

Prospective Study on the Diagnostic Accuracy of the Immunochemical Fecal Occult Blood Test in a Single Round for Colorectal Cancer Screening in Average Risk Patients in Argentina

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ABSTRACT

Background: Colorectal cancer (CRC) is the second leading cause of cancer death in Argentina. Due to its high prevalence, it is essential to standardize a screening program for prevention and early detection. According to international literature, the accuracy of the immunochemical fecal occult blood test (FIT) for CRC screening in an average-risk population has proven to be adequate, but there is no information at the local level.

Objective: To evaluate the diagnostic accuracy of the FIT test in a single round for CRC screening in average-risk patients in our setting.

Design: Diagnostic accuracy prospective study.

Material and methods: Average-risk patients who consulted for a CRC screening video colonoscopy (VCC) at the Hospital Alemán of Buenos Aires, between June 1, 2015 and December 31, 2017 were included. All patients with increased risk for CRC were excluded. All patients performed FIT and subsequently VCC. The endoscopists were blind to FIT result at the time of VCC. The diagnostic accuracy of FIT to detect advanced neoplastic lesions (ANL) was evaluated by calculating sensitivity (S), specificity (Sp), positive predictive value (PPV), negative (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR-). The accuracy for the detection of low-risk adenomas, serrated polyps and CRC was also evaluated.

Results: A total of 300 patients were included; 273 (91%) submitted the stool sample to perform FIT and completed VCC. The mean age of patients was 56.9 (40-85) years and 54% were men. Of the total number of patients who carried out both studies (273), 53 (19%) patients had at least one low-risk adenoma, 18 (6.59%) patients had at least one sessile serrated adenoma and 21 (7.7%) patients had at least one ANL. Only 4 (1.5%) patients presented CRC. The diagnostic accuracy of FIT in a single round to detect ANL was: S 30%, Sp 84%, PPV 13%, NPV 94%; for low-risk adenomas: S 13%, Sp 84%, PPV 17%, NPV 79%; for sessile serrated adenomas: S 16.7%, Sp 87%, PPV 11%, NPV 91% and for CRC: S 75%, Sp 83%, PPV 6%, NPV 99%. No post-procedure complications were observed.

Conclusions: The diagnostic accuracy of FIT in our setting is comparable to international results. However, the low precision observed in a single round highlights the need to do it annually or biannually in order to optimize its accuracy and achieve effective screening programs.

Keywords: Screening; Colorectal Cancer, Colon Polyp; Fecal Occult Blood Test

INTRODUCTION

Colorectal cancer (CRC) represents the third most frequently diagnosed cancer in men and the second in women worldwide, with more than 1.2 million new cases and 608.700 deaths according to the World Health Organization statistics for the year 2008.¹ Argentina is not the exception, and it is considered a country with a high prevalence of CRC, representing the second leading cause of cancer death.²

CRC in more than 60% of cases it is already locally ad-

vanced or metastatic when diagnosed. This is the main factor influencing overall survival. In contrast, when the diagnosis is made in early stages (stage 1 and 2), which occurs in only 37% of cases, overall survival can exceed 90%.³ In addition to this, 95% of CRC develop on a precursor lesion, the adenomatous polyp. The slow growth of these lesions allows early detection and timely resection through screening programs, thus reducing their incidence and mortality.

Ideally, a screening procedure should be a simple, low-cost test that can be easily applied to the entire population at risk. There are many factors that influence the choice of a screening test: evidence of efficacy, magnitude of effect (reduction in incidence or mortality), safety, convenience, comfort, availability, and cost-effectiveness.^{3,4}

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At present, there are different methods to perform CRC screening (colonoscopy, barium enema, fecal occult blood test (FOBT), sigmoidoscopy, virtual colonoscopy, and capsule endoscopy). In recent years, colonoscopy has become the “gold standard” and preferred method of screening for CRC, since it allows the diagnosis and treatment of precursor lesions and the decrease in mortality has already been shown in multiple studies with this method.⁵ The use of colonoscopy as a primary screening method can be considered in health systems where endoscopic resources are sufficient to guarantee accessibility and the corresponding quality indicators. However, its limitations such as need for preparation, sedation, risks (perforation, bleeding and abdominal pain occurring in approximately 2.8 per 1000 studies), high costs and necessary resources (number of endoscopes and trained endoscopists) make it difficult the use of this method in CCR screening programs. FOBT is based on the detection of negligible, intermittent losses of blood in the stool in the presence of advanced lesions or CRC, which can be detected before they are clinically visible. There are basically two options to perform the FOBT, the method based on the guaiac test (gFOBT) and the immunochemical test (iFOBT or FIT).^{6,7} FIT is more accurate than gFOBT because reacts only with human hemoglobin and do not detect hemoglobin of animal origin, so do not require a previous diet and, therefore, increasing considerably its acceptance. It is more accurate in detecting colonic lesions as it reacts with whole hemoglobin, and upper gastrointestinal bleeding may not be detected due to the fact that hemoglobin is digested during its passage through the digestive tract. Another advantage of immunochemical tests is that they require fewer stool samples (one or two, versus three for guaiac) and automated analysis can be done. Although FIT is more expensive, it has a savings potential due to fewer unnecessary colonoscopies indicated by false-positive results of the test.⁸⁻¹³

Nowadays, the performance of any of the FOBT methods is considered a valid CRC screening option by international guidelines, since there is strong evidence that it reduces mortality from this neoplasia.^{14,15} We consider it extremely important to know the characteristics of the population to be investigated and to validate the accuracy of the method available in our environment prior to starting a population-based CRC screening program.

Finally, we know that although FIT is effective, its adherence and annual repetition rate is very low, especially in our environment where we lack organized screening programs that guarantee the follow-up of patients and many of the take the test only once. For the aforementioned, knowing the precision of FIT in patients who perform this method in a single round is of utmost importance.

For this reason, we set out to determine the diagnostic accuracy of FIT in a single round for the detection of advanced neoplastic lesions (ANL), comparing it with the VCC. A secondary objective was to know the prevalence of neoplastic colon lesions in the average-risk population in our environment.

METHODS

An observational, prospective study of diagnostic accuracy was carried out. Healthy volunteer patients who consulted to undertake a VCC for CRC screening in the digestive endoscopy service of the Hospital Alemán of Buenos Aires between June 1, 2014 and December 31, 2017 were included. Patients aged ≥ 50 and ≤ 75 years, asymptomatic from the digestive point of view, without risk factors for CRC and who consented to participate voluntarily in the study were included.

For the correct analysis of the results, individuals with a higher risk of CRC (family history of sporadic cancer, familial hereditary syndromes such as polyposis or Lynch and inflammatory bowel disease) were excluded. These individuals were invited to carry out specific screening strategies according to the risk group.

Patients with serious and / or chronic associated diseases were excluded. In these cases, according to medical criteria, the risk-benefit of inclusion in the screening program was analyzed.

Patients with a history of recent gastrointestinal bleeding (last 2 months) or who had been studied by barium enema in the last 5 years, or colonoscopy in the last 10 years, were excluded.

Finally, patients who could not undergo a colonoscopy, or who had a lack of consent or an evident unwillingness to carry out or continue the study according to the presumption of the interviewer, were excluded.

Patients were free to drop out of the study when they decided. The possibility of early interruption was considered in the event of intercurrent disease, surgical interventions, or other causes that would distort the established protocol.

The patients were interviewed by medical professionals specializing in gastroenterology or coloproctology, who registered all personal and family history. The purpose of the study was explained to all patients, evaluating whether they met the inclusion requirements. The patients signed an informed consent stating the scope of the project and the eventual consequences related to the findings or complications of the study or therapeutics instituted.

On the day of the interview, the patients were given an immunological test kit (Immunochromatographic) for fecal occult blood (MONTEBIO FOB®). This test is quick

to qualitatively detect low levels of occult blood in feces. The test uses a double antibody sandwich assay to selectively detect fecal occult blood at concentrations of 50 ng/mL or $>6 \mu\text{g/g}$ feces. The accuracy of the test is not affected by diet. The patient was asked to perform a single stool sample collection prior to the beginning of the bowel preparation to perform the endoscopic study. It was required that no more than a week elapse between the taking and delivering of the sample, which was the same day of the VCC. All patients were given instructions to perform the bowel preparation. The type of preparation was individualized for each patient according to the doctor criteria.

The immunological test was received and processed by a physician from the endoscopy service the same day that the patient attended to perform the VCC. Interpretation of the result by the physician was based on the kit manufacturer's recommendations. This professional did not participate in the endoscopic study and did not reveal information about the test results to the VCC operating physicians. The results of FIT were communicated in writing to all individuals participating in the study.

All patients underwent VCC. The endoscopic procedure was the usual one, performed by endoscopists trained in colorectal cancer screening, blinded to the result of FIT. High-resolution video endoscopes were used, supplemented when necessary with chromoendoscopy. The size and morphology of the lesions (Paris classification), the technique used for resection (forceps biopsy, polypectomy or mucosectomy), the cecal intubation and quality of bowel preparation using a validated scale were registered. All the excised lesions were sent for pathological study. The endoscopy service has currently accepted quality parameters in CRC screening: adenoma detection rate $> 20\%$, cecal intubation rate $> 95\%$ of colonoscopies, colonic perforation rate $< 1/1000$, post-polypectomy bleeding rate $< 1/200$. Poorly prepared patients (Boston < 6) were excluded.

The histological examination was performed by expert gastroenterology pathologists, who were blind to the result of FIT. Colorectal lesions were classified according to the Vienna classification for gastrointestinal epithelial neoplasms.

Information gathering and analysis

The information gathering was carried out by physicians of the Gastroenterology and Digestive Endoscopy Services of the Hospital Alemán. An electronic data sheet especially designed for the project was used (Microsoft® Excel for Windows®). The clinical data obtained in the evaluation prior to the colonoscopy, and the follow-up data pertaining to the endoscopic and histopathological findings were recorded in this form.

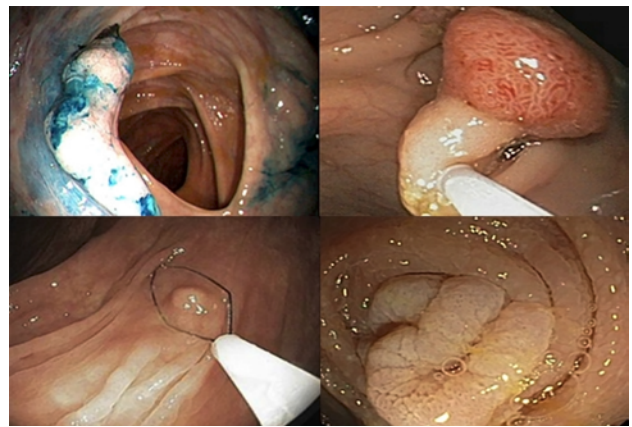


Figure 1. Colonic lesions found during colonoscopy. A. Colorectal cancer. B. Advanced neoplastic lesion. C. Low-risk adenoma. D. Serrated adenoma.

Data were presented as mean values \pm standard deviation, ranges and/or percentages as correspond to continuous or categorical variables.

The presence of ANL (defined as size > 1 cm, high-grade dysplasia and/or $> 25\%$ villous component), low-risk adenoma, sessile serrated adenomas and CRC was recorded (Fig. 1).

The positivity rate of the test was calculated, as well as the necessary number of population to be screened with FIT to find an advanced adenoma and the necessary number of population to be performed VCC in order to detect an ANL. The diagnostic accuracy of the immunological test to detect ANL was evaluated by calculating the sensitivity, specificity, positive and negative predictive value, positive and negative probability coefficient.

As a secondary objective, we set out to know the prevalence of neoplastic lesions according to the classification of the guidelines presented by the national program for the prevention and early detection of colorectal cancer,⁵ which divides them into low risk: 1 or 2 adenomas ≤ 10 mm of tubular type and with low-grade dysplasia, intermediate risk: 3 to 10 adenomas ≥ 10 mm villous type or with high-grade dysplasia and high risk: more than 10 adenomas, or one ≥ 20 mm, or one or more serrated polyps ≥ 10 mm with dysplasia.

The statistical analysis was carried out using the SPSS statistical package version 20.0 for Windows (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 300 patients were interviewed and invited to participate; 273 (91%) submitted the stool sample to perform FIT and completed the VCC.

The mean age of patients was 56.9 (40-85) years, and 54% were men. The general characteristics of the popula-

TABLE 1. GENERAL CHARACTERISTICS OF THE POPULATION

Characteristics	n
Age (years, range)	57,9 (30-85)
Male	147 (53,8)
Weight (Kg)	75,8
Height (m)	1,68
BMI: Kg/m2 (range)	26,6 (16,3-42,9)
Overweight : BMI 25-29.9	16 (5,8)
Obesity: BMI >30	53 (19,4)
Current smoking	35 (12,8)
Ex-smoker	102 (37,4)
Frequent exercise *	113 (41,4)
Diet rich in fruits and vegetables (fiber) †	236 (86,4)
Diet habitual consumption of red meat ‡	147 (53,8)
1st degree family history with colorectal polyps	18 (6,6)
1st-degree family history of colorectal cancer	25 (9,1)
2nd-degree family history of colorectal cancer	20 (7,3)
Diabetes mellitus	22 (8)
History of hemorrhoidal disease	120 (43,9)
Aspirin consumption	49 (17,9)
Consumption of NSAIDs	41 (15)
Consumption of oral anticoagulants (warfarin, acenocoumarol, rivaroxaban)	3 (1,1)

*Figures in parentheses are percentages, except where otherwise indicated. BMI: Body mass index. NSAIDs: Nonsteroidal anti-inflammatory drugs. * Aerobic exercise ≥3 times per week. † Consumption of fruits and vegetables that contribute fibers >3 times per week. ‡ Red meat consumption ≥3 times per week.

tion studied are summarized in Table 1.

When we analyzed the prevalence of neoplastic lesions, we observed that at least one low-risk adenoma was diagnosed in 53 (19%) patients, at least one sessile serrated adenoma in 18 (6.6%) patients, at least one ANL in 21 (7.7%) patients. CRC was diagnosed in 4 (1.5%) patients (Table 2).

When we analyzed the accuracy of the method, we observed for detecting ANL sensitivity was 30, specificity 84%, PPV 13%, NPV 94%, LR+ 1.9 and LR- 0.8. The accuracy was lower for both low-risk adenomas and sessile serrated adenomas (Table 3).

Regarding the secondary objective of our study, we observed the following positivity of FIT in relation to the classification of lesions as low, moderate and high risk of progression to CRC: 4/31 (12%), 10/48 (21%) and 2/14 (15%) of patients with small (<10 mm) hyperplastic adenomas in the rectum or sigmoid, 1 or 2 small tubular adenomas (<10 mm) and 3 to 10 tubular adenomas were positive, respectively. We also found FIT was positive in 8/20 (40%) of patients with one or more tubular adenomas >10 mm. FIT was positive in 5/9 (55%) patients with one or more villous adenomas, and in 8/22 (36%) patients with ANL.

Regarding sessile serrated adenomas <10 mm, FIT was positive only in 3/15 (20%) patients.

No FIT was positive in patients with polyps ≥10 mm, traditional serrated adenomas, or patients with serrated

TABLE 2. ENDOSCOPIC FINDINGS IN THE PATIENTS INCLUDED IN THE STUDY

Findings	n (%)
Normal VCC without polyps	21 (43,7)
Hyperplastic polyps	8 (16,6)
Advanced neoplastic lesions	7 (14,6)
Low risk adenoma	8 (16,6)
Serrated adenomas	3 (6,25)
Colorectal cancer	3 (6,25)

*VCC: Videocolonoscopy.

polyposis syndrome (Table 4).

No complications were recorded in the procedure or in the follow-up.

DISCUSSION

In our study the results of FIT for CRC screening in the average-risk population is similar to that reported internationally, however, when is carried out in a single round its accuracy is low to detect ANL and intermediate to detect CRC. The diagnostic accuracy can increase with annual or bi-annual repetition of the test.

Three Japanese studies which evaluated the efficacy of FIT coincide in the finding of a significant reduction in mortality from CRC, ranging from 23 to 81%, depending on the time of follow-up since last exam.¹⁶⁻¹⁸

Many studies have shown a high sensitivity and speci-

TABLE 3. DIAGNOSTIC ACCURACY OF THE SOMFI TEST IN A SINGLE ROUND

	Sensitivity	Specificity	PPV	NPV	LR+	LR-
	(95% IC)	(95% IC)	(95 % IC)	(95% IC)	(95 % IC)	(95 % IC)
Colon neoplastic lesion						
Low risk adenoma	13%	84%	17%	79%	0,8	1,03
Serrated adenoma	(6-24)	(82-87)	(8-32%)	(77-81)	(0,3-1,8)	(0,8-1,4)
ANL	16,70%	87%	87%	91%	1,25	0,9
CRC	(4-39)	(85-89)	(85-89)	(90-94)	(0,3-3,6)	(0,7-1,1)
LNA	30%	84%	13%	94%	1,9	0,8
	(13-53)	(83-86)	(6-23)	(92-96)	(0,8-3,9)	(0,5-1)
CRR	75%	83%	6%	99%	4,4	0,3

*CI: Confidence interval. PPV: Positive predictive value. NPV: Negative likelihood ratio. LR+: Positive likelihood ratio. LR-: Negative likelihood ratio. ANL: Advanced colorectal lesion. CRR: Colorectal cancer.

TABLE 4. ENDOSCOPIC FINDINGS IN PATIENTS WITH POSITIVE FIT

Colorectal Lesion	Sensitivity	Specificity	Diagnostic accuracy	p
	(95% CI)	(95% CI)		
Hyperplastic polyp in rectum or sigmoid <10 mm	0% (0-10)	95% (95-97)	71%	0,6
1 or 2 tubular adenomas <10 mm	33% (18-79)	75% (73-79)	69%	0,2
3 to 10 tubular adenomas	9% (1-20)	90% (89-93)	79%	0,9
1 or more tubular adenomas ≥10 mm	28% (15-43)	90% (88-94)	80%	0,005
1 or more villous adenomas	16% (5-28)	96% (93-98)	83%	0,001
Sessile serrated adenoma	14% (4-31)	87% (85-90)	80%	0,012
Advanced neoplastic lesion	29% (15-45)	89% (86-92)	80%	0,012
Colorectal cancer	75% (22-98)	83% (82-84)	85%	0,001

*FIT: Immunochemical fecal occult blood test.

ficity of this method for the detection of ANL and CRC, such as that of Freitas et al.,¹⁹ who in a prospective study observed a sensitivity of 63% and specificity of 87% for advanced adenomas and more than 88% sensitivity and specificity for CRC. However, most of the studies reported in the bibliography are with the sampling on an annual or bi-annual basis, which increases the accuracy of the method. In our study we perform the test in a single round to determine the accuracy under these circumstances, since in our country we currently do not have an organized screening program that guarantees the correct follow-up of patients and many individuals do not repeat the test.

In our series we observed a sensitivity of 30% and a specificity of 84% for ANL, while for CRC the sensitivity and specificity were 75% and 83%, respectively. Our results are comparable to those of Morikawa et al.,²⁰ who observed with FIT in a single round a sensitivity of 65% for CRC and 27% for ANL, with a 30% adherence to follow-up. Although the results observed in both studies highlight the need to perform this test annually, the similarity of the results allows us to validate the method in our setting.

To our knowledge, this is the first prospective study carried out in Argentina comparing FIT to the gold standard (video colonoscopy), with the purpose of evaluating its accuracy to detect ANL in average-risk patients. For

this reason, the results of this study are essential for the implementation of local CRC prevention strategies.

Although in our study we observed how with a single round of FIT we could detect 75% of CRC, we also demonstrated a low precision in detecting ANL and low-risk adenomas. This shows that precursor lesions of CRC can be missed by the test in a single round and only in the annual repetition could be detected when become larger and more likely to bleed. However, the challenge is to achieve acceptable adherence to the repetition of FIT, since otherwise we will be unable to detect these neoplasms early.

Finally, we found that the population of patients with average risk for CRC in our setting has a prevalence of neoplastic lesions (low-risk adenomas, ANL, serrated adenomas and CRC) comparable to that reported in international studies. This allows us to know the true risk of CRC in this group in our population and to be able to extrapolate the results of different interventions reported in other studies.

CONCLUSIONS

The diagnostic accuracy of FIT in a single round in our setting is comparable to international results. However, the low accuracy highlights the need to perform it annua-

lly or bi-annually to improve its accuracy and be able to apply it to a CCR screening program. The information

provided by this study could be very useful to plan future CRC screening programs in our population.

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COMMENT

It is not redundant to repeat what was outlined in this article on the prevalence of colorectal cancer in Argentina, it ranks third among the causes of neoplasia and second in mortality, its prevalence has increased significantly in the last decade and unfortunately 60% of diagnoses are made in advanced stages, determining an overall survival of 60%. However, with early detection, it increases to 90%. Despite the fact that this neoplasm has been associated to dietary factors and lifestyle, changing these habits is often not possible, making primary prevention impossible. Given these circumstances, secondary prevention through early diagnosis is essential.

The natural history of colorectal carcinoma makes it one of the most preventable, since it has a precursor lesion, the slow-growing adenomatous polyp, whose detection and resection by colonoscopy allows an effective reduction of its incidence, thus complying with the requirements described by the WHO in the 1970s for the implementation of a screening system.

Differences in equipment and financing in our country, added to the absence of a national registration system, make it difficult to implement the proposed screening programs.

Although videocolonoscopy is the gold standard for the detection of these lesions, it follows that it is impossible to apply to the entire population. Hence, this article is important to make the reader aware of the relevance of immunological tests, and how they are applied in order to achieve greater precision. For a screening program is fundamental that

in the event of a positive result the endoscopy is available, to certify the diagnosis and apply a treatment, situation that is not simple to solve throughout the national territory.

It should be noted that the comparison is made with the gold diagnostic standard, videocolonoscopy, and that its quality standards are highlighted.

On the other hand, it is relevant that statistics are taken from our population in order to adapt the screening programs, since, as previously described, the incidence varies according to environmental and nutritional factors. For instance, it is difficult to homologate with Japanese studies whose screening program begins a decade before ours.

The immunological test has shown greater accuracy, which is associated with a reduction in mortality of up to 60% in the countries that have implemented it in their screening program.

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