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ORIGINAL PAPERS

Colonoscopy quality assessment in a mass population screening programme based on faecal occult blood test

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ABSTRACT

Background and aim: the success of colorectal cancer (CRC) screening programmes largely depends on the quality of the events, processes and outcomes and therefore, quality assurance of endoscopy is an essential component. The quality indicators for colonoscopy in a screening programme setting are different from those performed in symptomatic people. The objective of this study was to report the main quality indicators of colonoscopies performed after a positive faecal occult blood test (FOBT) in a CRC screening programme in Catalonia.

Methods: the period of study includes three rounds of the CRC screening programme from June 2006 to July 2013. Two types of FOBT were used: a qualitative biochemical guaiac-based test (gFOBT) and a quantitative immunochemical test (FIT). Quality indicators analysed in this study were compared to recommended colonoscopy standards from the published guidelines.

Results: during the study period, 1,806 colonoscopies were performed in 1,691 individuals with a positive FOBT. All indicators were within the standard except waiting time to colonoscopy. Caecal intubation rate was 95.6 % and adequate bowel cleansing 93.6 %. Adenoma detection rate was better using FIT than gFOBT, 30.7 and 3.8 per 1,000 screenees, respectively. Cancer detection rate was also greater using FIT. Nearly 62 % of cancers were diagnosed at an early stage. The overall complication rate was 10.7 ‰.

Conclusion: although the majority of results reached the recommended standards, some areas have been identified for quality enhancement. Continuous monitoring of quality indicators is essential for improving the current effectiveness of CRC screening programmes.

Key words: Colonoscopy. Quality indicators. Colorectal cancer. Mass screening programme.

INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer in Europe and is one of the leading causes of cancer death. An estimated 432,414 new CRC cases and 212,219 CRC deaths occur annually, which represents an age-standardized rate of 29.6 and 12.4 per 100,000, respectively (1). In Spain, CRC is the most incident cancer when considering both sexes together. There is a marked geographic variation in CRC rates, with Catalonia being the region with the highest incidence of this tumour with an adjusted rate above the European average, particularly in men (2,3).

Screening for early detection of CRC and its premalignant precursors with the faecal occult blood test (FOBT) has demonstrated efficacy in reducing mortality and is the recommended strategy in the European Union (4,5). During the last decade, organised CRC screening programmes have been increasingly adopted throughout Europe (6,7). In Spain, CRC screening programmes are implemented and managed on a regional basis. In 2000, the first population-based pilot screening programme for CRC using biennial FOBT was implemented in Catalonia (8). At present, twelve out of 17 Spanish regions have initiated screening programmes, 8 of them with results of at least one screening round (9). There is consensus regarding the need to extend this preventive task to the whole country in the coming years (10).

The success of screening programmes largely depends on the participation achieved and the quality of the pro-

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cedures used. Thus, the adoption of quality improvement measures and continuous quality assessment is imperative to improve the current effectiveness of CRC screening programmes (11,12). A very important point in this sense is the colonoscopy, which is a procedure that is not only diagnostic but also therapeutic. Colonoscopy in the screening context must be performed according to high-quality standards, especially regarding detection rates and safety (13-15). Individuals with a normal colonoscopy will be temporarily excluded from the screening programme, usually for a 10-year period, which means a lack of prevention for CRC when the diagnostic colonoscopy has been suboptimal and lesions have been overlooked. Measurement of quality indicators for colonoscopy reporting can help us identify areas for quality improvement.

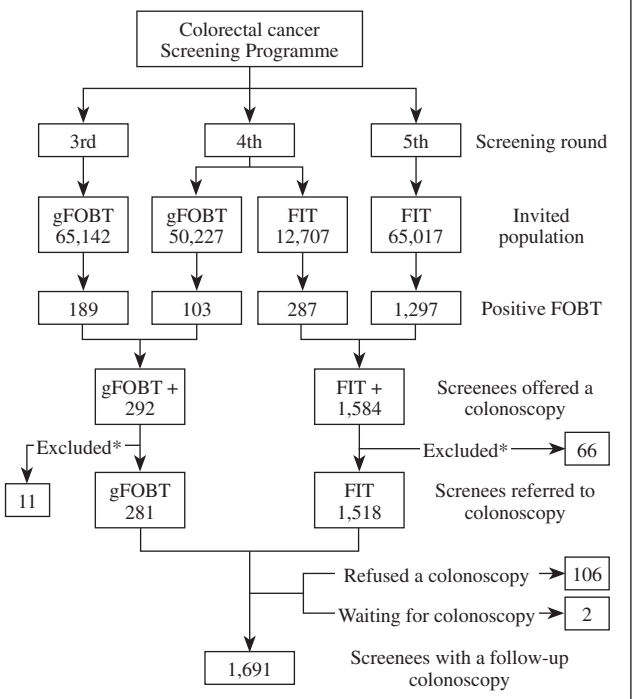
The objective of this study was to report the main quality indicators of colonoscopies performed in three rounds of the CRC screening programme in Catalonia, Spain.

METHODS

The CRC screening programme was addressed at asymptomatic men and women aged 50-69 years who lived in *L'Hospitalet de Llobregat,* an industrial city in the metropolitan area of Barcelona. Subjects who did not meet the inclusion criteria for CRC screening were definitely or temporally excluded according to the following criteria: Personal history of CRC or adenomas, hereditary and familial CRC, inflammatory bowel disease, colonoscopy in the previous 5 years, FOBT in less than 2 years, terminal disease and severe disabling condition. Subjects moving out of the screening area or whose invitation letter was returned because of an invalid mailing address were also excluded (16).

The period of study includes three rounds of the CRC screening programme, from June 2006 to July 2013. Two screening test strategies were used along that period. A qualitative biochemical guaiac-based test (gFOBT) was used in the third and fourth round (Hema-screen™, immunostics.inc), and a quantitative faecal immunochemical test (FIT), which was introduced as an alternative test in the fourth round and remained as the only strategy for the fifth round (OC Sensorμ, Palex) (17). Participants with gFOBT collected six faecal samples (two samples from three separate bowel movements) whereas only one sample was needed with FIT. The presence of faecal occult blood in five or six samples (or in any sample after retesting) and a cut off of 100 ng/mL were used to designate a positive FOBT result, for gFOBT and FIT respectively. All participants with a positive test result were advised to have colonoscopy.

The study population consisted of participants in the CRC screening programme during the study period with a positive FOBT who were offered a colonoscopy for diagnostic confirmation (Fig. 1).



FOBT: faecal occult blood test (gFOBT: guaiac test; FIT: immunochaemical test).

*Subjects with personal history of CRC, adenomas or inflammatory bowel disease, hereditary CRC syndromes, colonoscopy in the previous 5 years, terminal disease or severe disabling condition.

Fig. 1. Flow chart of the study population.

Procedure for further screening examination

All screenees with a positive FOBT were contacted by phone to provide information regarding the screening result and to advise them that they will be referred for colonoscopy examination. A preoperative evaluation was routinely required (haemostasis test and electrocardiogram for all individuals and a chest x-ray only for individuals older than 64 years or with a chronic disease). In addition to the preoperative exams, bowel-cleansing preparation was provided by primary health centres, either polyethylene glycol or sodium phosphate. Colonoscopies were scheduled in the afternoon on a specific agenda, taking the bowel-cleansing preparation the same morning, with 6 h complete fasting until the examination. For those who chose the private practice, a postage paid envelope was provided by the screening programme in order to receive a copy of the colonoscopy report. All the available information was included in the CRC screening programme, and therefore, in the analysis.

Four days prior to colonoscopy, patients were called to remind them about the appointment and to provide instructions for the bowel preparation.

Colonoscopies were performed with sedation on an outpatient basis at the Endoscopy Unit of the two coun-

ty Hospitals of L'Hospitalet by an expert team including a gastroenterologist, an anaesthesiologist, a nurse and a nurse's aide.

During the study period, a total of 16 gastroenterologists were part of the programme, some of them repeated round by round and other only took part in a short period of time or a specific round. The gastroenterologist screening team was composed by specialists, which are the ones who fulfil the experience criteria. All endoscopists achieved the minimum number of colonoscopies required before joining the screening programme.

Propofol was the drug used for sedation and was administered by the anaesthesiologists. Any detected polyp was described and removed when endoscopically possible. Number, size (mm), morphology (pedunculated, sessile or flat) and location (rectum, sigmoid, descending, transverse, ascending or caecum) were documented. Location was recoded as proximal (caecum, ascending and transverse) or distal (descending, sigmoid and rectum).

For incomplete colonoscopies, patients were offered a new attempt of colonoscopy or another diagnostic exploration, usually a barium enema. Subjects with cancer or polyps too large or complicated to be removed endoscopically were referred to surgery. Major immediate complications were also documented.

Polyp specimens and biopsies were analysed by pathologists and classified according to World Health Organization criteria, considering a high risk adenoma (HRA) or advanced adenoma any polyp larger than or equal to 10 mm, more than 2 adenomas, tubulo-villous or villous histology, high-grade dysplasia or carcinoma *in situ*; low risk adenoma (LRA), 1 or 2 adenoma smaller than 10 mm, with tubular histology and low grade dysplasia. The criterion for cancer diagnosis was an invasion of malignant cells beyond the *muscularis mucosa*. Tumour staging was performed according to the tumour node metastasis (TNM) system, which was gathered from the anatomic pathology result of the cancerous lesion and the extension study. Early-stage cancers were those classified as I or II according to the TNM system. Cases with more than one lesion were classified according to the most advanced lesion.

Follow-up colonoscopy was recommended to patients with adenomatous polyps detected in the screening programme. According to the Spanish CRC prevention practice guideline (18) a surveillance colonoscopy was recommended at 3 or 5 years when the baseline diagnostic was HRA and LRA, respectively. Cancers were referred to the tumour committee to begin treatment as soon as possible. If no adenomatous polyp was found, subjects would be invited again for screening with FOBT or a surveillance colonoscopy would be recommended after 10 years, according to age.

According to the result of the colonoscopy and polyp characteristics (number, size, histology and grade of dysplasia), each patient was classified in: normal colonoscopy, hyperplasic polyp, LRA, HRA, or cancer.

Data collection and analysis

The information system to manage the CRC screening programme included data on patient identification, participation, appointment dates, screening test and colonoscopy results.

Quality indicators analysed in this study were classified according to the endoscopic examination in three groups: pre-procedure, procedure and post-procedure (19).

The *pre-procedure* period starts with the first contact with the patient until administration of sedation. We considered the following pre-procedural indicators: a) colonoscopy compliance defined as the proportion of people with a positive FOBT who underwent colonoscopy; b) time interval (days) to colonoscopy after a positive FOBT. This was assessed using the proportion of screenees who were scheduled for a colonoscopy within 31 days; and c) sedation use, calculated as the proportion of colonoscopies performed under sedation.

The *procedure* refers to the colonoscopy examination (from insertion to withdrawal). We calculated procedural-related indicators (events and processes) as well as procedural outcomes: a) bowel cleansing, using the Aronchick scale (20) (Excellent/Good/Fair/Poor/Insufficient). All cases were categorized at the end of the procedure as "adequate examination" (Excellent/Good/Fair), or "not adequate examination" (Poor/Insufficient); b) caecal intubation rates, calculated as the proportion of colonoscopies that reached the caecum. Visualization of the ileocaecal valve and/or intubation of the terminal ileum provided reassurance of the procedure's completeness; c) polyp-retrieval rate, calculated as the proportion of retrieved polyps from those removed; d) time interval (days) to the anatomic pathology result after the colonoscopy; e) adenoma and CRC positive predictive value (PPV), defined as the proportion of colonoscopies in which an adenoma or a CRC was found (documented on the anatomic pathology report); f) adenoma and CRC detection rate defined as the number of adenomas or CRC detected among those screened (FOBT done); and g) proportion of CRC diagnosed at an early stage.

Detection rates and PPV were analyzed by test (gFOBT *vs.* FIT) and by type of screening (prevalent or first screen *vs.* incident or subsequent screen).

Post-procedure: The adverse effects recorded were: perforation and post-polypectomy bleeding (involving transfusion or hospitalisation of at least 24 hours) and death (within 30 days).

Quality indicators calculated for this study were compared with standards proposed by the "European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis" (21), the Spanish "Clinical Practice Guideline: Quality of Colonoscopy in CRC Screening" (22).

Due to differences in some terms and indicators among health professionals (endoscopists and epidemiologists), main definitions and measures of each indicator used in our screening programme are shown in the Appendix.

RESULTS

From June 2006 to July 2013, 1,806 colonoscopies were performed in 1,691 individuals with a positive FOBT in the CRC screening programme of l'Hospitalet de Llobregat. The results of colonoscopies were: 31.4 % negatives (without any kind of lesion), 4.2 % hyperplasic polyps, 13.3 % LRA, 43.8 % HRA and 7.3 % cancer.

The main quality indicators related to colonoscopy and the standards established in the different guidelines mentioned are showed in table I.

Pre-procedure indicators

Colonoscopy compliance

From the 1,876 individuals with a positive FOBT, colonoscopy was not recommended in 77 cases due to medical criteria. The main reason was having a recent exploration. Thus, 1,799 people were referred to colonoscopy and the compliance was 94.0 % (Fig. 1). Most people had only one colonoscopy performed but 7.5 % needed a second one or other examinations. The most common reason was an incomplete polypectomy (i.e. the polyp size) or a polypectomy indication in patients receiving anticoagulant or anti-platelet agents without discontinuing the treatment 3-7 days prior to the colonoscopy.

Waiting time to colonoscopy

The median waiting time between the positive FOBT result and the colonoscopy was 55 days (range 38-69 days). Only the 14.2 % of patients had the colonoscopy performed within the European guideline standard of 31 days.

Sedation use

All except seven colonoscopies (3 for self-request, 2 for liquid intake within the 6 hours prior to colonoscopy, 1 for going on his/her own and 1 unknown) were done with sedation, which represented 99.6 %.

Intra-procedure indicators

Bowel cleansing and caecal intubation

Adequate colonic cleansing was observed in the 93.6 % of cases. The bowel preparation most frequently used was the polyethylene glycol.

The caecal intubation rate was within the range set by the European guidelines as desirable (95.6%). The most common reason for not reaching the caecum was stenosis (20 cases).

Polyp-retrieval

In 1,806 colonoscopies, 2,774 polyps were detected and 2,404 removed. The polyp-retrieval rate was 86.7 %, being higher for polyps larger than or equal to 10 mm (96.5 %) than for polyps smaller than 10 mm (82.6 %). These results met the standard of the gastroenterologist's clinical guidelines.

Adenomas and cancers detected: PPV and detection rates

In 90.0 % of colonoscopies, the anatomic pathology report of the polyps removed was obtained within 19 days.

A final diagnosis of adenoma was established in 960 patients (737 HRA and 223 LRA), which represented a PPV of 44.6 % for gFOBT and a 59.5 % for FIT.

Detection rates and PPV exceeded the standard values of both reference guidelines.

The adenoma detection rate was much higher in the FIT group than in the gFOBT, 30.7 and 3.8 per 1,000 screenees, respectively, and was also higher in initial than successive screening irrespectively of the test used.

Considering that carcinoma *in situ* was not classified as cancer, 122 adenocarcinomas were confirmed, 40 with gFOBT and 82 with FIT. The overall cancer detection rate was more than two-fold with the FIT (3.0 ‰) compared to the gFOBT (1.2 ‰). Cancer detection rate in initial screenees was greater than in subsequent.

Near 62 % of cancers were diagnosed at an early stage with clear differences regarding the screening group (47.8 % in initial screening *vs.* 69.7 % in successive screening).

Post-procedure indicators

Colonoscopy complication

Eighteen severe complications were detected by the screening programme along the period of study: 3 perforations and 15 lower gastrointestinal bleeding. This represented an overall complication rate of 10.7 ‰ which is stated as acceptable according to the range established in the European Guideline but not according to the Spanish Clinical Guideline.

DISCUSSION

This paper analyses the main quality indicators related to colonoscopy of three screening rounds of the first population-based CRC screening programme implemented in Spain. All indicators were within the standard except waiting time to colonoscopy.

Table I. Quality indicators related to colonoscopy

	*Catalan Screening Programme**	*European Guidelines (21)*	*Gastroenterologist's Clinical Guidelines*** (22)*
Colonoscopy compliance	94.0%	> 85 % acceptable; > 90 % desirable	-----
Waiting time to colonoscopy	14.2 % within ≤ 31 days	> 90 % within ≤ 31 days acceptable > 95 % within ≤ 31 days desirable	< 6 weeks
Sedation use	99.6 %	-----	> 90 %
Adequate bowel cleansing	93.6 %	-----	> 90 % with good or excellent preparation
Caecal intubation	95.6 %	> 90 % acceptable; > 95 % desirable	> 95 %
Polyp-retrieval rate	Overall: 86.7 % 96.5 % polyps ≥ 10 mm 82.6 % polyps < 10 mm	-----	----- > 95 % polyps ≥ 10 mm > 80 % polyps < 10 mm
Waiting time to pathology result	98.1 % within ≤ 31 days	> 95 % within ≤ 31 days	-----
Early stage cancers (I and II)	61.5 %	Favourable	-----
Complication rate	Overall: 10.7 ‰ Perforation: 1.8 ‰ Postpolypectomy bleeding: 8.9 ‰	Overall: 5.0-16.0 ‰ ----- -----	----- Perforation: < 1.0 ‰ Postpolypectomy bleeding < 5.0 ‰

	gFOBT			*FIT*			*gFOBT*		*FIT*		
	n	*PPV*	*Detection rates*	*n*	*PPV*	*Detection rates*	*PPV*	*Detection rates*	*PPV*	*Detection rates*	
Adenomas detected (HRA, LRA)											
Initial screening	55	51.4 %	5.3 ‰	304	59.7 %	35.8 ‰	-----	5.2-10.5 ‰	19.6-40.3 %	13.3-22.3 ‰	-----
Successive screening	68	40.2 %	3.1 ‰	533	59.4 %	28.9 ‰	-----	3.3-4.7 ‰	-----	-----	-----
Total	123	44.6 %	3.8 ‰	837	59.5 %	30.7 ‰	30.3 %	-----	-----	-----	PPV > 40 %**
Cancer detected											
Initial screening	16	15.0 %	1.5 ‰	30	5.9 %	3.5 ‰	6.2-8.5 %	1.2-2.3 ‰	4.5-8.6 %	1.8-9.5 ‰	-----
Successive screening	24	14.2 %	1.1 ‰	52	5.8 %	2.8 ‰	5.3-10.6 %	0.9-0.94 ‰	4.0 %	1.3 ‰	
Total	40	14.5 %	1.2 ‰	82	5.8 %	3.0 ‰					

*Screenees with follow-up colonoscopy (n = 1,691); colonoscopies performed (n = 1,806); polyps detected (n = 2,774) and cancers (n = 122). **Detection rate according to endoscopist´s definition. ***Sedation use, caecal intubation, polyp-retrieval rate and complication rate were not calculated by endoscopists despite Gastroenterologist´s Clinical Guidelines recommendation. HRA: high risk adenoma; LRA: low risk adenoma; PPV: positive predictive value; gFOBT: guaiac faecal occult blood test; FIT: Immunochaemical faecal occult blood test.

Many attempts have been made to define useful quality indicators through the implementation and consolidation of screening programmes. In recent years, its use has been gradually extended and finally accepted by different professional societies. However, there is still much work to do to in order to ensure everyone is using the same definitions and standard values. As shown in this study, from the information sources used, reference values differ on some cri-

teria and the definitions were not exactly the same, which makes it difficult to compare between different screening programmes. We chose the published guidelines (21,22) for our comparison and analysis because they were developed through a consensus and peer-review process.

The effectiveness of a colonoscopy depends on the adequate visualization of the entire colon which relies on bowel cleansing and the expertise of the endoscopist in performing careful examinations in order not to miss any lesion, reach the caecum and remove all the polyps detected (11,23). Various studies suggest that some endoscopists could leave up to half of the adenomas undiagnosed (24). A difference of up to 20 % has been described in the proportion of colonoscopies with at least one adenoma and up to 9 times in the proportion of patients with advanced adenomas (25-27). In this context, where the detection of lesions is crucial, each endoscopist must be an experienced examiner, having performing a minimum of procedures annually and before entering the screening program (22).

Colonoscopy compliance is a key indicator to consider in the effectiveness of the programme. We obtained good results which might be partially due to the sedation use (risk of discomfort may impact adversely on the acceptance) and also due to the follow-up done by the screening technical office to all people with a positive FOBT.

The time interval from a positive FOBT to colonoscopy was one of the worse process indicators in our screening programme. Although prolonged waiting time for colonoscopy has not been associated with an increase in the proportion of late-stage cancers diagnosed, it is associated with higher levels of anxiety. For this reason, the guidelines recommend a maximum benchmark of one month set as desirable. The Catalonian Advisory Group for the CRC Screening Programme has established this indicator in 60 days. According to this, we increased to 58.0 % the population with a colonoscopy performed within 60 days.

In our study, adequate bowel cleansing was one of the highest rates reported in a screening programme (28,29). We think that this excellent result is because of the exhaustive work done by the administrative staff who widely explained the whole process for a good bowel-cleansing and made a reminder some days previous to the colonoscopy appointment.

Missing lesions may be attributed to inadequate bowel preparation, an incomplete procedure, or failure to identify a lesion due to inadequate time spent examining the colonic mucosa (30). Inadequate bowel preparation not only limits the visibility of the mucosa and prolongs caecal intubation and withdrawal time, it also leads to a shorter interval for the next exam (19). Nevertheless, the quality of bowel cleansing is a subjective measure and efforts to increase reproducibility and validity are needed (31).

Colonoscopy completion rate is associated with sedation as the patient's welfare eases an entire exploration. The need for caecal intubation is based on the findings that an important number of CRC (near 30 %) are located in the proximal colon. According to the colonoscopy report, more than 95.6 % of the screening programme colonoscopies reached the caecum. However, this information was not supported by photo documentation as the guidelines on quality assurance of colonoscopies suggested.

Every lesion detected during colonoscopy must be removed and analysed, independently of its size. However, small polyps are harder to remove, which emphasise the importance of having expert colonoscopists with sufficient technical skill in the screening programmes.

The PPV for adenoma was above the standard and has been increasing from the first round (30.2 %) to the last one (60.9 %). This is a very good result because a low PPV indicates less false positive results. A high proportion of false-positive results leads to unnecessary colonoscopies with associated costs and risks. Factors associated with a false-positive result in the Catalan CRC Screening Program were: Being women (more than a twofold likelihood than men), the first prevalence round and the successive screening (32).

Regarding detection rates, it is important to note that endoscopists refer to detection rate, what epidemiologists refer to as positive predictive value. In this article, we use the epidemiologist definitions. Positive predictive value takes into account the lesions detected among those with a positive FOBT result who underwent a colonoscopy, while detection rate takes into account lesions detected among people who have had a screening test (see definitions in Appendix).

Consistent with previous results (33-35), FIT obtained much better detection rates than the gFOBT. Our results should be interpreted carefully when compared with other screening programmes. The Italian CRC screening programme (36), with 4 rounds completed, has always used the FIT as screening test. On the contrary, the English programme (37), has used the guaiac in its three concluded rounds. In our programme two tests were simultaneously used and we have to take into account that some people who participated with FIT, had used the guaiac in the previous round.

Most cancers were diagnosed at an early stage. However, we consider that achieving a high detection rate for pre-neoplastic advanced lesions is even more relevant because these lesions could progress to cancer in the near future. It is also important to note that, unlike other screening programme protocols, the Catalan CRC screening programme does not include carcinoma *in situ* in the cancer group, which would increase cases of cancer at early stage.

According to the European Guideline (21), major complications (perforation and bleeding) occur in 3 ‰ of colonoscopies in a high-quality CRC screening programme using colonoscopy as a primary screening test. On the other hand, the standard regarding major complications in programmes based in FOBT screening is 5.0-16.0 ‰. This higher complication rate is because colonoscopies are performed in individuals with a positive screening test (FOBT), which makes it more probable that they will have

a neoplastic lesion, hence the need for polypectomy and therefore an upper risk of perforation.

The complication rate could be underestimated because perforations may only be apparent after the patient has been discharged and patients are sometimes treated in a different hospital. We believe it is necessary to establish a system to detect complications after the patient has left the endoscopy department. One study found that a simple phone call 30 days after the colonoscopy identified more delayed complications than was previously known about (38). Our screening programme is working on a telephone survey to get information about complications that may arise before, during or after the colonoscopy.

Although colonoscopy withdrawal time is considered an important quality indicator, at the moment our screening programme does not collect this information. We are working to incorporate this indicator in the CRC screening software, as well as other that were not contemplated when the screening was implemented in 2000.

Effective quality assurance is critical to ensure that the benefits of screening outweigh the harms and it is a very important aspect in the screening program which invites healthy people who have no symptoms of CRC and have different expectations than symptomatic patients (39).

In conclusion, although the Catalan Colorectal Cancer Screening programme achieved the standard values in the majority of colonoscopy key indicators, there are still some areas to improve. To achieve good results we must work together with all the professionals involved. There is a long way and the first step should be the accreditation of the endoscopy units of the colorectal cancer screening programme.

Appendix. Colorectal cancer screening measures and indicators*

Screening measures	*Indicators*
Eligible = A1 Total number of people eligible for screening according to the program policy *Missed invitations* = A0 Total number of eligible people who did not receive the screening invitation (wrong address) *Invited* = A2 = A1 – A0 Total number of people who received an invitation for screening according to the program policy *Tested* = B Total number of people who have used and returned an FOBT kit irrespective of result. This includes people with inadequate/incomplete results. Note that each person is counted once regardless of the number of tests performed	Participation (%) = (B / A2) * 100
Adequately tested = C Total number of people who have returned an FOBT and achieved a conclusive result (positive or negative) *Positive FOBT* = D Total number of people who have a positive result with FOBT	*Positivity* (%) = (D / C) * 100
Referred to colonoscopy = E Total number of people presenting with a positive FOBT and referred for colonoscopy *Diagnostic/therapeutic colonoscopy* = F Total number of people who have undergone a colonoscopy, including those whose colonoscopy was inadequate/ incomplete. Note that each person is counted once regardless of the number of colonoscopies performed	Colonoscopy compliance (%) = (F / E) * 100
Date of positive FOBT result = G *Date of colonoscopy after positive screening* = H We used the date recorded by the laboratory after analysing the FOBT and the date when the colonoscopy was performed	*Waiting time to colonoscopy* (days) = H - G
Sedation = I Total number of people who have undergone a colonoscopy under sedation (Propofol)	*Sedation use* (%) = (I / F) * 100
Colonic cleansing = J Total number of people who have undergone a colonoscopy, with adequate colonic cleansing (mucosa well seen throughout or with liquid content easily suctioned)	*Adequate colonic cleansing* (%) = (J / F) * 100
Caecal intubation = K Total number of complete colonoscopies (complete intubation of the colon and to carefully inspect the mucosa during withdrawal)	*Caecal intubation* (%) = (K / F) * 100

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Appendix. Colorectal cancer screening measures and indicators* (continuation)

Screening measures	*Indicators*
Polyps removed = L1 Total number of polyps detected from one colonoscopy *Polyps retrieved* = L2 Total number of polyps retrieved from those detected from one colonoscopy	*Polyp-retrieval* (%) = (L2 / L1) * 100
Date of pathology results = M We used the date of the pathology result after a colonoscopy with polypectomy	*Waiting time to colonoscopy pathology results* (days) = M - H
Colonoscopy complications = N Total number of severe complications such as perforation and post-polypectomy bleeding (involving transfusion or hospitalisation of at least 24 hours) and death (within 30 days)	*Colonoscopy complications* (‰) = (N / F) * 1000
Cancers = O Total number of people diagnosed with colorectal cancer by or as a direct result of the screening program	*Cancer detection rate* (‰) = (O / C) * 1000 *PPV Cancer* (%) = (O / F) * 100
HRA = P1 Total number of people whose pathological specimens removed at endoscopy or surgery has been reported by a pathologist to be either adenomatous polyps larger than or equal to 10 mm, more than 2 adenomas, tubulo-villous or villous histology, high-grade dysplasia or carcinoma *in situ* *LRA* = P2 Total number of people whose pathological specimens removed at endoscopy or surgery has been reported by a pathologist to be 1 or 2 adenoma smaller than 10 mm with tubular histology and low-grade dysplasia	*HRA detection rate* (‰) = (P1 / C) * 1000 *PPV HRA* (%) = (P1 / F) * 100 *LRA detection rate* (‰) = (P2 / C) * 1000 *PPV LRA* (%) = (P2 / F) * 100
Early-stage cancers (I and II) = Q Total number of screen-detected cancers that were staged as I-II using the international TNM classification (carcinoma *in situ* is classified as HRA, not cancer)	*Early-stage cancers* (%) = (Q / O) * 100

*Based on European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis – First Edition. FOBT: Faecal occult blood test; HRA: High risk adenoma; LRA: Low risk adenoma; PPV: Positive predictive value.

REFERENCES

1. Ferlay J, Shin HR, Bray F, Forman D, Mathers C, Parkin DM. GLOBOCAN 2008 v2.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer 2010. Available at: http://globocan.iarc.fr [accessed on 09/07/2013].
2. López-Abente G, Ardanaz E, Torrella-Ramos A, Mateos A, Delgado-Sanz C, Chirlaque MD. Changes in colorectal cancer incidence and mortality trends in Spain. Ann Oncol 2010;21(Supl.3):iii76-iii82.
3. Ferlay J, Parkin DM, Steliarova-Foucher E. Estimates of cancer incidence and mortality in Europe in 2008. Eur J Cancer 2010;46:765-81.
4. Hewitson P, Glasziou P, Watson E, Towler B, Irwig L. Cochrane systematic review of colorectal cancer screening using the fecal occult blood test (hemoccult): An update. Am J Gastroenterol 2008;103:1541-9.
5. Europe against colorectal cancer. Declaration of Brussels, 9 may 2007. Available at: http:// www.future-health-2007.com [Accessed August 2013].
6. Von Karsa L, Anttila A, Ronco G, Ponti A, Malila N, Arbyn M, et al. Cancer screening in the European Union. Report on the implementation of the Council Recommendation on Cancer Screening. International Agency for Research of Cancer. European Communities; 2008.
7. Benson VS, Patnick J, Davies AK, Nadel MR, Smith RA, Atkin WS. Colorectal cancer screening: A comparison of 35 initiatives in 17 countries. Int J Cancer 2008;122:1357-67.
8. Peris M, Espinas JA, Muñoz L, Navarro M, Binefa G, Borràs JM. Lessons learnt from a population-based pilot program for colorectal cancer screening in Catalonia (Spain). J Med Screen 2007;14:81-6.
9. Red de Programas de Cribado de Cáncer. Available at: http://www.cribadocancer.com/index.php/cancer-colorrectal/red-de-programas-de-cribado-espanoles/situacion [Accessed August 2013].
10. Borras JM, Colomer C, Soria P, López R. Priorities for cancer control in Spain. Ann Oncol 2010;21(Supl. 3):iii111-iii114.
11. Allison J. The best screening test for colorectal cancer is the one that gets done well. Gastrointest Endosc 2010;71:342-5.
12. Bretagne JF, Hamonic S, Piette C, Manfredi S, Leray E, Durand G, et al. Variations between endoscopists in rates of detection of colorectal neoplasia and their impact on a regional screening program based on colonoscopy after fecal occult blood testing. Gastrointest Endosc 2010;71:335-41.
13. Macken E, Moreels T, Vannoote J, Siersema PD, Van Cutsem E. Quality assurance in colonoscopy for colorectal cancer diagnosis. Eur J Surg Oncol 2011;37:10-5.
14. Baxter NN, Sutradhar R, Forbes SS, Paszat LF, Saskin R, Rabeneck L. Analysis of administrative data finds endoscopist quality measures associated with postcolonoscopy colorectal cancer. Gastroenterology 2011;140:65-72.
15. Kaminski MF, Regula J, Kraszewska E, Polkowski M, Wojciechowska U, Didkowska J, et al. Quality indicators for colonoscopy and the risk of interval cancer. New Engl J Med 2010;362:1795-803.
16. Navarro M, Binefa G, Blanco I, Guardiola J, Rodríguez-Moranta F, Peris M. Colorectal cancer screening: Strategies to select populations with moderate risk for disease. Rev Esp Enferm Dig 2009;101:855-60.
17. García M, Binefa G, Milà N, Rodríguez F, Gonzalo N, Muñoz C, et al. Evaluación de dos estrategias de cribado de cáncer colorrectal: test inmunológico versus test bioquímico. Cataluña, 2008-2010. Rev Esp Salud Publica 2011;85:593-602.
18. Clinical practice guide for colorectal cancer. 2009 update. AEG, SemFyC y Centro Cochrane Iberoamericano. Barcelona: Elsevier; 2009 [in Spanish].
19. Rex DK, Petrini JL, Baron TH, Chak A, Cohen J, Deal SE, et al. Quality indicators for colonoscopy. Am J Gastroenterol 2006;101:873-85.
20. Lorenzo-Zúñiga V, Moreno-de-Vega, V, Boix J. Preparation for colonoscopy: types of scales and cleaning products. Rev Esp Enferm Dig 2012;104:426-31.

21. Valori R, Rey FJ, Atkin W, Michael Bretthauer, Carlo Senore, Geir Hoff, et al. Guidelines for quality assurance of endoscopy in colorectal cancer screening (and diagnosis). In: Patnick J, Segnan N, Von Karsa L, editors. European guidelines for quality assurance in colorectal cancer screening and diagnosis. 1st ed. Luxembourg: European Commission, Publications Office of the European Union; 2010: doi:10.2772/1458.
22. Grupo de trabajo de la Asociación Española de Gastroenterología y de la Sociedad Española de Endoscopia Digestiva. Guía de Práctica Clínica de Calidad en la colonoscopia de cribado del cáncer colorrectal. Madrid: EDIMSA. Editores Médicos S.A., 2011.
23. Imperialli G, Minolli G, Meucci M, Spinzi G, Strocchi E, Terruzzi V, et al. Effectiveness of a continuous quality improvement program on colonoscopy practice. Endoscopy 2007;39:314-8.
24. Rex DK. Maximizing detection of adenomas and cancers during colonoscopy. Am J Gastroenterol 2006;101:2866-77.
25. Chen SC, Rex DK. Endoscopist can be more powerful than age and male gender in prediction adenoma detection at colonoscopy. Am J Gastroenterol 2007;102:856-61.
26. Rex DK, Hewett DG, Snover DC. Detection targets for colonoscopy: From variable detection to validation. Am J Gastroenterol 2010;105:2665-9.
27. Corley DA, Jensen CH, Marks AM. Can we improve adenoma detection rates? A systematic review of intervention studies. Gastrointest Endosc 2011;74:656-65.
28. Lee TJW, Rutter MD, Blanks RG, Moss SM, Goddard AF, Chilton A, et al. Colonoscopy quality measures: experience from the NHS Bowel Cancer Screening Programme. Gut 2012;61:1050-7.
29. Morán S, Torrella E, Esteban P, Baños R, García A, Ono A, et al. Colonoscopy quality assessment. Rev Esp Enferm Dig 2009;101:107-12.
30. Robertson DJ, Geenberg ER, Beach M, Sandler RS, Ahnen D, Haile RW, et al. Colorectal cancer in patients under close colonoscopic surveillance. Gastroenterology 2005;129:34-41.
31. Lieberman D, Nadel M, Smith R, Atkin W, Duggirala SB, Fletcher R, et al. Standardized colonoscopy reporting and data system: Report of the Quality Assurance Task Force Group of the National Colorectal Cancer Roundtable. Gastrointestinal Endosc 2007;65:757-66.
32. García M, Milà N, Binefa G, Borràs JM, Espinàs JA, Moreno V. False-positive results from colorectal cancer screening in Catalonia (Spain), 2000-2010. J Med Screen 2012;19:77-82.
33. Park DI, Ryu S, Kim YH, Lee SH, Lee CK, Eun CS, et al. Comparison of guaiac-based and quantitative immunochemical fecal occult blood testing in a population at average risk undergoing colorectal cancer screening. Am J Gastroenterol 2010;105:2017-25.
34. 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;128:2415-24.
35. Haug U, Hundt S, Brenner H. Quantitative immunochemical fecal occult blood testing for colorectal adenoma detection: Evaluation in the target population of screening and comparison with qualitative tests. Am J Gastroenterol 2010;105:682-90.
36. Crotta S, Segnan N, Paganin S, Dagnes B, Rosset R, Senore C. High rate of advanced adenoma detection in 4 rounds of colorectal cancer screening with the fecal immunochemical test. Clin Gastroenterol Hepatol 2012;10:633-8.
37. Moss SM, Campbell C, Melia J, Coleman D, Smith S, Parker R, et al. Performance measures in three rounds of the English bowel cancer screening pilot. Gut 2012;61:101-7.
38. Zubarik R, Fleischer DE, Mastropietro C, López J, Carroll J, Benjamin S, et al. Prospective analysis of complications 30 days after outpatient colonoscopy. Gastrointest Endosc 1999;50:322-8.
39. Valori R, Nicolaas JS, de Jonge V. Quality assurance of endoscopy in colorectal cancer screening. Best Prac Res Clin Gastroenterol 2010;24:451-64.