List of abbreviations

AA	Advanced adenoma
ADK	Adenocarcinoma
AJCC	American Join Committee on Cancer
AN	Advanced neoplasia
CTC	Computed Tomographic Colonography
DR	Detection rate
FIT	Fecal Immunochemical test
FOBT	Fecal occult blood test
g-FOBT	Guaic- fecal occult blood test
ISC	In situ carcinoma
PPV	Positive predictive value

Plan

Contribution of the OC Sensor® immunoassay in comparison to the Hemoccult II® guaiac-test in organized colorectal cancer screening.

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ABSTRACT

Introduction: Colorectal cancer (CRC) is a real public health issue, with high incidence and mortality rate, accessible to a screening program in France, first with guaiac-based fecal occult blood test (g-FOBT) then with fecal immunochemical test (FIT), since 2015 because of better accuracy. The aim of our retrospective study was to compare 2 successive CRC screening campaigns, using 2 different tests (Hemoccult II® and OC Sensor®) in Maine-et-Loire department, to precise population participation (PP), positivity and detection rates (PR, DR), positive predictive value (PPV) and to describe characteristics of CRC and adenomas screened between the two tests.

Methods: Participants, invited by CAP SANTE 49, with polyps or cancer detected at the colonoscopy after a positive screening test between 01/01/2013 and 31/12/2016 were included.

Results: 2621 individuals, 648 with g-FOBT and 1973 with FIT had lesions. PP was not different between tests (p=0.104). PR, DR and PPV were statistically higher in FIT for all lesions (4.4, 95%CI [4.2-4.5]; 2.35, 95%CI [2.25-2.47]; 65.92, 95%CI [64.20-67.60] versus 1.9, 94%CI [1.8-2.1]; 0.84, 95%CI [0.78-0.91]; 50.23, 95%CI [47.51-52.96] for g-FOBT respectively; all p<0.0001). DR for CRC was also significantly higher in (p<0.0001), without statistical differences in type, localization, differentiation or stage, even after stratification by sex. A higher proportion of proximal colon cancer in patients who made a g-FOBT two years before the FIT was found (p=0.049).

Conclusion: FIT doesn't increase participation rate to CRC screening but DR and PPV of all lesions was higher. A higher proportion of right colon cancer was diagnosed by FIT in patients who made a negative g-FOBT 2 years before.

INTRODUCTION

Colorectal Cancer (CRC) is the 3rd most common cancer in France with 42152 new patients in 2012 (18926 women, 44.90% and 23226 men, 55.10%) (1). It was the 2nd cause of mortality with 17722 deaths to this date (1). The French Institute for Public Health Surveillance made a projection which showed in 2015 there would be an increase of CRC incidence with 43068 new patients and an increase of mortality with 17833 deaths (2). The European 5-year relative survival rate was 57% for the colon and 56% for the rectum in the EUROCARE-5 study (3). All stages combined, the survival rate at 5 years is about 60% in France (4). Given its considerable impact on population, CRC is a real public health issue. Therefore, there is a need to develop strategies to reduce the risk of developing and dying from CRC.

Fortunately, effective interventions to reduce these risks exist, including screening. Screening aims to detect cancerous or precancerous lesion before symptoms appear and when they are more likely to be curable. Test used for screening should be safe, precise and validated. Safety is important because screening tests, unlike diagnostic test, are being used in asymptomatic populations whose pretest probability of disease is low. The most sensitive test for detection of CRC or adenoma is colonoscopy but it is an expensive, invasive procedure and requires hospital attendance and administration of a bowel preparation that is often inconvenient and unpleasant for the patient. Fecal occult blood tests (FOBT) are better able to meet constraints imposed by mass screening. They include guaiac based test and immunochemical tests.

Guaiac-based fecal occult blood tests (g-FOBT) were the earliest approach to CRC screening. This approach is based on the pseudo peroxidase activity of the haem, which

facilitates oxidation of guaiac when hydrogen peroxide is added (5). The test consists of 3 separate cards, each should be used on a consecutive day with defecation and on each card 2 samples of different parts of the defecation should be applied with a separate applicator stick. It gives qualitative result, 1 of the 6 samples defined a positive test. Several studies have proved that g-FOBT can reduce mortality related to CRC by up to 20% (6–12). Although g-FOBT has a good clinical specificity, it has low clinical sensitivity with a relatively high false negative rate for detecting CRC and adenomas. However, g-FOBT has several disadvantages. It is not specific for human blood and it is susceptible to interfere with some foods involving dietary restriction during fecal sample collection. Finally, test-reading is visual and does not depend on an automated system.

Fecal Immunochemical tests (FIT) have been developing since the 2000's. The OC Sensor® test consisted of a single sampling tube, filled with stabilizing buffer, used with a fecal probe. OC Sensor® test uses monoclonal or polyclonal antibodies against blood protein (more often human globin). It has an automatic reading system and gives quantitative result (usual cut off: 150 ng/mg).

This test has also proved a decrease in CRC mortality (13–15) and better performance in randomized controlled trials (16–18) than g-FOBT. As shown in a French study in 2007, FIT increase the number of cancers detected by 1.5 to 2 times and 3 to 4 times the number of adenomas found. It also decreases the number of false positive results by 1.5 (17).

Established in France in 2002, in 23 pilot areas, the organized screening program for colorectal cancer was widespread throughout the country in December 2008. The test was proposed to the asymptomatic 50-74 years old people with any risk factors

(medium risk population). The method was to examine for blood in the stool every 2 years using a guaiac test Hemoccult II® and to propose a colonoscopy if the test was positive, to search for a lesion (polyp or cancer).

Nevertheless, participation rate with Hemoccult II® in France is low and has never exceeded 30%, far from the 45% acceptable rate, even further from the 65% recommended by European standards (19). Improved screening participation with FIT compared to g-FOBT is therefore important. Four population-based randomized controlled trials and a meta-analysis of studies comparing FIT to g-FOBT have found an absolute increase in participation ranging from 5.4% to 16.2% (16,20–23).

Since June 2015, FIT have been commonly used in France and OC Sensor® test (FIT) replaced Hemoccult II® test (g-FOBT) in French screening campaigns (24).

The aim of our retrospective study was to compare 2 successive screening colorectal cancer campaigns, using the 2 different tests (Hemoccult II® and OC Sensor®) in the department of Main-et-Loire from 2013 to 2016. Goals were to precise population participation, positivity and detection rates, positive predictive value of tests, and to describe characteristics of colorectal cancers and adenomas screened in each campaign.

METHODS

Screening:

People aged from 50 to 74 years, with no personal or family history of CRC and adenoma, with no colonoscopy for the past five years, no inflammatory bowel disease and no terminal disease or bedridden patient, received a letter from CAP SANTE 49, the departmental analysis center that organizes CRC screening in Maine-et-Loire, and were invited to contact their general practitioner to undergo the screening test.

General practitioners were giving them information about the test, verifying the absence of contraindications (blood in the stool, anorexia, transit disorder…) and delivered the screening test. Individuals did the test at home and sample were sent to IRSA (Institut interRegional pour la Santé, Tours) for g-FOBT and CERBA Laboratory (Cergy-Pontoise) for FIT, to be analyzed.

If result was positive, patients were invited to contact their general practitioner and a gastroenterologist to perform a colonoscopy under general anesthesia. If a polyp or a cancer was found, it was sent to a pathologist.

Inclusion criteria:

Patients with polyps or cancer at the colonoscopy after a positive screening test between 01/01/2013 and 31/12/2016 in Maine-et-Loire were included.

We also get data from CAP SANTE 49 database about all the individuals invited to participate in CRC- screening between 01/01/2013 and 31/12/2016.

Exclusion criteria:

Individuals with a positive test from CAP SANTE 49 database, who have refused or have a contraindication to colonoscopy were excluded from the analysis.

Fecal occult blood tests:

Hemoccult II® was used from 01/01/2013 to 31/12/2014 in the first campaign in our study and OC Sensor® test was used in the second campaign from 01/06/2015 to 31/12/2016. No invitation was sent from 01/11/2014 to 01/06/2015.

Data collection:

Gastroenterologists and pathologists have sent a copy of results of colonoscopy and histopathological results of the samples to CAP SANTE 49.

Thanks to their registry, individuals with polyps or cancers were identified. Age, gender and date of positive test were collected for all individuals.

Concerning the colonoscopy: date of colonoscopy, quality of preparation (insufficient, average, good), if the exam was complete or not, localization (rectum, left, transversal and right colon) and size of lesions were collected.

Histological data was collected thanks to CAP SANTE 49 and thanks to histopathological departments of Maine-et-Loire in Centre de Pathologie de l'Ouest or Angers University Hospital. Only information about the 3 most pejoratives lesions per colonoscopy were analyzed. Histological analysis concerning the type of polyp (tubular adenoma, tubulovillous or villous adenoma, serrated adenoma, hyperplastic polyp and others), dysplasia (low or high-grade) and the presence of carcinoma with or without presence of a colloid component were collected.

If a cancer was diagnosed, other datas were collected: date of resection, differentiation (low – moderately - well-differentiated), staging tumor according to the AJCC classification (25), anterior participation to screening CRC campaign and date of the last screening test result.

The criteria for diagnosing cancer, in accordance with the international classification, was an invasion of malignant cells beyond the muscularis mucosa. Intramucosal carcinoma and carcinoma in situ were classified as adenoma with high grade dysplasia (26).

Advanced adenoma (AA) was defined by size $\geqslant$10 mm, tubulovillous or villous adenoma, high grade dysplasia (26).

Advanced neoplasia (AN) was an advanced adenoma or a colorectal cancer.

Collection data was retrospectively performed to 1/05/2017.

Data analysis:

The participation rate was calculated as the ratio of number of individuals returning the screening test to the number of individuals invited during the corresponding screening campaign. Detection rate was calculated as the number of persons with a lesion at colonoscopy relative to the number of participants in CRC screening. The positive predictive value (PPV) was the proportion of true positives (persons with a lesion at colonoscopy) relative to the total number of patients who were screened positive and underwent colonoscopy or Computed Tomographic Colonography (CTC). Detection rate and PPV are expressed as percentages with 95% confidence intervals (95% CI).

Characteristics of subjects were expressed as mean +/- standard deviation or frequency (%). Continuous variables were compared between groups (FIT versus g-FOBT) using the Student's t-test. Categorical variables were compared between groups using the Chi-square test or the Fisher's exact test where it was appropriate.

All statistical analyses were performed using IBM SPSS version 15 for Windows.

RESULTS

1. Participation in CRC screening campaigns

In overall 391 932 individuals were invited to participate in CRC screening campaigns between 01/01/2013 and 31/12/2016; 188 815 received an invitation for g-FOBT-based CRC screening (2013-2014) and 203 117 for a FIT-based CRC screening (2015-2016). 143 408 individuals performed a screening test, 69 326 did an Hemoccult® test (g-FOBT) and 74 082 an OC Sensor® test (FIT). Main characteristics are presented in the Flow chart (Figure 1).

4565 participants had a positive screening test: 1346 g-FOBT (1.9%) and 3219 FIT (4.3%) ($p<0.0001$).

Among participants who were screened positive, 93.5% (4266 of 4565) patients underwent a colonoscopy. Colonoscopy rate was 95.5% for g-FOBT-based campaign and 92.6% for FIT-based campaign ($p=0.0003$). 10 patients in g-FOBT group and 23 in FIT group refused or had contraindication for colonoscopy. Furthermore, 51 patients in g-FOBT group and 215 in FIT group did not undergo further exploration after positive test; these patients were excluded of the study (61 and 238 respectively).

Colonoscopy was performed within 3 months after the test reading for 50% of the patients and within 8 months for 97% of patients. Among them 55 had an incomplete colonoscopy, 7 (1.1%) in the g-FOBT group and 48 (2.4%) in the FIT group.

2621 subjects had screen-detected colorectal lesion: 648 in g-FOBT group (50.4% of patients who had been screened positive) and 1973 in FIT group (66.2% of patients who had been screened positive) (p<0.0001).

2. Characteristics of patients with screen-detected lesion according to screening campaign

Mean +/ SD age of patients was 63.1 years (63.1+/-6.93), no difference in age was observed according to screening campaigns (Table I): 62.7 (62.7+/-7.1) for g-FOBT group and 63.4 (63.4+/-6.9) for FIT group, p=0.062. For each screening campaign, there were a higher proportion of men than women among patients with screen-detected lesion: 60.8% versus 39.20% in the g-FOBT group and 63.2% versus 36.8% in the FIT group (p=0.273).

3. Performance comparison between g-FOBT and FIT-based screening campaigns

A total of 292 colorectal cancers were diagnosed, 63 cancers in g-FOBT and 229 cancers in FIT groups (Table II). 2329 patients were diagnosed with at least one polyp and no cancer was registered, with 5019 polyps.

The detection rate for any type of colorectal lesions was significantly higher in FIT group than in g-FOBT (2.66, 95%CI [2.55-2.78] in FIT versus 0.93, 95%CI [0.86-1.01] in g-FOBT, p<0.0001). Significant higher detection rates in FIT group were also observed for advanced lesions (AA, AN and CRC) (Table II).

Predicative positive value (PPV) was significantly higher in FIT (65.92, 95%CI [64.20-67.60]) versus in g-FOBT (50.23, 95%CI [47.51-52.96], p<0.0001), significant differences in favor of FIT were also found for advanced lesions (AA, CRC and AN).

4. Characteristics of screen-detected lesions

2329 patients with at least one polyp and no cancer were registered, with 5019 polyps. Among them, there were 884 hyperplasic polyps, 343 with g-FOBT and 541 with FIT. There were 122 lesions non-collected after colonoscopy, 28 for the g-FOBT and 94 for the FIT.

4.1. Polyps

Sex-repartition wasn't different between screening campaigns. There were 293 men and 176 women with polyps diagnosed by g-FOBT whereas 963 men and 542 women in FIT group (p=0.552).

There was a significant difference in types of screen-detected polyps between the two groups (p=0.008), with more adenomas and less serrated polyps in FIT group as compared to g-FOBT group (Table III). But, there was no significant difference in polyps localization (p=0.225) nor in their dysplasia degree (p=0.142). Polyps size was available only in 67.5% in g-FOBT group and in 80.9% in FIT group. Polyps size was significantly more important in FIT group (p<0.0001).

4.1.1. Tubular and/or villous Adenomas

FIT detected more tubulovillous and villous adenomas than g-FOBT ($p<0.0001$). Sizes were significantly different for adenomas between groups, with bigger sizes in FIT group ($p<0.0001$) as shown in Table IV.

4.1.2. Advanced adenomas and In Situ Carcinomas (ISC)

Advanced Adenomas (AA) were defined by size ≥ 10mm, villous component or high-grade dysplasia (including In Situ Carcinomas). There were significantly more AA diagnosed by FIT (48.0%) versus g-FOBT (35.1%) ($p<0.0001$), without difference in AA localizations. Nevertheless, there was no significantly difference of ISC between the groups ($p=0.591$) (Table V).

In sex-specific analyses, types and size of polyps weren't significantly different between the groups (Table VI). There wasn't more AA in male (140 in g-FOBT and 612 in FIT group) than in female group (71 in g-FOBT group and 346 in FIT group) ($p=0.498$).

4.1.3. Serrated polyps

There were statistically less serrated polyps in FIT group than in g-FOBT ($p=0.003$), but no difference concerning adenomas size and localization ($p=0.412$) (Table VII). One serrated polyp was in high dysplasia grade in FIT group.

4.2. Invasive cancers

The detection rate for CRC was significantly higher in FIT group (0.31, 95%CI [0.27-0.35] versus g-FOBT (0.09, 95%CI [0.07-0.12]) (p<0.0001).

There were 63 invasive cancer diagnosed after a g-FOBT: 61 adenocarcinomas, 1 lymphoma and 1 neuro endocrine carcinoma, and 229 after a FIT: 227 adenocarcinomas and 2 neuroendocrine carcinomas. Sex repartition wasn't different between the groups (40 and 149 cancers in men; 23 and 80 cancers in women respectively for g-FOBT and FIT) (p=0.817).

CRC localization, type of cancer, differentiation and stage of disease were not statistically different between the two screening campaigns (Tables VIII), even in sex-specific analyses (Tables IX).

Among the 229 CRC diagnosed after a positive FIT, 64.6% individuals had made a g-FOBT test 2 years before. As shown in Table X, there were statistically more right colon cancer in subjects who made a g-FOBT 2 years before versus subjects who had screening test for the first time (p=0.049), with no statistical difference between men (64.3%) and women (35.7%) compared to other localizations (p=0.840). However, there was no difference in the stages of CRC at screening between these groups (p=0.396).

DISCUSSION AND CONCLUSION

Screening by FOBTs has been shown in randomized trials to reduce colorectal cancer (CRC) incidence and mortality (9–12). In these trials, g-FOBTs have been used with high specificity (>80% for all tests on all measured outcomes) but relatively low sensitivity (from 47.4% to 73.4%) to detect CRC and its precursors (27).

More recently, FITs have been developed and have a higher specificity for human blood than g-FOBTs, hence removing any need for dietary restriction and have a higher sensitivity (from 25.6% to 97.7%) (27). However, the effectiveness of any screening program depends not only on the diagnostic performance of the screening but also on the compliance and general acceptance of the test by the public. The participation rate with g-FOBT in France is low and has never exceeded 30%. In our study, colonoscopy was only performed to subjects with a positive test. So, sensitivity and specificity of each test could not be directly estimated.

Our study showed several interesting results. First, despite studies in Holland and Italy that have found higher participation rate with FIT (16,20), in our study, this rate remains low (36.5%) and no difference has been highlighted versus g-FOBT (36.7%).

Moreover, these data are in line with national registries data of the 2015-2016 campaign, with a national average rate at 29.4% (28). Reluctance to do the test in France is probably far from relying just from the test used.

Invitations to participate at CRC screening with FIT test began belatedly (01/06/2015), so a part of the population had been invited late, and had probably not yet performed the test at the end of 2016, decreasing the participation rate in FIT group.

It can also be explained by the fact that the FIT tests were not delivered with the second dunning letters contrary to g-FOBT. However, this action would allow an increase of the participation rate of 10% (29). 77.09 % of individuals who made a FIT had already participated in a campaign with g-FOBT. The participants in CRC screening program appeared to be loyal but it had to be verified during next screening campaigns.

Colonoscopy rate was higher after a positive test in g-FOBT group (92.6% in FIT versus 95.5% in g-FOBT), but individuals invited late in FIT group may not have realized their colonoscopy at the collection data date. Other screening studies have shown an equal number of colonoscopy undergone between the two tests (16,30).

Secondary, as it was expected, the FIT positivity rate was more than twice as high compared to the g-FOBT (respectively 4.35% and 1.94%).

Whatever the lesion (polyp, advanced adenoma or invasive cancer), detection rates and predictive positive values were significantly higher with FIT, as reported in several studies (31–34). Compared to g-FOBT, and based on our data, FIT can detect more AA and more invasive cancer than g-FOBT. This increase of detection rate was not explained by a most important first participation in FIT group, contrary to 2 studies that reported an increase detection rate of lesions in population who had never been screened before, creating a bias (16,32). In our study, only 22.9% of the subjects in FIT group participated for the first time in screening campaign.

Colorectal cancer detection rate was statistically higher in FIT group compared to g-FOBT group (0.09 [0.07-0.12]; 0.31 [0.27-0.35]; difference 0.22 [0.17-0.27], p<0.0001)).

No difference was found concerning localization or stage of invasive cancer between the tests, even after adjusting on sex, as reported in the literature (16,17,34–38).

One study, in French screening conditions, has compared g-FOBT (Hemoccult II®) and another FIT (MAGSTREAM®) for detection of colonic lesions according to lesion type and location. The authors found a gain in sensitivity restricted in rectal cancer in early stage (there were no differences depending on location in advanced adenomas) (32). In other studies comparing FIT to colonoscopy, FIT had lower sensitivity to diagnose CRC in distal colon than proximal colon and rectum (39,40).

We haven't found better accuracy for the diagnostic of rectal, distal or proximal colon cancer by FIT compared to g-FOBT.

Interestingly, among patients with CRC, subjects who did the last g-FOBT have significantly more proximal cancers. Given the average 10-year delay for an adenoma to become cancer, it is highly likely that these lesions were already present two years earlier (when the g-FOBT was performed). As FIT detects more AA, invasive CRC and right colon cancer after a negative screening test, interval cancers could be decreased in future as reported by Portillo *et al.* (41); proximal location or right-sided colon seem to be a risk factor when developing an interval cancer (OR=0.28, 95%CI: 0.20-0.40, $p < 0.0001$)

More adenomas were diagnosed by FIT than g-FOBT, and more adenomas with a higher risk of malignant transformation (more villous and tubulovillous lesions). g-FOBT had

poor sensitivity to screen advanced neoplasia (advanced adenomas and CRC) (42,43). FIT permitted to screen 4.7 times more advanced neoplasia.

However, we didn't identify differences between polyp's localization between the 2 tests, even after adjusting on sex.

Serrated polyps can represent 9% of all ones after 50 years (44). We now know that serrated polyps had potential for dysplasia and malignant transformation, and can represent up to 30% of all CRC (45), because of a specific epigenetic malignant pathway (46), particularly in interval cancer. In our study, more serrated polyps were found with g-FOBT (6.3% vs 3.8%) but the most of them were not degenerated, except 1 polyp in FIT group in high grade dysplasia. Our results are in line with a recent study that did not find any association between FIT and detection of serrated adenomas (47).

Our study had also several drawbacks. This is a retrospective study, monocenter (one department).

Individuals with insufficient preparation were very low, probably because bowel preparation, defined by Boston's score, is not always mentioned in colonoscopy's reports. In CAP SANTE 49 registry, if caecum was intubated, the colonoscopy was considerate as well prepared.

There was a lot of missing information regarding the lesion's size. Sizes were recorded by endoscopists and not by pathologists such as in literature. As proved in several studies, macroscopic evaluation by endoscopist was neither reproducible nor reliable and pathologist evaluation should be preferred (48). 122 lesions weren't collected after colonoscopy for anatomopathological analysis and could create a bias in polyp analysis.

In conclusion, in our study FIT doesn't increase participation rate to CRC screening but the positivity rate and the detection rate of polyps, advanced adenomas and cancers was higher than g-FOBT. There was a higher proportion of right colon cancer in patients who have done a g-FOBT two years before being diagnosed by FIT. This could decrease interval cancer in the future.

BIBLIOGRAPHY

1. Bossard N B-FF. Estimation nationale de l'incidence et de la mortalité par cancer en France entre 1980 et 2012. Partie 1 - Tumeurs solides. Saint-Maurice (Fra) : Institut de veille sanitaire ; 2013. 122p. [Internet]. [cited 2017 Apr 19]. Available from: http://invs.santepubliquefrance.fr/Dossiers-thematiques/Maladies-chroniques-et-traumatismes/Cancers/Surveillance-epidemiologique-des-cancers/Estimations-de-l-incidence-de-la-mortalite-et-de-la-survie/Estimation-de-l-incidence-et-de-la-mortalite-par-cancer-en-France-metropolitaine-entre-1980-et-2012-Tumeurs-solides

2. Leone N, Voirin N, Roche L, Binder-Foucard F, Woronoff A-S, Delafosse P, et al. Rapport technique. 2015 [cited 2017 May 20]; Available from: http://invs.santepubliquefrance.fr/%20fr/content/download/119170/419329/version/2/file/rapport_projection_incidence_mortalite_cancer_france_2015.pdf

3. Holleczek B, Rossi S, Domenic A, Innos K, Minicozzi P, Francisci S, et al. On-going improvement and persistent differences in the survival for patients with colon and rectum cancer across Europe 1999-2007 - Results from the EUROCARE-5 study. Eur J Cancer Oxf Engl 1990. 2015 Oct;51(15):2158–68.

4. Cowppli-Bony A, Uhry Z, Remontet L, Guizard A-V, Voirin N, Monnereau A, et al. Survie des personnes. 2016 [cited 2017 Sep 20]; Available from: http://invs.santepubliquefrance.fr/content/download/121812/430132/version/1/file/rapport_survie_personnes_atteintes_cancer_france_metropolitaine_1989_2013_tumeurs_solides.pdf

5. Tinmouth J, Lansdorp-Vogelaar I, Allison JE. Faecal immunochemical tests versus guaiac faecal occult blood tests: what clinicians and colorectal cancer screening programme organisers need to know. Gut. 2015 Aug;64(8):1327–37.

6. Wahrendorf J, Robra BP, Wiebelt H, Oberhausen R, Weiland M, Dhom G. Effectiveness of colorectal cancer screening: results from a population-based case-control evaluation in Saarland, Germany. Eur J Cancer Prev Off J Eur Cancer Prev Organ ECP. 1993 May;2(3):221–7.

7. Selby JV, Friedman GD, Quesenberry CP, Weiss NS. Effect of fecal occult blood testing on mortality from colorectal cancer. A case-control study. Ann Intern Med. 1993 Jan 1;118(1):1–6.

8. Lazovich D, Weiss NS, Stevens NG, White E, McKnight B, Wagner EH. A case-control study to evaluate efficacy of screening for faecal occult blood. J Med Screen. 1995;2(2):84–9.

9. Hardcastle JD, Chamberlain JO, Robinson MH, Moss SM, Amar SS, Balfour TW, et al. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. Lancet Lond Engl. 1996 Nov 30;348(9040):1472–7.

10. Kronborg O, Fenger C, Olsen J, Jørgensen OD, Søndergaard O. Randomised study of screening for colorectal cancer with faecal-occult-blood test. The Lancet. 1996 Nov 30;348(9040):1467–71.

11. Faivre J, Dancourt V, Lejeune C, Tazi MA, Lamour J, Gerard D, et al. Reduction in colorectal cancer mortality by fecal occult blood screening in a French controlled study. Gastroenterology. 2004 Jun;126(7):1674–80.

12. Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, et al. Reducing Mortality from Colorectal Cancer by Screening for Fecal Occult Blood. N Engl J Med. 1993 May 13;328(19):1365–71.

13. Saito H, Soma Y, Koeda J, Wada T, Kawaguchi H, Sobue T, et al. Reduction in risk of mortality from colorectal cancer by fecal occult blood screening with immunochemical hemagglutination test. A case-control study. Int J Cancer. 1995 May 16;61(4):465–9.

14. Chiu H-M, Chen SL-S, Yen AM-F, Chiu SY-H, Fann JC-Y, Lee Y-C, et al. Effectiveness of fecal immunochemical testing in reducing colorectal cancer mortality from the One Million Taiwanese Screening Program. Cancer. 2015 Sep 15;121(18):3221–9.

15. Zorzi M, Fedeli U, Schievano E, Bovo E, Guzzinati S, Baracco S, et al. Impact on colorectal cancer mortality of screening programmes based on the faecal immunochemical test. Gut. 2015 May;64(5):784–90.

16. van Rossum LG, van Rijn AF, Laheij RJ, van Oijen MG, Fockens P, van Krieken HH, et al. Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population. Gastroenterology. 2008 Jul;135(1):82–90.

17. Guittet L, Bouvier V, Mariotte N, Vallee JP, Arsène D, Boutreux S, et al. Comparison of a guaiac based and an immunochemical faecal occult blood test in screening for colorectal cancer in a general average risk population. Gut. 2007 Feb;56(2):210–4.

18. Hol L, van Leerdam ME, van Ballegooijen M, van Vuuren AJ, van Dekken H, Reijerink JCIY, et al. Screening for colorectal cancer: randomised trial comparing guaiac-based and immunochemical faecal occult blood testing and flexible sigmoidoscopy. Gut. 2010 Jan 1;59(01):62–8.

19. von Karsa L, Patnick J, Segnan N, Atkin W, Halloran S, Lansdorp-Vogelaar I, et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: Overview and introduction to the full Supplement publication. Endoscopy. 2013;45(1):51–9.

20. Federici A, Rossi PG, Borgia P, Bartolozzi F, Farchi S, Gausticchi G. The immunochemical faecal occult blood test leads to higher compliance than the guaiac

for colorectal cancer screening programmes: a cluster randomized controlled trial. J Med Screen. 2005;12(2):83–88.

21. Hoffman RM, Steel S, Yee EFT, Massie L, Schrader RM, Murata GH. Colorectal cancer screening adherence is higher with fecal immunochemical tests than guaiac-based fecal occult blood tests: a randomized, controlled trial. Prev Med. 2010 Jun;50(5–6):297–9.

22. Cole SR, Young GP, Esterman A, Cadd B, Morcom J. A randomised trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. J Med Screen. 2003;10(3):117–22.

23. Hassan C, Giorgi Rossi P, Camilloni L, Rex DK, Jimenez-Cendales B, Ferroni E, et al. Meta-analysis: adherence to colorectal cancer screening and the detection rate for advanced neoplasia, according to the type of screening test. Aliment Pharmacol Ther. 2012 Nov;36(10):929–40.

24. Rapport - Place des tests immunologiques de recherche de sang occulte dans les selles (iFOBT) dans le programme de dépistage organisé du cancer colorectal en France - rapport_-_place_des_tests_immunologiques_de_recherche_de_sang_occulte_dans_les_selles_ifobt.pdf [Internet]. [cited 2017 Aug 19]. Available from: file:///C:/Users/M&J/AppData/Roaming/Mozilla/Firefox/Profiles/kfsppfn6.default/zotero/storage/UK4ZHBZ8/rapport_-_place_des_tests_immunologiques_de_recherche_de_sang_occulte_dans_les_selles_ifobt.pdf

25. Edge SB, Compton CC. The American Joint Committee on Cancer: the 7th edition of the AJCC cancer staging manual and the future of TNM. Ann Surg Oncol. 2010 Jun;17(6):1471–4.

26. Winawer SJ, Zauber AG, Fletcher RH, Stillman JS, O'Brien MJ, Levin B, et al. Guidelines for Colonoscopy Surveillance After Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. Gastroenterology. 2006 May 1;130(6):1872–85.

27. Burch JA, Soares-Weiser K, St John DJB, Duffy S, Smith S, Kleijnen J, et al. Diagnostic accuracy of faecal occult blood tests used in screening for colorectal cancer: a systematic review. J Med Screen. 2007;14(3):132–137.

28. Taux de participation au programme de dépistage organisé du cancer colorectal 2015-2016. [Internet]. [cited 2017 Sep 24]. Available from: http://invs.santepubliquefrance.fr/Dossiers-thematiques/Maladies-chroniques-et-traumatismes/Cancers/Evaluation-des-programmes-de-depistage-des-cancers/Evaluation-du-programme-de-depistage-du-cancer-colorectal/Indicateurs-d-evaluation/Taux-de-participation-au-programme-de-depistage-organise-du-cancer-colorectal-2015-2016

29. Piette C, Durand G, Bretagne J-F, Faivre J. Additional mailing phase for FIT after a medical offer phase: The best way to improve compliance with colorectal cancer screening in France. Dig Liver Dis Off J Ital Soc Gastroenterol Ital Assoc Study Liver. 2017 Mar;49(3):308–11.

30. Ko CW, Dominitz JA, Nguyen TD. Fecal occult blood testing in a general medical clinic: comparison between guaiac-based and immunochemical-based tests. Am J Med. 2003 Aug 1;115(2):111–4.

31. Allison JE, Tekawa IS, Ransom LJ, Adrain AL. A Comparison of Fecal Occult-Blood Tests for Colorectal-Cancer Screening. N Engl J Med. 1996 Jan 18;334(3):155–60.

32. Guittet L, Bouvier V, Mariotte N, Vallee JP, Levillain R, Tichet J, et al. Comparison of a guaiac and an immunochemical faecal occult blood test for the detection of colonic lesions according to lesion type and location. Br J Cancer. 2009 Mar 31;100(8):1230–5.

33. De Wijkerslooth TR, Stoop EM, Bossuyt PM, Meijer GA, Van Ballegooijen M, Van Roon AHC, et al. Immunochemical fecal occult blood testing is equally sensitive for proximal and distal advanced neoplasia. Am J Gastroenterol. 2012;107(10):1570.

34. Castiglione G, Zappa M, Grazzini G, Mazzotta A, Biagini M, Salvadori P, et al. Immunochemical vs guaiac faecal occult blood tests in a population-based screening programme for colorectal cancer. Br J Cancer. 1996;74(1):141.

35. Levi Z, Birkenfeld S, Vilkin A, Bar-Chana M, Lifshitz I, Chared M, et al. A higher detection rate for colorectal cancer and advanced adenomatous polyp for screening with immunochemical fecal occult blood test than guaiac fecal occult blood test, despite lower compliance rate. A prospective, controlled, feasibility study. Int J Cancer. 2011 May 15;128(10):2415–24.

36. Nakama H, Kamijo N, Abdul Fattah AS, Zhang B. Validity of immunological faecal occult blood screening for colorectal cancer: a follow up study. J Med Screen. 1996;3(2):63–5.

37. Robinson MH, Marks CG, Farrands PA, Thomas WM, Hardcastle JD. Population screening for colorectal cancer: comparison between guaiac and immunological faecal occult blood tests. Br J Surg. 1994 Mar;81(3):448–51.

38. Petrelli N, Michalek AM, Freedman A, Baroni M, Mink I, Rodriguez-Bigas M. Immunochemical versus guaiac occult blood stool tests: results of a community-based screening program. Surg Oncol. 1994 Feb;3(1):27–36.

39. Morikawa T, Kato J, Yamaji Y, Wada R, Mitsushima T, Shiratori Y. A Comparison of the Immunochemical Fecal Occult Blood Test and Total Colonoscopy in the Asymptomatic Population. Gastroenterology. 2005 Aug 1;129(2):422–8.

40. Chiu H, Lee Y, Tu C, Chen C, Tseng P, Liang J, et al. Association Between Early Stage Colon Neoplasms and False-negative Results From the Fecal Immunochemical Test. Clin Gastroenterol Hepatol. 2013 Jul;11(7):832–838.e2.

41. Portillo I, Arana-Arri E, Idigoras I, Bilbao I, Martínez-Indart L, Bujanda L, et al. Colorectal and interval cancers of the Colorectal Cancer Screening Program in the Basque Country (Spain). World J Gastroenterol. 2017 Apr 21;23(15):2731–42.

42. Graser A, Stieber P, Nagel D, Schäfer C, Horst D, Becker CR, et al. Comparison of CT colonography, colonoscopy, sigmoidoscopy and faecal occult blood tests for the detection of advanced adenoma in an average risk population. Gut. 2009 Feb;58(2):241–8.

43. Jouve JL, Remontet L, Dancourt V, Lejeune C, Benhamiche AM, Faivre J, et al. Estimation of screening test (Hemoccult®) sensitivity in colorectal cancer mass screening. Br J Cancer. 2001 Jun;84(11):1477–81.

44. Abdeljawad K, Vemulapalli KC, Kahi CJ, Cummings OW, Snover DC, Rex DK. Sessile serrated polyp prevalence determined by a colonoscopist with a high lesion detection rate and an experienced pathologist. Gastrointest Endosc. 2015 Mar;81(3):517–24.

45. Rex DK, Ahnen DJ, Baron JA, Batts KP, Burke CA, Burt RW, et al. Serrated Lesions of the Colorectum: Review and Recommendations From an Expert Panel. Am J Gastroenterol. 2012 Sep;107(9):1315–29.

46. Ma MX, Bourke MJ. Sessile Serrated Adenomas: How to Detect, Characterize and Resect. Gut Liver [Internet]. [cited 2017 Sep 16]; Available from: http://www.gutnliver.org/journal/view.html?doi=10.5009/gnl16523

47. Zorzi M, Senore C, Da Re F, Barca A, Bonelli LA, Cannizzaro R, et al. Detection rate and predictive factors of sessile serrated polyps in an organised colorectal cancer screening programme with immunochemical faecal occult blood test: the EQuIPE study (Evaluating Quality Indicators of the Performance of Endoscopy). Gut. 2017 Jul;66(7):1233–40.

48. Chaptini L, Chaaya A, Depalma F, Hunter K, Peikin S, Laine L. Variation in polyp size estimation among endoscopists and impact on surveillance intervals. Gastrointest Endosc. 2014 Oct 1;80(4):652–9.

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Figure 1 : Flow Chart

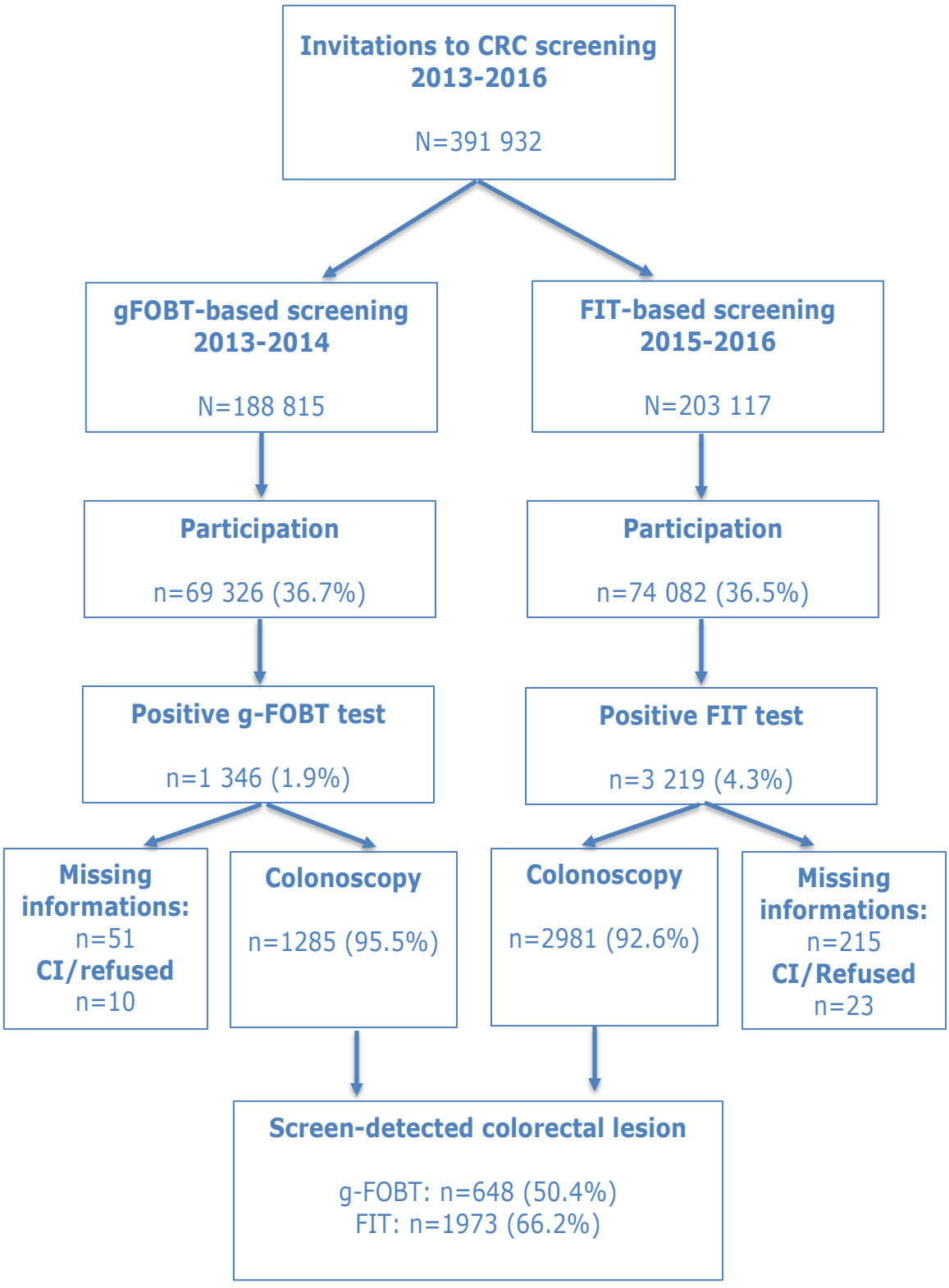

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Table I: Characteristics of patients with screen-detected colorectal lesion.

	Overall (N=2621)		**g-FOBT (n=648)**		**FIT (n=1973)**		***p-value***
Age: mean +/- SD	63.1+/-6.9		62.7+/-7.1		63.4+/-6.9		*0.062*
	n	%	n	%	n	%	
Age class							*0.541*
<55	422	16.1	115	17.7	307	15.5	
55-59	490	18.7	125	19.3	365	18.5	
60-64	561	21.4	141	21.8	420	21.3	
65-69	634	24.2	145	22.4	485	24.8	
70+	514	19.6	122	18.8	392	19.9	
Gender							*0.273*
Male	1641	62.6	394	60.8	1247	63.2	
Female	980	37.4	254	39.2	726	36.8	
1st participation in CRC screening	590	22.5	138	21.3	452	22.9	*0.394*

Table II: Test performance of g-FOBT (Hemoccult II®) versus FIT (OC Sensor®).

	g-FOBT			FIT			*p-values*
	n	**%**	**CI 95%**	**n**	**%**	**CI 95%**	
Participation rate	69326	36.7	[36.5-36.9]	74082	36.5	[36.3-36.7]	0.1045
FOBT positive patient	1346	1.9	[1.8-2.1]	3219	4.4	[4.2-4.5]	**<0.0001**
Completed screening	1290	95.8	[94.6-96.8]	2993	93.0	[92.0-93.8]	**0.0003**
Detection Rate°							
Any lesion	648	0.93	[0.86-1.01]	1973	2.66	[2.55-2.78]	**<0.0001**
AA	266	0.38	[0.34-0.43]	1230	1.66	[1.57-1.75]	**<0.0001**
CRC	63	0.09	[0.07-0.12]	229	0.31	[0.27-0.35]	**<0.0001**
AA or CRC	289	0.42	[0.37-0.47]	1459	1.98	[1.89-2.09]	**<0.0001**
PPV#							
Any lesion	648	50.2	[47.6-53.0]	1973	65.9	[64.2-67.6]	**<0.0001**
AA	266	20.6	[18.5-22.9]	1230	41.1	[39.4-42.9]	**<0.0001**
CRC	63	4.9	[3.8-6.2]	229	7.7	[6.8-8.7]	**0.001**
AA or CRC	289	22.4	[20.2-24.8]	1459	48.8	[47.0-50.6]	**<0.0001**

°detection rate: percentage of individuals with lesions relative to the total number of participants in CRC screening campaigns
#positive predictive value: percentage of individuals with lesions relative to the number of participants who screened positive and underwent colonoscopy or CTC
AA: Advanced Adenomas, CRC: Colorectal Cancer, PPV: Positive Predictive Value

Table III: Comparison of polyps characteristics diagnosed after a g-FOBT versus a FIT.

	g-FOBT		**FIT**		***p-values***
Number of polyps	**n=757**		**n=2565**		
	n	**%**	**n**	**%**	
Subdivision of polyps @					***0.008***
Adenoma	695	91.8	2411	94.0	
Serrated polyps	48	6.3	98	3.8	
ISC	12	1.6	34	1.3	
Others	2	0.3	22	0.9	
Localization of polyps @					*0.225*
Rectum	76	10.1	242	9.5	
Left colon	384	50.9	1381	54.4	
Transverse and Right colon	295	39.1	915	36.1	
Missing data	2		27		
Dysplasia @					*0.142*
Low grade	624	88.4	2109	86.3	
High grade + carcinoma	70+12	11.6	302+34	13.7	
No dysplasia	2		22		
Missing data	49		98		
Size of polyps (mm) @					***<0.0001***
≤5	219	42.9	668	32.2	
6-9	100	19.6	458	22.1	
≥10	192	37.6	950	45.8	
Missing data	246		489		

@: the worse 3 by colonoscopy

Table IV: Characteristics of adenomas diagnosed after a FIT versus a g-FOBT.

	g-FOBT		FIT		*p-value*
	n	**%**	**n**	**%**	
Subdivision of adenomas					***<0.0001***
Tubular	516	74.2	1579	65.5	
Tubulovillous or villous	179	25.8	832	34.5	
Size of Adenomas (mm)					***<0.0001***
≤5	204	43.5	641	32.6	
6-9	90	19.2	435	22.1	
≥10	175	37.3	888	45.3	
Missing data	226		447		
Localization of adenomas					*0.4*
Rectum	72	10.4	228	9.6	
Left colon	364	52.5	1322	55.4	
Transverse and Right colon	257	37.1	836	35.0	
Dysplasia					*0.086*
Low grade	624	89.9	2109	87.5	
High grade	70	10.1	301	12.5	
Missing data	1		1		

ISC not include

Table V: Characteristics of Advanced adenomas and In Situ Carcinoma diagnosed after a FIT versus a g-FOBT.

	g-FOBT		FIT		*p value*
	n	**%**	**n**	**%**	
Advanced adenomas (AA)°	**266**	**35.1**	**1230**	**48.0**	***<0.0001***
Localization of AA					*0.068*
Rectum	36	13.6	146	12.0	
Left colon	182	68.9	780	64.0	
Transverse and Right colon	46	17.4	292	24.0	
Missing data	2		12		
In Situ Carcinomas (ISC)°	**12**	**1.6**	**34**	**1.3**	*0.591*
Size of ISC (mm)					*0.976*
≤5	0	0	0	0	
6-9	1	10	3	9.7	
≥10	9	90	28	90.3	
Unknown	2		3		
Localization of ISC					*0.879*
Rectum	2	16.7	6	17.6	
Left colon	8	66.6	24	70.6	
Transverse and Right colon	2	16.7	4	11.8	

° percentage of all polyps diagnosed
AA: size ≥ 10mm, villous component or high-grade dysplasia

Table VI: Main characteristics of polyps including adenomas in male and female diagnosed after a g-FOBT or a FIT.

	Female				**Male**				***p-value***	
	g-FOBT		**FIT**		**g-FOBT**		**FIT**		**Female**	**Male**
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**		
Subdivision°									***0.037***	***0.022***
Adenoma	161	91.5	499	92.2	274	93.5	929	97.0		
Serrated polyps	13	7.4	21	3.9	9	3.1	16	1.7		
ISC	2	1.1	21	3.9	10	3.4	13	1.4		
Localization of Adenomas									*0.109*	*0.102*
Rectum	18	10.3	51	9.5	33	11.3	100	10.4		
Left colon	93	53.1	332	61.8	155	53.1	575	60.0		
Transverse and right colon	64	36.6	154	28.7	104	35.6	284	29.6		
Missing data	1		5		1		4			
Size of Adenomas*									***0.006***	***<0.0001***
≤5	50	39.1	123	25.6	69	33.8	162	19.1		
6-9	24	18.8	89	18.5	35	17.2	180	21.3		
≥10	54	42.2	269	55.9	100	49.0	505	59.6		
Missing data	48		61		89		116			
Localization of AA									*0.378*	*0.882*
Rectum	10	14.3	35	10.2	20	14.4	78	12.8		
Left colon	50	71.4	239	69.7	91	65.5	405	66.5		
Transverse and right colon	10	14.3	69	20.1	28	20.1	126	20.7		
Missing data	1		3		1		3			

° subdivision in all polyps
** Size in millimeters*

Table VII: Characteristics of serrated polyps diagnosed after a g-FOBT versus a FIT.

	g-FOBT		**FIT**		***p-value***
	n	**%**	**n**	**%**	
Serrated polyps §	**48**	**6.3**	**98**	**3.8**	***0.003***
Localization					
Rectum	1	2.1	3	3.1	*1*
Left colon	11	22.9	23	24.0	
Transverse and right colon	36	75	70	72.9	
Missing data	0		2		
Size (mm)					
≤5	15	46.9	24	36.9	*0.412*
6-9	9	28.1	16	24.6	
≥10	8	25	25	38.5	
Missing data	16		33		
Dysplasia					
No	48	100	97	99.0	
High grade	0	0	1	1.0	

§ percentage of all polyps diagnosed

Table VIII: Characteristics of Invasive cancers diagnosed after a g-FOBT or a FIT.

Invasive cancer	**g-FOBT n=63**		**FIT n=229**		***p-value***
	n	**%**	**n**	**%**	
Localization					*0.551*
Rectum	16	25.4	67	29.3	*0.547*
Left colon	28	44.4	108	47.2	*0.702*
Transverse and right colon	19	30.2	54	23.6	*0.286*
Subdivision of cancers					*0.108*
ADK	51	81.0	206	90.0	
ADK with colloid component	10	15.9	21	9.2	
Other	2	3.2	2	0.9	
Differentiation for ADK					0.962
Well	23	39.0	84	39.4	
Intermediate	34	57.6	123	57.7	
Low	2	3.4	6	2.8	
Missing data	2		14		
Subdivision in Stages					0.987
1	24	40.0	92	41.1	
2	14	23.3	53	23.7	
3	16	26.7	60	26.8	
4	6	10	19	8.5	
NA or Missing data	3		5		

NA: not applicable ; ADK: adenocarcinoma

Table IX: Characteristics of invasive cancer in male and female diagnosed after a g-FOBT or a FIT.

	Females				**Males**				***p-values***	
	g-FOBT		**FIT**		**g-FOBT**		**FIT**		**Females**	**Males**
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**		
Localization										
Rectum	3	13	18	22.5	13	32.5	49	32.9	*0.393*	*0.963*
Left colon	10	43.5	40	50.0	18	45	68	45.6	*0.581*	*0.943*
Transverse and right colon	10	43.5	22	27.5	9	22.5	32	21.5	*0.144*	*0.889*
Differentiation for ADK									*0.391*	*0.659*
Well	7	30.4	27	36.0	17	45.9	57	41.3		
Intermediate	14	60.9	46	61.3	20	54.1	77	55.8		
Low	2	8.7	2	2.7	0	0	4	2.9		
Missing data	0		2		0		7			
Subdivision in Stages									*0.689*	*0.620*
1	7	31.8	30	39.5	17	44.7	62	41.9		
2	6	27.3	18	23.7	8	21.1	35	23.6		
3	8	36.4	20	26.3	8	21.1	40	27		
4	1	4.5	8	10.5	5	13.2	11	7.4		
NA or Missing data	1		4		2		1			

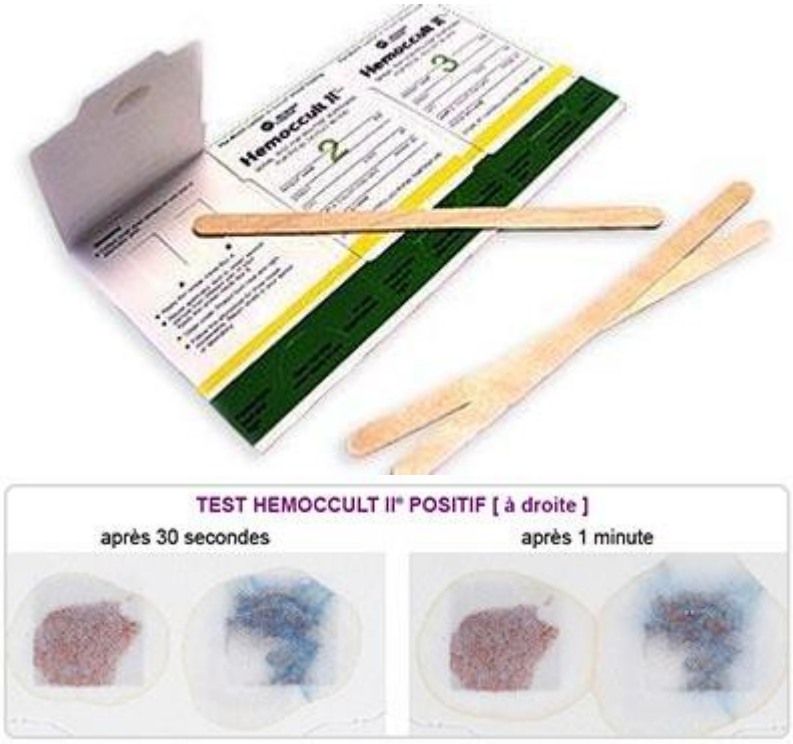
ADK: adenocarcinoma; NA: not applicable

Table X: Characteristics of Invasive cancers diagnosed after an OC Sensor® test.

	First test or last test > 2 years		**Negative Hemoccult II® test 2 years before**		***p-value***
	n	**%**	**n**	**%**	
Gender					*0.838*
Male	52	64.2	97	65.5	
Female	29	35.8	51	34.5	
Localization					***0.049***
Rectum	29	35.8	38	25.7	*0.107*
Left colon	40	49.4	68	45.9	*0.618*
Transverse and right colon	12	14.8	42	28.4	***0.021***
Subdivision in Stages					*0.396*
1	38	48.1	54	36.7	
2	15	19.0	38	25.9	
3	19	24.1	41	27.9	
4	7	8.9	14	9.5	
NA or Missing data	2		1		

NA: not applicable

ANNEX



g-FOBT: Hemoccult II® - cost : 1.16 euros

FIT: OC Sensor® – cost : 1.50 euros

LALY Margot

Apports du test immunologique OC Sensor® par rapport au test au gaïac Hemoccult II® dans le dépistage organisé du cancer colorectal.

RÉSUMÉ

Introduction: Le cancer colorectal est un véritable enjeu de santé publique du fait de son incidence importante et de son taux de mortalité élevé. Le dépistage organisé du cancer colorectal, instauré en France depuis 2008 avec des tests fécaux de recherche de sang occulte au gaïac (g-FOBT) puis immunochimiques (FIT) depuis 2015. L'objectif de notre étude rétrospective était de comparer deux campagnes successives de dépistage, utilisant les deux tests (Hemoccult II® et OC Sensor®), pour préciser les taux de participation (PP), de positivité (PR), de détection (DR) et les valeurs prédictives positives (VPP), ainsi que de décrire les caractéristiques des adénomes et des cancers diagnostiqués.
Méthodes: Tous les individus, âgés de 50 à 75 ans, invités par CAP SANTE 49 à participer au dépistage (avec un g-FOBT du 01/01/2013 au 31/12/2014 puis un FIT du 01/06/2015 au 31/12/2016) et ayant eu une coloscopie positive après un test positif ont été recueilli.
Résultats: Il n'y a pas de différence statistique entre les PP quelque soit le test utilisé (p=0.104). Les PR, DR et PPV sont statistiquement plus élevées avec le FIT quelques soient les lésions détectées (1.9%, 95%CI [1.8-2.1] ; 2.35%, 95%CI [2.25-2.47]; 65.92%, 95%CI [64.20-67.60] versus 4.4%, 95%CI [4.2-4.5] ; 0.84%, 95%CI [0.78-0.91] ; 50.23%, 95%CI [47.51-52.96] avec le g-FOBT respectivement, tous p<0.0001). 2621 individus avaient au moins une lésion, 648 après un g-FOBT et 1973 après un FIT. Concernant les cancers colorectaux, le DR était significativement plus élevé avec le FIT (p<0.0001), sans différence significative concernant les localisations, différenciations ou stades au diagnostic, même après stratification sur le sexe. Une plus grande proportion de cancers proximaux a été retrouvée chez les patients qui avaient fait un g-FOBT deux ans avant le FIT (p=0.049).
Conclusion: Aucune différence entre les taux de participation n'a été mise en évidence entre les 2 tests mais les PR, DR et PPV étaient supérieures quel que soit le type de lésion trouvée. Le FIT a permis de diagnostiquer plus de cancer du côlon droit chez les patients ayant fait un g-FOBT 2 ans auparavant, laissant entrevoir la possibilité de diminuer à terme le taux de cancers d'intervalle.

Mots-clés : cancer colorectal, dépistage organisé, test immunologique, adénome

Contribution of the OC Sensor® immunoassay in comparison to the Hemoccult II® guaiac-test in organized colorectal cancer screening.

ABSTRACT

Introduction: Colorectal cancer (CRC) is a real public health issue, with high incidence and mortality rate, accessible to a screening program in France, first with guaiac-based fecal occult blood test (g-FOBT) then with fecal immunochemical test (FIT), since 2015, because of better accuracy. The aim of our retrospective study was to compare 2 successive CRC screening campaigns, using 2 different tests (Hemoccult II® and OC Sensor®) in Maine-et-Loire department, to precise population participation (PP), positivity and detection rates (PR, DR), positive predictive value (PPV) and to describe characteristics of CRC and adenomas screened between the two tests.
Methods: Participants, invited by CAP SANTE 49, with polyps or cancer detected at the colonoscopy after a positive screening test between 01/01/2013 and 31/12/2016 were included.
Results: 2621 individuals, 648 with g-FOBT and 1973 with FIT had lesions. PP was not different between tests (p=0.104). PR, DR and PPV were statistically higher in FIT for all lesions (4.4, 95%CI [4.2-4.5]; 2.35, 95%CI [2.25-2.47]; 65.92, 95%CI [64.20-67.60] versus 1.9, 94%CI [1.8-2.1]; 0.84, 95%CI [0.78-0.91]; 50.23, 95%CI [47.51-52.96] for g-FOBT respectively; all p<0.0001). DR for CRC was also significantly higher in (p<0.0001), without statistical differences in type, localization, differentiation or stage, even after stratification by sex. A higher proportion of proximal colon cancer in patients who made a g-FOBT two years before the FIT was found (p=0.049).
Conclusion: FIT doesn't increase participation rate to CRC screening but DR and PPV of all lesions was higher. A higher proportion of right colon cancer was diagnosed by FIT in patients who made a negative g-FOBT two years before.

Keywords : colorectal cancer; mass screening; Fecal Immunochemical Test; adenoma

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