growths when accompanied by associated ulceration.

Definition of Operational Terms:

- **Polyps:** Abnormal growths of tissue projecting from a mucous membrane.
- **Diverticula:** Small, bulging pouches or sacs that form in the lining of a hollow organ, most commonly the colon.
- **Sensitivity:** The probability that a test correctly identifies those with the disease (true positive rate).
- **Specificity:** The probability that a test correctly identifies those without the disease (true negative rate).
- **NPV (Negative Predictive Value):** The probability that individuals with a negative test result truly do not have the condition.
- **PPV (Positive Predictive Value):** The probability that individuals with a positive test result truly have the condition.

Study Procedures

1. **Pre-Analytical Phase (Training and Preparation):** Following the procurement of ethical and administrative authorizations, the principal investigator conducted comprehensive training sessions for all participating gastroenterologists and endoscopy unit nurses on the precise SD BIOLINE FOB® test procedure. Nurses received specialized instruction in standardized stool sample collection protocols, test preparation techniques, and accurate data recording practices, in strict adherence to the established study protocol. To ensure procedural fidelity, a pre-study test run was executed to verify comprehension and adherence to these standardized procedures by all personnel involved.
2. **Analytical Phase (Test Execution):** For each eligible patient, a single, fresh stool sample was meticulously collected prior to the administration of any bowel preparation for colonoscopy. From this single collected specimen, both the SD BIOLINE FOB® and Hemoccult® tests were performed concurrently by trained laboratory personnel, strictly following the respective manufacturer's guidelines.

- *SD BIOLINE FOB® Test:* This is a qualitative, rapid immunochemical test specifically designed to detect human hemoglobin in stool. The test was executed precisely according to the instructions provided by the manufacturer (Abbott, formerly Standard Diagnostics, Korea). Results were visually interpreted within the prescribed timeframe of 5 to 10 minutes.
- *Hemoccult® Test:* This guaiac-based test detects pseudo-peroxidase activity, indicative of heme, in stool. The test was performed following the manufacturer's specific recommendations (Beckman Coulter, USA). Results were visually interpreted after 2 minutes. To ensure utmost objectivity and minimize bias, personnel responsible for interpreting the FOBT results were rigorously blinded to the patient's clinical history and subsequent colonoscopy findings. Conversely, gastroenterologists conducting the colonoscopies were deliberately kept unaware of the FOBT results.

3. **Post-Analytical Phase (Result Interpretation):** Results for the SD BIOLINE FOB® test were interpreted based on the visual appearance of control and test lines on each cassette. A test was deemed valid if a line appeared under the "C" letter, and positive if an additional line appeared under the "T" letter. Invalid tests were promptly discarded and repeated if sufficient sample material remained available. All test outcomes were meticulously recorded on standardized collection forms.

Endoscopic Exploration and Histopathological Examination Colonoscopy procedures were conducted under sedation by experienced gastroenterologists utilizing advanced video endoscopes (Storz® and Fujinon® systems). Bowel preparation protocols involved a specific low-residue diet followed by the administration of an osmotic laxative, as per standard clinical guidelines. Any suspicious lesions identified during the endoscopic examination were promptly biopsied for subsequent histopathological analysis. Histopathological results, typically available within 10 days, served as the definitive reference standard for confirming the presence, nature, and clinical significance of all colorectal abnormalities.

Data Analysis All collected data were meticulously analyzed using CSPRO 7.2 software, complemented by R statistical software (version 4.2.2) for advanced diagnostic accuracy metrics and confidence interval calculations.

1. **Descriptive Analysis:** Qualitative variables were comprehensively described using frequencies and percentages. Quantitative variables were characterized by their means and standard deviations (SD).

2. **Diagnostic Accuracy Metrics:** Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Youden's Index were calculated for both index tests. For each metric, 95% Confidence Intervals (CIs) were robustly estimated using the exact binomial method. These metrics were derived from 2x2 contingency tables, systematically comparing each index test's result (positive/negative) against the definitive colonoscopy outcome (presence/absence of colorectal abnormalities).

    - *Sensitivity:* Represents the proportion of individuals with confirmed colorectal abnormalities who were correctly identified as positive by the test. Calculated as: True Positives (TP) / (TP + False Negatives (FN)).

    - *Specificity:* Denotes the proportion of individuals without colorectal abnormalities who were correctly identified as negative by the test. Calculated as: True Negatives (TN) / (TN + False Positives (FP)).

    - *Youden's Index (J):* Calculated as Sensitivity + Specificity - 1, this metric quantifies the overall diagnostic effectiveness of the test, ranging from 0 (no diagnostic value) to 1 (perfect diagnostic value).

    - *Negative predictive value:* probability of not having a colorectal abnormality when the test is negative.

    - *Positive predictive value:* probability of having a colorectal abnormality when the test is positive.

3. **Logistic Regression:** While univariate logistic regression was initially considered to explore potential associations between patient characteristics and test positivity, multivariate logistic regression analysis was not performed. This decision was primarily driven by the relatively small sample size and a limited number of actual colorectal cancer or advanced adenoma cases, which would likely have led to unstable and unreliable estimates. Comparisons of proportions between qualitative variables were thus predominantly presented descriptively, with the robust diagnostic accuracy metrics serving as the central statistical output.

Results

Throughout the specified study period, 323 patients slated for colonoscopy were identified across the participating study sites. From this initial pool, 215 patients were excluded for various defined reasons, including overt rectal bleeding (n=75), refusal to participate (n=60), incomplete data collection (n=40), recent use of medications known to interfere with gFOBT (n=20), or having undergone a prior colonoscopy within the preceding year (n=20). Consequently, a final cohort of 108 patients who impeccably met all stipulated inclusion criteria was retained for comprehensive analysis (Figure 1).

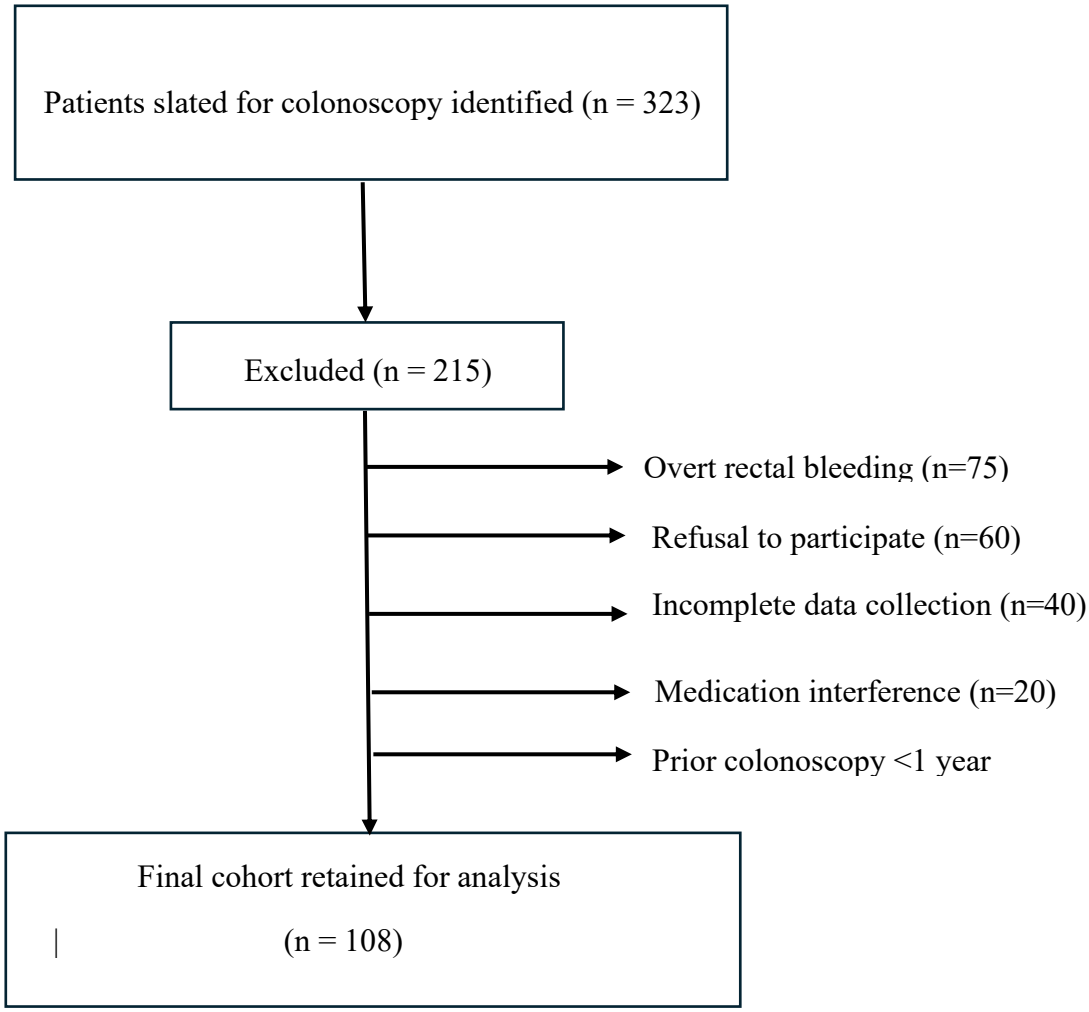


Figure 1: STARD Flow Diagram of Study Participants

Patient Characteristics The study population presented with a mean age of 48.49 ± 15.4 years. A notable demographic feature was the fact that 52.78% (57/108) of participants were under the age of 50. Gender distribution showed a clear male predominance, accounting for 67.59% (73/108) of the cohort. The most frequently cited indications for colonoscopy included abdominal pain (50.93%, 55/108), followed by altered general status (31.48%, 34/108), and chronic constipation (30.56%, 33/108).

Table I: Socio-demographic and Clinical Characteristics of the Study Population (n = 108)

Variable	Count (n)	Percentage (%)
Mean Age (SD)	48.49 ± 15.4	—
Gender		
Male	73	67.59
Female	35	32.41
Indications for Colonoscopy*		
Abdominal pain	55	50.93
Altered general status	34	31.48
Chronic constipation	33	30.56
Diarrhea	23	21.30
CRC screening	17	15.74
Abdominal mass	13	12.04
Unexplained anemia	11	10.19
Normal radiological picture	11	10.19
Monitoring after polypectomy	9	8.33
Follow-up for IBD	4	3.70

**Note: Patients may present with multiple indications, hence percentages do not sum to 100%. IBD: Inflammatory Bowel Disease.*

Colorectal Abnormalities and FOBT Positivity Of the 108 enrolled patients, 56 (51.85%) were found to have at least one colorectal abnormality identified by colonoscopy, with histopathological confirmation where biopsies were performed. The detailed distribution of these abnormalities and their respective associations with FOBT positivity are presented in

Table II. The SD BIOLINE FOB® test detected occult blood in 49 (45.37%) of the patients, while the Hemoccult® test yielded positive results in a smaller proportion, 34 (31.48%) patients.

Table II: Colorectal Abnormalities Detected by Colonoscopy and Corresponding FOBT Positivity

Colorectal Abnormality	Total Patients (n)	SD BIOLINE FOB® +	Hemoccult® +
Polyps	56	22	15
Hemorroidal protusions	18	13	15
Exophytics lesions	13	8	5
Diverticula	10	4	2
Other lesions	4	4	3
Ulcerated exophytic lesions	3	3	0
Ulcers	3	2	1

**Note: Individual patients may present with multiple abnormalities. Counts reflect the number of patients diagnosed with a specific abnormality who also tested positive for the respective FOBT.*

The SD BIOLINE FOB® method consistently demonstrated a higher number of positive detections across all categories of abnormalities compared to Hemoccult®. Specifically, it identified more cases of polyps (22 vs. 15), hemorrhoidal protrusions (13 vs. 5), and exophytic lesions (8 vs. 5). Furthermore, it uniquely detected 3 cases of ulcerated exophytic lesions, for which the guaiac test yielded no positive results.

Diagnostic Performance of FOBTs

The comprehensive diagnostic performance indicators for both tests are presented in Tables III and IV, offering a detailed comparison. For the Hemoccult® test, considering 56 patients with colorectal abnormalities (True Positives + False Negatives) and 52 patients without (False

Positives + True Negatives), the distribution was: 23 True Positives, 11 False Positives, 33 False Negatives, and 41 True Negatives. For the SD BIOLINE FOB® test, against the same reference standard of 56 patients with abnormalities and 52 without, the distribution was: 38 True Positives, 11 False Positives, 18 False Negatives, and 41 True Negatives.

Table III: Diagnostic Performance Indicators for the Hemoccult® Test (n=108)

Parameter	**Value (95% CI)**
True Positives (TP)	23
False Positives (FP)	11
False Negatives (FN)	33
True Negatives (TN)	41
Sensitivity	**41.1% (28.0–55.2%)**
Specificity	**78.8% (66.0–88.7%)**
Positive Predictive Value (PPV)	67.6% (50.2–81.8%)
Negative Predictive Value (NPV)	55.4% (43.9–66.5%)
Youden's Index	0.199

Table IV: Diagnostic Performance Indicators for the SD BIOLINE FOB® Test (n=108)

Parameter	Value (95% CI)
True Positives (TP)	38
False Positives (FP)	11
False Negatives (FN)	18
True Negatives (TN)	41
Sensitivity	**67.9% (54.1–80.1%)**
Specificity	**78.8% (66.0–88.7%)**
Positive Predictive Value (PPV)	77.6% (63.5–88.2%)
Negative Predictive Value (NPV)	69.5% (56.0–80.9%)
Youden's Index	0.467

The SD BIOLINE FOB® test demonstrated a higher sensitivity (67.9% vs. 41.1%) and a significantly superior Youden's Index (0.467 vs. 0.199) when directly compared to the Hemoccult® test. Interestingly, the specificity was found to be statistically comparable for both tests (78.8%). Consistently, the predictive values (both PPV and NPV) were higher for the SD BIOLINE FOB® test, unequivocally indicating its enhanced overall diagnostic accuracy within this symptomatic patient population.

Discussion

This cross-sectional diagnostic accuracy study conducted between November 2021 and August 2022 across four distinct healthcare facilities in Yaoundé and Douala, Cameroon, sought to compare the diagnostic performance of the immunochemical SD BIOLINE FOB® test and the guaiac-based Hemoccult® test, using colonoscopy as the definitive reference standard for detecting colorectal abnormalities. Our study population was composed of symptomatic adults, aged 21 years or older, who were referred for colonoscopy, and from whom specific exclusion criteria were rigorously applied to mitigate potential confounding factors.

The inclusion of individuals aged 21 years and older was deliberately chosen to align with Cameroon's legal age of majority while also recognizing the observed younger onset of CRC in African populations [8–10]. The demographic profile of our cohort, characterized by a mean age of 48.49 years and over half of the patients being under 50, mirrors trends observed in other African studies [11]. This distinct epidemiological pattern suggests that CRC in the region may manifest at an earlier age compared to Western populations. The male predominance (67.59%) in our study, while consistent with some regional reports [12], might also reflect variations in healthcare-seeking behaviors or specific referral pathways within the local context.

The prevailing symptomatic indications for colonoscopy, particularly abdominal pain, reflect the current diagnostic paradigm in Cameroon, where organized population-based CRC screening programs are currently absent [13]. This approach contrasts sharply with Western countries where colonoscopies are frequently driven by established screening guidelines [14]. Our deliberate exclusion of overt rectal bleeding means that our findings are less influenced by acute, immediate bleeding events, allowing for a clearer focus on occult blood associated with underlying colorectal pathology. The observed spectrum of colorectal abnormalities, encompassing polyps, exophytic lesions, and hemorrhoidal protrusions, is generally consistent with findings reported in local and regional literature [15].

Comparison with Local Research Our findings are particularly relevant when considered alongside the study by Jovanka et al. [5]. Both investigations assessed the performance of iFOBTs for detecting colorectal pathology in symptomatic patients referred for colonoscopy in Yaoundé, with colonoscopy serving as the gold standard. Whereas Jovanka et al. examined the predictive values of a generic iFOBT, our study provides a direct, head-to-head comparison between a specific iFOBT (SD BIOLINE FOB®) and a gFOBT (Hemoccult®). This comparative approach offers new insights into the relative diagnostic performance of these widely used tests within the same local context. Our results, which demonstrate the superior

sensitivity of iFOBT, not only corroborate but also extend the conclusions of Jovanka et al., reinforcing their findings on positive predictive value. Together, these converging lines of evidence highlight the urgent need for robust, evidence-based diagnostic tools for colorectal disease in Cameroon.

Test Performance Analysis The immunochemical SD BIOLINE FOB® test notably demonstrated superior diagnostic performance, achieving a sensitivity of 67.9% (95% CI: 54.1–80.1%) and a specificity of 78.8% (95% CI: 66.0–88.7%). In contrast, the Hemoccult® (guaiac) test exhibited a markedly lower sensitivity of 41.1% (95% CI: 28.0–55.2%) but registered a statistically comparable specificity of 78.8% (95% CI: 66.0–88.7%). These findings align consistently with the global scientific literature, which widely reports the superior sensitivity of iFOBTs over gFOBTs for detecting colorectal lesions [7,16,17]. The similar specificity observed for both tests in our cohort implies that both methods are comparably effective at correctly identifying individuals without colorectal abnormalities within this symptomatic patient population. The higher Youden's Index for SD BIOLINE FOB® further solidifies its overall superior diagnostic effectiveness.

The enhanced performance of iFOBTs largely stems from their inherent immunological specificity for human hemoglobin. This key characteristic renders them significantly less susceptible to dietary interferences (e.g., consumption of red meat, vitamin C intake) that can frequently lead to false positive or false negative results with gFOBTs, which rely on the non-specific peroxidase-like activity of heme [18]. Furthermore, the SD BIOLINE FOB® test was consistently associated with a higher detection rate across various colorectal abnormalities, encompassing polyps, exophytic lesions, and ulcerated exophytic lesions. This highlights its broader utility in identifying a more comprehensive spectrum of underlying pathologies.

Population and Spectrum Bias: Diagnostic vs. Screening Context It is paramount to recognize that this study was executed within a diagnostic-referral population, comprising symptomatic patients already referred for colonoscopy. This particular patient group inherently possesses a higher pre-test probability of colorectal abnormalities compared to an asymptomatic screening population. Consequently, our results are subject to selection bias. This implies that the diagnostic performance metrics, especially the predictive values, observed within this relatively high-risk cohort may not be directly generalizable to a broader, asymptomatic population-based CRC screening program. While our findings undeniably demonstrate promising diagnostic utility for SD BIOLINE FOB® in symptomatic individuals, they should

not be directly extrapolated to advocate for its widespread implementation as a primary screening tool in an average-risk population without further dedicated and rigorous evaluation in true screening settings. The high prevalence of colorectal abnormalities in our cohort (51.85%) contributes to the relatively high PPV observed, which would predictably be lower in a general population screening program.

Clinically Relevant Endpoints For effective CRC prevention and screening, the most clinically relevant outcomes are typically colorectal cancer and advanced adenomas (or advanced neoplasia). Our study reported a broad category of "colorectal abnormalities" that included a range of conditions, from polyps and exophytic lesions (which can be pre-neoplastic or neoplastic) to benign entities such as diverticula and hemorrhoidal protrusions. The inclusion of these benign conditions within the overall "abnormality" category means that our reported sensitivity and specificity figures inherently capture the detection of a broader spectrum of conditions beyond solely CRC or advanced adenomas. While identifying a wide range of abnormalities can be diagnostically invaluable for symptomatic patients seeking a cause for their symptoms, future studies, ideally with larger sample sizes, should differentiate these outcomes to provide more precise performance metrics specifically tailored for advanced neoplasia and CRC. Such focused data will be crucial for informing targeted screening strategies.

Study Limitations Several inherent limitations warrant careful consideration when interpreting our findings. The primary constraint was the relatively small sample size (n = 108). Although sufficient for basic statistical analysis, this limited the precision of diagnostic accuracy estimates, as reflected in the wide 95% confidence intervals. It also precluded reliable multivariate logistic regression, which would have enabled adjustment for potential confounders such as age, sex, and comorbidities, factors that may influence test performance and the presence of colonic lesions. Participant recruitment predominantly from private, urban healthcare facilities introduces a potential selection bias. The study population largely comprised individuals with the financial means to afford both FOBT and colonoscopy, thereby limiting the generalizability of our findings to the broader Cameroonian population, particularly those in rural or lower-income settings where access to care remains constrained. Another limitation was the absence of a formal, a priori sample size calculation, although the reported confidence intervals provide context regarding the precision of our estimates. Moreover, while polyps and exophytic lesions were identified, the study design did not permit a detailed classification of colorectal cancer diagnoses or grading of advanced adenomas within the “abnormalities” category—an important consideration for direct CRC screening applications.

Finally, logistical challenges during data collection, including scheduled gastroenterologist absences and the start of the academic year, further restricted both sample size and patient recruitment.

Conclusion

Our study clearly demonstrates that the SD BIOLINE FOB® immunochemical test possesses superior sensitivity and comparable specificity when directly compared to the Hemoccult® guaiac test for detecting colorectal abnormalities in symptomatic Cameroonian patients undergoing colonoscopy. These results firmly support the adoption of iFOBTs as a more reliable diagnostic aid in clinical practice for individuals exhibiting symptoms suggestive of colorectal pathology, particularly within resource-limited settings where structured CRC screening programs are still nascent or underdeveloped. However, it is imperative to acknowledge the inherent spectrum bias stemming from our symptomatic study population. Therefore, future, larger-scale studies involving asymptomatic cohorts and focusing specifically on clinically relevant endpoints like colorectal cancer and advanced adenomas, coupled with long-term follow-up, are essential to validate these findings and rigorously evaluate the clinical impact of these tests in population-based colorectal cancer screening in Africa, especially in settings with limited healthcare infrastructure.

Declarations

Informed Consent: Ethical approval for this study was duly obtained from the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences, University of Yaoundé I (reference number: N° 408/UY1/FMSB/VDRC/DAASR/CSR, granted in 2022), as well as from the directors of all participating healthcare facilities. Prior to the commencement of the study, all potential participants received comprehensive information regarding its purpose, methodological approaches, and any potential risks or benefits associated with their involvement. Following this thorough informed review process, participants provided their voluntary informed consent, which was meticulously documented either verbally (with the presence of an independent witness) or by signing a dedicated consent form.

Administrative Permissions: Before the initiation of any participant recruitment, administrative authorization was formally secured from the Ethics Committee of the Faculty of Medicine and Biomedical Sciences and from the directors of all involved healthcare facilities, ensuring full compliance with institutional regulations.

Author Contributions: Kengne Willy Stéphane drafted the protocol, contributed to the study design, data collection, and writing. Larry Tangie Ngek assisted in the revision of the protocol and the initial draft. Daniel Tchamdeu reviewed the initial draft. Patrick Fouegap performed the data analysis. Gilles Wandji Yebchue supervised and reviewed the final version of the study. Philippe Albert Lingo designed the study and supervised the entire process, providing strategic guidance.

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Data Availability: All supplementary tables and research queries utilized in this study are made available within the manuscript itself. The authors affirm that all raw data and materials pertinent to this study are accessible upon reasonable request directed to the corresponding author. The principal investigator, Kengne Willy Stéphane, can be contacted via email at stephiwilly@yahoo.fr for any data-related inquiries.

Conflicts of interest: The authors declare no conflicts of interest.

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