

## Clinical practice Guidelines: quality of colonoscopy in colorectal cancer screening



On behalf of the SPANISH SOCIETY OF GASTROINTESTINAL ENDOSCOPY and the SPANISH ASSOCIATION OF GASTROENTEROLOGY.

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### Goals of this clinical practice guideline:

1. Collecting the evidence about the quality of colonoscopy screening for colorectal cancer (CRC) in order to serve as a tool for screening programs, endoscopy units and endoscopists that perform screening colonoscopies.
2. Defining and establishing quality indicators and minimum requirements based on available evidence that endoscopy units and endoscopists involved in CRC screening programs should meet.
3. Providing evidence about procedures that may improve the quality of colonoscopy.

### Methods

A previously designed strategy was used to do an exhaustive search for the available evidence. First, selection of topics related to the quality of colonoscopy in CRC screening was performed by the working group. Those topics were: *quality indicators before colonoscopy, management of anticoagulation and antiplatelet therapy, colonic cleansing, adenoma detection rate, value of endoscopist training and experience, cecal intubation rate, colonoscopy withdrawal time, quality in endoscopic polypectomy, polyps retrieval, complications of colonoscopy and polypectomy, sedation in colonoscopy, procedures after an incomplete colonoscopy, disinfection of endoscopy equipment and quality indicators after colonoscopy*. Finally, a list of suggested indicators for monitoring was performed. Search was carried out in MEDLINE, EMBASE and Cochrane Library. Internet addresses for CpG were searched,

as well as secondary publications (Bandolier, ACP Journal Club, Clinical Evidence, UpToDate) and Internet searchers TRIP database and SumSearch. Selection of articles and materials of every topic was performed by two people independently. Relevant references from different documents provided by members of the working group were also studied. In a second stage, several studies of every topic in the guideline were included. Search strategies were designed aimed to find the more important studies. Additional articles were identified by manual search of the reference lists of retrieved papers. Scientific evidence has been classified following the Center for Evidence Based Medicine (CEBM) from Oxford (Tab. 1). The working group and external reviewers have evaluated both. Evidence tables were generated for every key question, based on meta-analyses or randomized controlled trials (RCTs) if these were available; otherwise, case-control studies, retrospective analyses, and case series were included.

### Quality indicators before colonoscopy

- ▶ The informed consent must be complete and must comprise a clear explanation of the procedure and the preparation required, with a realistic discussion of discomforts, risks and benefits. Patient and physician performing the colonoscopy must sign the informed consent. (**recommendation grade (rec) C, level of evidence (LE) 4**).
- ▶ This clinical practice guideline recommends that screening colonoscopies should be performed in distinct programs, independent from the diagnostic and therapeutic colonoscopies performed on symptomatic patients (**rec D, LE 5**).

- ▶ Complications of colonoscopy due to a lack of prior assessment should be less than 10% of recorded complications (**rec D, LE 5**).
- ▶ It is estimated that the average time needed to perform screening colonoscopy should be 60 minutes (**rec D, LE 5**).
- ▶ Delays longer than 6 weeks between notification of a positive FOBT and the performance of colonoscopy should be avoided [1](**rec D, LE 5**).

### Management of anticoagulation and antiplatelet therapy

- ▶ Diagnostic endoscopy, with or without biopsy, is considered a low-risk procedure. Endoscopic polypectomy is considered a high-risk procedure.
- ▶ The risk of bleeding after polypectomy does not increase significantly in patients taking aspirin or NSAIDs at standard doses and, therefore, the endoscopic procedure can be performed without removing these drugs [2–4] (**rec B, LE 3b**).
- ▶ The risk of bleeding after polypectomy does not seem to increase with the isolated use of clopidogrel in polyps smaller than 1 cm. Concomitant use of clopidogrel and aspirin or NSAIDs increases the risk of bleeding [5,6] (**rec B, LE 2b**).
- ▶ Endoscopic polypectomy should not be performed in patients taking oral anticoagulants [7,8] (**rec B, LE 2b**).

### Colonic cleansing

- ▶ There is no evidence about the superiority of any colon-cleansing product over the others [9] (**rec A, LE 1a**).
- ▶ Effective bowel cleansing is essential for high quality colonoscopy. Good bowel preparation improves the detection of neoplasia, reduces procedure time and complications [10–12] (**rec B, LE 2b**).
- ▶ This clinical practice guideline recommends that in screening colonoscopies, colonic cleansing should be considered excellent or good in at least 90% of examinations performed.
- ▶ Polyetilenglicol (PEG) preparations are faster, more effective and better tolerated than a restrictive diet combined with laxatives, high-volume enema or mannitol [13,14] (**rec A, LE 1a**).
- ▶ The addition of ascorbic acid to PEG-3350 improves the taste, induces diarrhoea, inhibits bacterial reproduction and gas generation and seems as effective

| Recommendation grade (rec) | Level of evidence (LE) | Source  |
|----------------------------|------------------------|---|
| A                          | 1 a                    | Systematic review or meta-analysis of randomized clinical trials (RCTs) |
|                            | 1 b                    | High quality individual RCT   |
|                            | 1 c                    | Efficacy demonstrated by practice and not by experimentation            |
| B                          | 2 a                    | Systematic reviews of cohort studies                                    |
|                            | 2 b                    | Individual cohort studies or low quality RCT (< 80% of follow-up)       |
|                            | 2 c                    | Investigation of health results   |
|                            | 3 a                    | Systematic reviews of case-control studies                              |
|                            | 3 b                    | Individual case-control studies   |
| C                          | 4                      | Case series, or low quality cohort or case-control studies              |
| D                          | 5                      | Expert opinion  |

**Table 1** Definitions of categories for recommendation grade and levels of evidence used in this guideline.

tive as the standard preparation of PEG [15] (rec A, LE 1a).

- ▶ Preparations of sodium phosphate, low-volume hyperosmolar solutions, should not be used in patients with electrolyte disorders [16] (rec A, LE 1a).
- ▶ The combination of magnesium citrate and sodium picosulfate shows a similar efficacy to traditional preparations of PEG and sodium phosphate [17] (rec C, LE 4).
- ▶ Regardless the type of preparation, splitting the volume between the day before the test and the day of the examination allows the detection of more polyps and improves tolerance and security [18–21] (rec B, LE 2b).
- ▶ Time between the last dose and the start of the examination should be lower than 6 hours and greater than 2 hours [19,22,23] (rec A, LE 1a).
- ▶ Endoscopy reports should contain details of what type of bowel cleansing has been used and should state the degree of colonic cleansing achieved. Any of the validated classifications can be used for this purpose [24–26] (rec B, LE 2b).

#### Adenoma detection rate

- ▶ The Adenoma Detection Rate (ADR) may be defined as the number of colonoscopies at which one or more histologically confirmed adenomas are founded divided by the total number of colonoscopies performed.
- ▶ ADR appears as a direct parameter of quality, reliable and easy to obtain, that assesses the skill of the endoscopist involved in CRC screening program [27–29] (LE 2b).
- ▶ ADR is an independent factor predicting the risk of interval cancer after a screening colonoscopy [30] (LE 1b).

- ▶ Expected ADR in western populations when colonoscopy is used as the initial strategy of CRC screening should be at least 20% [30] (rec A, LE 1b).
- ▶ Expected ADR in western populations when the initial strategy of screening is the immunological FOBT should be higher than 40% [31–34] (rec A, LE 1c).

#### Value of endoscopist training and experience

- ▶ The endoscopist experience in screening colonoscopy is directly related to many aspects of quality such are cecal intubation rate, ADR or the complications rate. Therefore, it is recommended that endoscopists performing screening colonoscopies meet minimum standards for life-time experience and annual number of procedures [35–37] (rec B, LE 2b).
- ▶ Screening colonoscopies performed by non-gastroenterologists are more often related to the appearance of interval CRC [38,39] (rec B, LE 2b).
- ▶ This clinical practice guideline recommends a minimum experience in colonoscopy (at least 200 colonoscopies and 200 supervised colonoscopies as a specialist) and a continuous dedication (at least 200 colonoscopies per year) for performing CRC screening colonoscopy.
- ▶ Endoscopists especially dedicated to the implementation of CRC screening colonoscopies have better detection rates of adenomas [40] (rec B, LE 2b).
- ▶ Nurses experience performing colonoscopy also influences the rate of colonoscopy complications, the exploration time and the cecal intubation rate [41,42] (rec A, LE 1b).

#### Cecal intubation rate

- ▶ Cecal intubation is defined as the insertion of the endoscope tip to a point proximal to the ileocecal valve so that the entire cecal pole, including the medial wall (located between the ileocecal valve and appendicular orifice) is visualized and explored.
- ▶ Photographic documentation is recommended in every endoscopic procedure as a quality parameter [43] (rec B, LE 2b).
- ▶ Cecal intubation rate must be greater than or equal to 95% when the indication for colonoscopy is CRC screening in healthy adults [43–45] (rec B, LE 2b).
- ▶ Incomplete procedures due to poor preparation or severe colitis and colonoscopies performed for a therapeutic purpose should be excluded to determine the cecal intubation rate. All other procedures should be included.
- ▶ Female gender, advanced age and history of abdominal-pelvic surgery, especially hysterectomy, have been associated with lower cecal intubation rates [46–48] (LE 1b).
- ▶ The use of small calibre endoscopes (pediatric endoscope) and variable stiffness endoscope can facilitate intubation of the cecum when there is a difficult sigmoid colon [49] (rec D, LE 5).
- ▶ Instillation of water into the sigmoid colon instead of air can facilitate the passage of the endoscope [50,51] (rec C, LE 4).
- ▶ Straightening maneuvers, change of body position and abdominal pressure can help to complete the exploration when cecal intubation is difficult due to a redundant colon [40,52] (rec D, LE 5).

**Table 2** Quality indicators and auditable outcomes for quality monitoring in colorectal cancer screening colonoscopy.

| Indicator  | Definition  | Indicator type    | Acceptable level                                | Recommendation grade and level of evidence | Subject        |
|--|---|-------------------|---|--|----------------|
| <b>Adenoma detection rate</b>  | Proportion of colonoscopies performed in asymptomatic individuals over 50 in which at least one adenoma has been detected.                            | Quality indicator | > 20%   | A; 1b                                      | Endoscopist    |
| <b>Adenoma detection rate after positive FOBT</b>                          | Proportion of colonoscopies performed in individuals after a positive FOBT in which at least one adenoma has been detected.                           | Quality indicator | > 40%   | A; 1c                                      | Endoscopist    |
| <b>Colonoscopy withdrawal time</b>   | Mean time from cecal intubation to colonoscopy extraction through the anus.   | Quality indicator | > 6 minutes                                     | B; 2b                                      | Endoscopist    |
| <b>Endoscopist experience</b>  | Number of colonoscopies performed during the endoscopist career (previous) and during the last year (annual).   | Quality indicator | Previous: 400<br>Annual: 200                    | D; 5                                       | Endoscopist    |
| <b>Cecal intubation rate</b>   | Proportion of procedures in which cecal intubation is achieved.   | Quality indicator | > 95%   | B; 2b                                      | Endoscopist    |
| <b>Waiting time from positive FOBT to colonoscopy</b>                      | Time from communication of positive FOBT result to follow-up colonoscopy.   | Quality indicator | < 6 weeks                                       | D; 5                                       | Endoscopy Unit |
| <b>Use of sedation</b>   | Proportion of colonoscopies performed under sedation.   | Auditable Outcome | > 90%   |  | Endoscopist    |
| <b>Appropriate bowel cleansing</b>   | Proportion of procedures in which colon cleansing is considered excellent or good.  | Auditable Outcome | > 90%   |  | Endoscopy Unit |
| <b>Colon perforation rate</b>  | Proportion of procedures in which a colon perforation is direct consequence of the procedure.   | Quality indicator | < 1 / 1000 colonoscopies                        | D; 5                                       | Endoscopist    |
| <b>Post-polypectomy bleeding rate</b>                                      | Proportion of individuals who have a significant bleeding requiring hospitalization as a consequence of an endoscopic polypectomy.                    | Quality indicator | < 1 / 200 polypectomies                         | D; 5                                       | Endoscopist    |
| <b>Description of polyp characteristics</b>                                | Appropriate description of polyps in shape, size, location and type following the Paris classification.   | Auditable Outcome | 100%  |  | Endoscopist    |
| <b>Staff, infrastructures, and endoscopy unit equipment</b>                |   | Auditable Outcome | At least 2 endoscopists fulfil acceptable level |  | Endoscopy Unit |
| <b>Independent screening colonoscopy program</b>                           | Screening colonoscopies are performed in independent programs, separated from diagnostic or therapeutic procedures performed in symptomatic patients. | Auditable Outcome | 100%  |  | Endoscopy Unit |
| <b>Record of complications</b>   | Existence of an active record of the complications arising in screening colonoscopies.  | Auditable Outcome | 100%  |  | Endoscopy Unit |
| <b>Endoscopic resection of pedunculated polyps and sessile/flat polyps</b> | All pedunculated polyps and sessile or flat polyps smaller than 2 cm are endoscopically resected.   | Auditable Outcome | Attempt: 100%<br>Extirpation > 95%              |  | Endoscopist    |
| <b>Retrieval rate of resected polyps</b>                                   | Proportion of resected polyps that are retrieved for pathological study.  | Auditable Outcome | > 95% polyps > 10 mm<br>> 80% polyps < 10 mm    |  | Endoscopist    |
| <b>Information and consent</b>   | Existence of an information sheet and a consent document signed by all the persons before the colonoscopy.  | Quality indicator | 100%  | C; 4                                       | Endoscopy Unit |

| Indicator   | Definition  | Indicator type    | Acceptable level | Recommendation grade and level of evidence | Subject        |
|---|---|-------------------|------------------|--|----------------|
| <b>Colonoscopy complications due to lack of previous assessment</b> | Colonoscopy complications related to the lack of knowledge of patient history or use of anti-platelet or anticoagulant therapy. | Auditable Outcome | < 10 %           |  | Endoscopy Unit |
| <b>Decontamination indicators</b>                                   | Appropriate control of endoscopy disinfection measures.   | Quality indicator | Every 3 months   | B; 2c                                      | Endoscopy Unit |
| <b>Existence of a program of quality improvement</b>                | Endoscopy unit is following an appropriate quality control program.   | Auditable Outcome | Yearly           |  | Endoscopy Unit |

\* FOBT: fecal occult blood test.

### Colonoscopy withdrawal time

- ▶ Colonoscopy withdrawal time was calculated as the time from cecal intubation to the extraction of the colonoscope through the anus.
- ▶ The longer is the colonoscopy withdrawal time, the higher ADR can be achieved [43] (LE 2b).
- ▶ Mean colonoscopy withdrawal time should be longer than 6 minutes [53] (rec B, LE 2b).
- ▶ An appropriate withdrawal technique, looking carefully into the proximal side of the haustra, folds and valves, cleaning and aspirating liquid stools and with adequate colonic distension, improves ADR.

### Quality in endoscopic polypectomy

- ▶ Polyps should be classified according to their macroscopic aspect (Paris classification) and size [54].
- ▶ All the detected polyps must be resected, even diminutive rectal polyps, except if they are obviously non neoplastic [55, 56] (rec A, LE 1c).
- ▶ It is not necessary to make routine blood test before colonoscopy and/or polypectomy [57] (rec B, LE 2b).
- ▶ Guillotine resection with cold snare seems more appropriate than extirpation with biopsy forceps for polyps smaller than 5–7 mm in order to avoid incomplete resections. [58, 59] (rec C, LE 4).
- ▶ Hot biopsy forceps technique could be used for polyps up to 5 mm in diameter and must be performed cautiously. This technique should be avoided in the right colon, especially in the cecum. [58, 60] (rec C, LE 4).
- ▶ 10% glycerine solution allows better and longer polyp elevation than saline, allowing higher in bloc resection rate in large flat lesions [61] (rec C, LE 4).
- ▶ Adrenaline injection in the polyp base has shown a prophylactic effect for

immediate bleeding, but not for late bleeding. [62, 63] (rec A, LE 1b).

- ▶ Treatment with argon gas after piecemeal resection in flat or sessile large polyps reduces recurrence rate [64] (rec A, LE 1b).
- ▶ Endoscopists should be able to resect any pedunculated polyp and flat or sessile polyps up to 2 cm in diameter.

### Polyp retrieval

- ▶ Retrieval of polyps must be reflected in the endoscopy report.
- ▶ Roth's basket has shown its efficacy for the retrieval of medium and large size polyps, especially in the right colon. [65]. (rec B, LE 2b).
- ▶ Small size polyps could be retrieved by aspiration through the endoscope working channel [66, 67] (rec C, LE 4).
- ▶ These clinical practice guidelines recommend a polyp retrieval rate higher than 80% for polyps smaller than 10 mm and 95% for polyps of 10 mm or larger.

### Colonoscopy and polypectomy complications

- ▶ Colonoscopy perforation rate should be lower than 1 / 1,000 procedures [68, 69] (rec D, LE 5).
- ▶ Women seem to have a higher frequency of minor complications such as pain or abdominal distension [70, 71] (LE 1b).
- ▶ Advanced age, comorbidity, obesity, diverticulosis, history of abdominal surgery, or low experienced endoscopist are associated with a higher perforation rate [72, 73] (LE 2b).
- ▶ Significant post-polypectomy bleeding should be lower than 1 / 200 endoscopic polypectomies [69] (rec D, LE 5).
- ▶ The main risk factors for bleeding are: age over 65, concomitant cardiovascular or renal disease, anticoagulant therapy, polyp size larger than 1 cm,

right-sided polyps, polyps with thick pedicle or lateral extension, poor bowel cleansing, use of cutting current or unnoticed cut of the polyp before applying current [74, 75] (LE 2b).

- ▶ The experience of the endoscopist is related to the post-polypectomy bleeding rate. [76, 77] (LE 2b).
- ▶ Prophylactic injection of epinephrine diminishes the risk of immediate post-polypectomy bleeding [78–82] (rec A, LE 1b).
- ▶ The use of epinephrine or endoloops significantly reduces the risk of bleeding when compared with no prophylaxis, but there are no differences between both procedures [62] (rec A, LE 1b).
- ▶ The use of combined techniques diminishes the risk of bleeding in large pedunculated polyps [83] (rec A, LE 1b).
- ▶ The risk of perforation and thermal injury is reduced when using cutting current, but it produces a lower grade of hemostasis with a higher risk of hemorrhage. Coagulation current is associated with an increased risk of delayed lesions and must be avoided in the right colon and with flat polyps [75, 84–86] (rec B, LE 2b).

### Sedation in endoscopy

- ▶ This guideline recommends that the endoscopy units involved in CRC screening must perform their colonoscopies under sedation in at least 90% of the patients.
- ▶ Sedation in colonoscopy is associated with a higher level of patient satisfaction [87, 88] (LE 1b).
- ▶ The use of sedation requires a specific informed consent (rec D, LE 5).
- ▶ Literature data available on effectiveness, recovering issues and complications seem to favour the use of propo-

fol over benzodiazepines. [89] (rec B; LE 2b).

- ▶ Oxygen saturation and heart frequency must be monitored along the procedure. In patients with heart diseases it is recommendable to obtain a continuous electrocardiography registry [90] (rec B, LE 2b).
- ▶ Safety of colonoscopy with propofol sedation when administered by a non-anesthesiologist is high and similar to the risk of sedation with benzodiazepines, regarding to hypoxia, hypotension and bradycardia [91] (rec A, LE 1a).
- ▶ Assistance from an anesthesiologist when using propofol in healthy people (ASA I-II) is very expensive and it has not shown any improvement in the patient safety or in the procedure outcome [91] (LE 2c).
- ▶ Personnel in charge of monitoring the vital signs and sedation of the patient must be trained in advanced cardiopulmonary resuscitation (rec D, LE 5).
- ▶ Sedation in colonoscopy increases the rate of cecal intubation and polyp detection. Deep sedation in screening colonoscopy favors the detection of more adenomatous polyps than moderate sedation [92] (LE 3).

### Procedures after an incomplete colonoscopy

- ▶ The reasons for an incomplete colonoscopy must be evaluated again. In the setting of intolerance or inexperienced endoscopist, a new test under deep sedation and with more experienced personnel must be scheduled (rec A, LE 1c).
- ▶ Several endoscopic techniques, such as the use of variable stiffness endoscopes, upper gastrointestinal endoscopy or enteroscopy may complete the study of the colon. [93] (LE 4).
- ▶ CT colonography is better than barium enema in the detection of colonic lesions, yielding better sensitivity and specificity. Therefore, this technique is preferred in the setting of incomplete screening colonoscopy [94–96] (rec B, LE 2a).
- ▶ CT colonography has shown a detection rate for polyps  $\geq 10$  mm and advanced neoplasia similar to the obtained with the colonoscopy. However, both sensitivity and specificity are lower than the obtained with the

colonoscopy for lesions  $< 10$  mm [97–99] (LE 1a).

- ▶ The results with MR colonography are similar to those obtained with CT colonography, although its use is not widespread [100–102] (LE 2a).

### Disinfection of endoscopy equipment

- ▶ Gastrointestinal endoscopy is an invasive procedure which may facilitate the transmission of viral or bacterial infections [103] (LE 1c).
- ▶ Endoscope reprocessing must be done by qualified personnel, with specific training and experience [104] (rec A, LE 1c).
- ▶ Proper manual cleaning alone eliminates 99% of infective agents and is the most important step in the reduction of the microbial load [105] (LE 1c).
- ▶ Automatic endoscope reprocessors provide a high-level disinfection, similar to the manual system, but with the advantage that the whole procedure is standardized and can be validated in every step [106, 107] (LE 1b).
- ▶ Reusable ancillary devices must be cleaned mechanically and then sterilized [104] (rec A, LE 1a).
- ▶ Ancillary devices must be single-use when possible [108] (rec A, LE 1c).
- ▶ Endoscope reprocessing must be done in a separate facility, specifically aimed to this function. This facility must be equipped with an adequate air cleaning and gas extraction system. [109] (rec A, LE 1c).
- ▶ It is advisable to obtain culture samples periodically from the endoscopes and ancillary devices in order to detect contamination. A three-month periodicity may be adequate [110] (rec B, LE 2b).

### Quality indicators after colonoscopy

- ▶ Recovery after colonoscopy will take place in a specific area, separated from the endoscopy room and fully equipped to provide postanesthetic care. [111, 112] (rec A, LE 1b).
- ▶ Before being discharged from the endoscopy unit, the patient must be conscious and oriented, with normal vital signs and with at least 9 points on the Modified Aldrete's Scoring System 8112,113] (rec A, LE 1b).
- ▶ Fulfilment of a satisfaction questionnaire is recommended. [114, 115] (rec C, LE 4).
- ▶ It is advisable to provide the patient with a contact phone, available at least

12 hours a day, to communicate any colonoscopy-related complication [116] (rec C, LE 5).

### Quality indicators and auditable outcomes

A **quality indicator** is an outcome supported by enough evidence to be strongly recommended as a quality standard. An **auditable outcome** is a result that should be measured, but there is not enough evidence yet for recommending it as a quality standard. Quality indicators and auditable outcomes can be seen in **Table 2**, with their suggested acceptable levels for endoscopy units and endoscopists participating in CRC screening programmes.

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