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Quality indicators in enteroscopy. Enteroscopy procedure

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ABSTRACT

Within the project "Quality Indicators in Gastrointestinal Endoscopy," under the leadership of the Sociedad Española de Patología Digestiva (SEPD), our goal is to propose the procedures and the structure, process, and outcome indicators required for the application and assessment of quality in enteroscopy.

To this end a search was performed for quality indicators in enteroscopy. Quality of evidence was measured by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system, and classified as high, moderate, low, and very low.

A total of 10 process indicators (one preprocedure, eight procedure, one postprocedure) were identified for enteroscopy, with appropriate indication and choice of most efficient route being most significant.

INTRODUCTION

Since implementing continuous quality improvement programs is primordial, and these require valid, reliable scientific evidence-based indicators, the Sociedad Española de Patología Digestiva (SEPD) has developed a quality indicator project concerning different gastrointestinal (GI) endoscopy techniques (1-4).

Currently, enteroscopy is carried out using devices fitted with specific overtubes and balloons, hence with enhanced advancement over push enteroscopy. Thus, device-assisted enteroscopy (DAE) for the examination of the small bowel (SB) includes double-balloon enteroscopy (DBE), first reported by Yamamoto in 2001 (5), and single-balloon enteroscopy (SBE) since 2008 (6), which have changed the management of SB disorders. Although the technique for insertion-progression in the SB varies, and differences in depth insertion, proportion of complete SB explorations, and/or procedure duration may exist, no significant differences in diagnostic, therapeutic or clinical impact, or in complication rate have been reported (7). Therefore, structure, process, and outcome quality indicators may be common for both techniques.

DBE is the technique that most scientific evidence has accumulated, with lots of information available on indications, safety, complications, and diagnostic-therapeutic aspects (8-10).

METHODOLOGY

Literature search and study selection strategies

A search for references was performed using the following search terms: enteroscopy *(enteroscopia),* quality *(calidad),* safety *(seguridad).* The search included reviews, articles, congresses, clinical practice guidelines, and clinical trials reported between 2014 and 2019. Searched databases using a reference manager (EndNote®) included: WoS (WoS, CCC, DIIDW, KJD, MEDLINE, RSCI, SCIELO) (https://www.recursoscientificos.fecyt.es/), PubMed (https://www.ncbi.nlm.nih.gov/pubmed?holding=iesctidslib), Cochrane (https://www.cochranelibrary.com/), TRIPDATABASE (http://www.tripdatabase.com/), DARE (https://www.crd.york.ac.uk/CRDWeb/), EMBASE (https://www.embase.com/login), Guías de práctica clínica (https://www.murciasalud.es/pagina.php?id=1683&idsec=22), NGC/AHRQ (https://www.ahrq.gov/gam/index.html), Guiasalud (https://portal.guiasalud.es/), Fisterra (http://www.fisterra.com/index.asp), and Centre for Reviews and Dissemination (https://www.york.ac.uk/crd/).

Enteroscopy procedure design

Indicator design

In order to obtain valid indicators the quality of available knowledge about procedure-related activities and documents selected from the search results was assessed. This was performed using the GRADE method, where quality of evidence is initially categorized as high or low, according to its source in experimental or observational studies. Then, depending upon a number of considerations (12,13) regarding applicability, which may reduce or increase baseline quality, evidence is further categorized as high, moderate, low, or very low. To ensure reliability and to facilitate indicator estimations in clinical units, each indicator is associated with a datasheet including: application setting (procedure[s] where it is applicable); denomination; calculation formula; type of indicator according to the model by Donabedian et al. (11); timing (preprocedure, intraprocedure, postprocedure); related quality dimension; justification, exclusions and clarifications; and supporting level of evidence (12,13).

RESULTS

Search results

A total of 220 studies were included in the peer review and assessed in full text, including both randomized and nonrandomized clinical trials, high-quality case series, reviews, and meta-analyses (a total of 129), of which 198 were excluded for being poorly referenced, for dealing with pediatric or veterinary enteroscopy, or for being published in a language other than Spanish or English. A total of 22 studies were then selected, to which further 21 papers were subsequently added for justification purposes, for a final total of 43 literature references (Fig. 1).

Enteroscopy procedure

Insertion may be performed through the per-oral (PO) route, a stoma, or the per-anal (PA) route. The steps involved in the DBE and SBE procedures are described in flow charts (Figs. 2 and 3).

Description of the DBE and SBE techniques

DBE involves the push and pull of SB loops, which allows the enteroscope to be advances using both the enteroscope balloon and overtube balloon (Figs.43 to 18).

SBE involves the use of the overtube balloon alone, the enteroscope having no balloon fitted, and allows the enteroscope to be advanced and straightened in the SB by anchoring the scope's distal end using retroflexion (Fig. 19).

Enteroscopy indicators

The various indicators are defined in table 1.

B.01. Appropriate indication

In general, it may be said that device-assisted enteroscopy is a second-line procedure for diagnostic management after other techniques such as capsule endoscopy (CE) or MR-enterography (MRE) (14). The diagnostic yields of CE and enteroscopy have been assessed in a systematic review, and were shown to be similar (56 % *vs* 62 %) (15). Given the similarity in diagnostic yield, CE is considered the fisrt-line approach in the study of SB conditions, particularly of its primary indication — obscure GI bleeding (OGIB) (16,17). Therefore, in most cases DAE should be reserved as second-line procedure after CE or less invasive radiographic tests that could define an indication, location, and approach (PO or PA) (18). DAE would be the first-line therapeutic procedure for SB conditions, and would also be indicated to collect tissue samples when lesions are suspected on imaging tests, as well as for the diagnosis of OGIB (15,16). It would be indicated first-line in case of altered anatomy (19) or massive OGIB with hemodynamic impact, as well as after a failed diagnostic CE when the clinical suspicion index is high.

The European Society of Gastrointestinal Endoscopy (ESGE) (19,20) recommends a follow-up standard of 95% for this recommendation (Table 2).

C.4 Patient preparation

Name
Patient preparation
Definition and formula
Percentage of patients who receive instructions for appropriate preparation: - Numerator: number of patients instructed - Denominator: total number of tests in the period
Type, temporal relationship, quality dimension
Process, preprocedure – effectiveness
Quality of evidence
Moderate

An appropriate preparation improves visualization of the SB mucosa. As with the rest of procedures, there is unanimity in recommending patient preparation before DAE; furthermore, recommendations are added for anesthesia monitoring and deep sedation for the procedure (21).

Within the frame of the ESGE clinical guidelines (8,19,20), the European small-bowel working group recommends patient preparation before DAE with a high grade of recommendation and moderate quality of evidence. For PO or anterograde DAE (aDAE) fasting is recommended for at least 8-12 h for solids and 4-6 h for liquids; for PA or retrograde DAE (rDAE) colonic preparation as for colonoscopy is recommended (22).

C.10 Depth estimation

Name
Depth estimation
Definition and formula
Percentage of patients where estimated insertion depth is recorded: - Numerator: number of procedures where depth is recorded - Denominator: total number of procedures in the period
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Very low

The technique reported by May et al. (23) in 2005 for DBE, where they measure each and every advance cycle (23), has proven most accurate for measuring insertion depth, and is the only one validated *in* an *ex vivo* model (24). Other techniques have been described to measure insertion depth based on counting SB folds on withdrawal (25) or on estimating overtube advancement (26,27), but none of them has been validated. These methods are also applicable to SBE. Because of inter-observer variability, and since insertion depth is an estimation, it is recommended that the most distal point reached be tattooed for comparison with estimates obtained with other procedures such as CE, which may help in planning potential surgery and in estimating depth should the need arise to use the PO or PA route, or both for a complete SB examination.

C.11 Diagnostic impact

Name
Diagnostic-therapeutic impact
Definition and formula
Percentage of patients where diagnostic goals are reached: - Numerator: number of tests where diagnostic goals are reached - Denominator: total number of tests in the period
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Low

Multiple studies have assessed the diagnostic impact of DAE, their results showing a variability of approximately 40 %-80 % according to the various series (15,28,29).

Previous diagnostic testing, selecting the most appropriate insertion route, an indication according to clinical guidelines, and the endoscopist's professional experience have all been associated with factors that improve the diagnostic impact of DAE.

A single-center, restrospective study (30) that measured the correlation between DAE indication and outcome in two different periods of time (2004 to 2006 *vs* 2006 to 2011) described an increased diagnostic impact in the second period, from 86.4 % to 93.9 %, which resulted in therapeutic management changes for 89.7 % of patients. DAE indications did not change in the study from one period to the next, but an improvement in patient selection is reported.

C.12 Therapeutic impact

Name
Therapeutic impact
Definition and formula
Percentage of patients where the therapeutic goal is reached: - Numerator: number of procedures where the therapeutic goal is reached - Denominator: total number of procedures in the period
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness

Quality of evidence
Very low

Evidence is scarce on the overall therapeutic impact of DAE, partly because there is no gold standard for comparison and studies assessing long-term clinical impact are few. Generally speaking, DAE is indicated with therapeutic intent in 15 % to 55 % of cases (28,29), and has an increased therapeutic impact in emergency procedures such as for active OGIB, polypectomy in the setting of hereditary syndromes involving the SB, or SB stenosis (19). It should also be borne in mind that appropriate patient selection, previous diagnostic testing, correct approach route selection, and lesion-reaching insertion depth would play a role in increasing the procedure's therapeutic impact.

C.13 Use of CO_2 during the procedure

Name
Use of CO_2 during the procedure
Definition and formula
Percentage of patients where the procedure is aided by CO_2 rather than environmental air: - Numerator: number of procedures where CO_2 is used - Denominator: total number of procedures
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Low

Although evidence is available that the use of CO_2 improves procedure tolerability and allows lower sedation doses, it has not been shown to improve access to the cecum during rDAE or procedure-associated adverse events; however, it does improve insertion depth (31-34).

C.14 Tattooing of lesions for subsequent treatment

Name
Tattooing of lesions for subsequent treatment
Definition and formula
Percentage of patients where lesions are tattooed for subsequent treatment:

- Numerator: number of patients with tattooed lesions - Denominator: number of patients where lesions are identified that will require treatment or surgical localization
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Very low

Tattooing lesions for subsequent treatment facilitates therapeutic intent for cases such as lesions with a high recurrence risk. Furthermore, marking lesions may facilitate their assessment during another procedure, as well as their localization during surgery.

C.15 Tattooing the point of maximal insertion

Name
Tattooing the point of maximal insertion
Definition and formula
Percentage of patients where the point of maximal insertion is tattooed: - Numerator: number of patients where the point of maximal insertion is tattooed - Denominator: total number of tests in the period
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Very low

Tattooing the point of maximal insertion is the only way to ensure that the whole SB has been examined by using both aDAE and rDAE.

C.16 Selection of the most effective access route

Name
Selection of the most effective access route
Definition and formula
Percentage of patients with a single appropriate access route as initial choice, either PO or PA,

where a second access route is not necessary to reach the suspected diagnosis: - Numerator: number of patients with a single appropriate access route as initial choice where a second access route is not necessary to reach the suspected diagnosis - Denominator: total number of patients undergoing DAE
Type, temporal relationship, and quality dimension
Process, intraprocedure – effectiveness
Quality of evidence
Low

The insertion route must be selected according to prevous testing and findings, most particularly to prior CE (18). For a lesion of unknown location the PO route is to be preferred for its higher diagnostic yield: 72.51 % *vs* 50.91 %; also in case of massive OGIB (35,36).

However, for CD or neuroendocrine tumors the PA route is to be advised (37,38), except when diagnostic findings are located in the upper SB.

E.1 Incidence of adverse events

The rate of DAE complications ranges from 0.9 % to 1.7 %, it being higher for therapeutic (4.3 %) versus diagnostic (0.8 %) procedures (39-42). Complications are mostly associated with therapeutic maneuvers such as polypectomy (up to 2 %, mainly related to large polyps or polyps with a wide base) and dilation. Overall, perforation is reported in 0.3-0.4 % of procedures. Bleeding is reported in 0.2-0.8 %, and post-enteroscopy pancreatitis in around 0.3 % of procedures.

In a systematic review by Xin et al. (42), including a total of 12,823 DBE procedures over 10 years from 66 selected originals, the authors identified a 0.7 % rate of major complications: perforation (n = 20), pancreatitis (n = 17), bleeding (n = 6), aspiration pneumonia (n = 8), and other (n = 10). Perforation was more common in patients with Crohn's disease (CD) (n = 5), prior surgery (n = 4), and SB tumors (n = 3).

Therefore, generally speaking, enteroscopy-related complications are similar to those reported for upper and lower GI endoscopy (2,4) except for acute pancreatitis, which is a complication associated with the DAE technique (43).

CONCLUSION

The present article defines 10 quality indicators for DAE that add to the general indicators and the indicators shared with other endoscopic techniques as described in previous studies (1-4) and listed in table 2. However, in the process of developing these indicators and their justification an overall low quality of the evidence stands out, hence further assessment in meta-analyses and randomized studies is needed to strengthen applicability. Similarly, we consider that the above indicators should be taken into account as a starting point for the implemenation and development of DAE in our endoscopy units with adequate quality standards.

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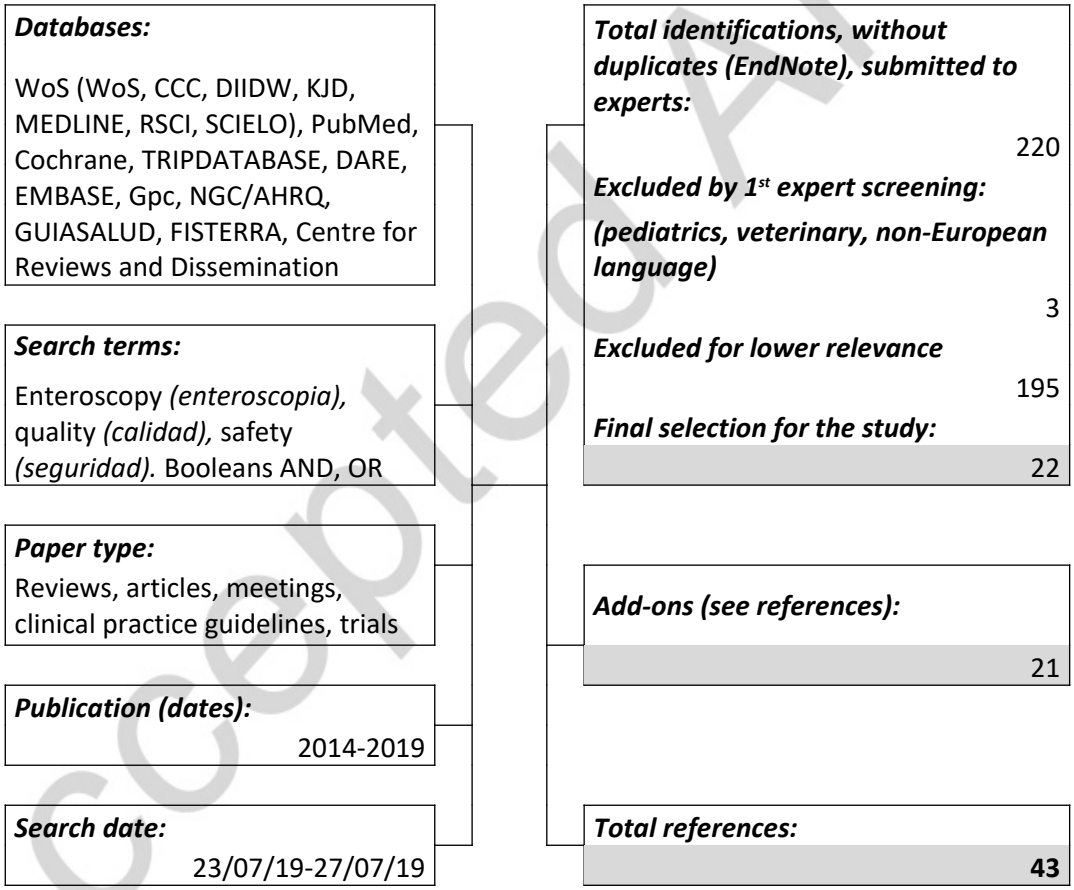

Fig. 1. Flow chart of literature search and selection.

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Fig. 2. Flow chart double balloon enteroscopy.

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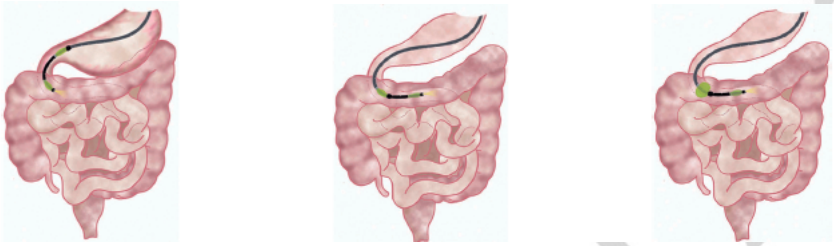
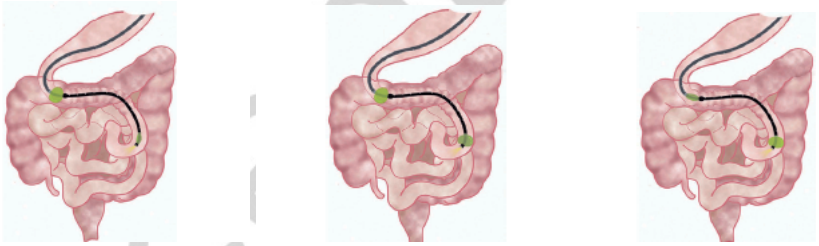
Fig. 3. Flowchart single ballon enteroscopy.



Figs. 4, 5, and 6. (4) Orally introduce the enteroscope and overtube with uninflated balloons to the pylorus. (5) Advance by pushing well beyond the ampullary area. (6) Inflate the overtube balloon also beyond the ampullary area. The enteroscope balloon remains uninflated (Source: own elaboration).



Figs. 7, 8, and 9. (7) Advance the enteroscope with the uninflated balloon to a depth of approximately 40 cm. (8) Inflate the enteroscope balloon. The overtube balloon remains inflated. (9) Deflate the overtube balloon. The enteroscope balloon remains inflated (Source: own elaboration).

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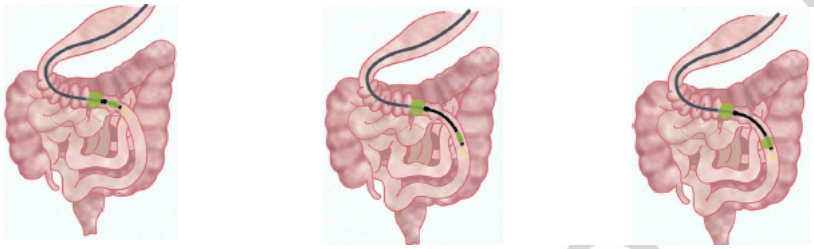
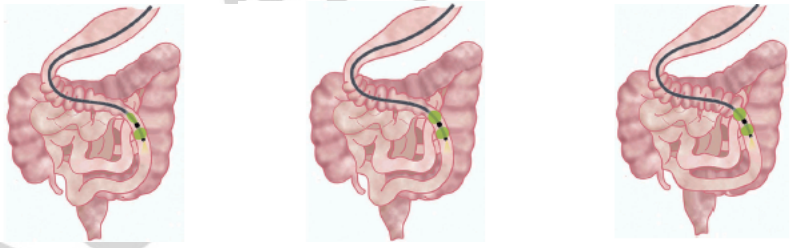
Figs. 10, 11, and 12. (10) Deflate the overtube balloon. The enteroscope balloon remains inflated. (11) Advance the overtube with the deflated balloon to the mark on the enteroscope tube, in contact with the distal end of the enteroscope. Inflate the overtube balloon. Both the overtube and enteroscope balloons are inflated at the distal end. (12) Retract (pull) both instruments en bloc. The SB portion proximal to the balloons folds back on itself (Source: own elaboration).



Figs. 13, 14, and 15. (13) Deflate the enteroscope balloon. (14) Advance (push) the enteroscope. (15) Inflate the enteroscope balloon (Source: own elaboration).



Figs. 16, 17, and 18. (16) Deflate the overtube balloon and advance the overtube. (17) Inflate the overtube balloon. (18) Again pull the overtube and enteroscope. Repeat maneuvers similar to the above successively until reaching the distal SB. Maneuver slowly being careful to aspirate SB air and contents (Source: own elaboration).

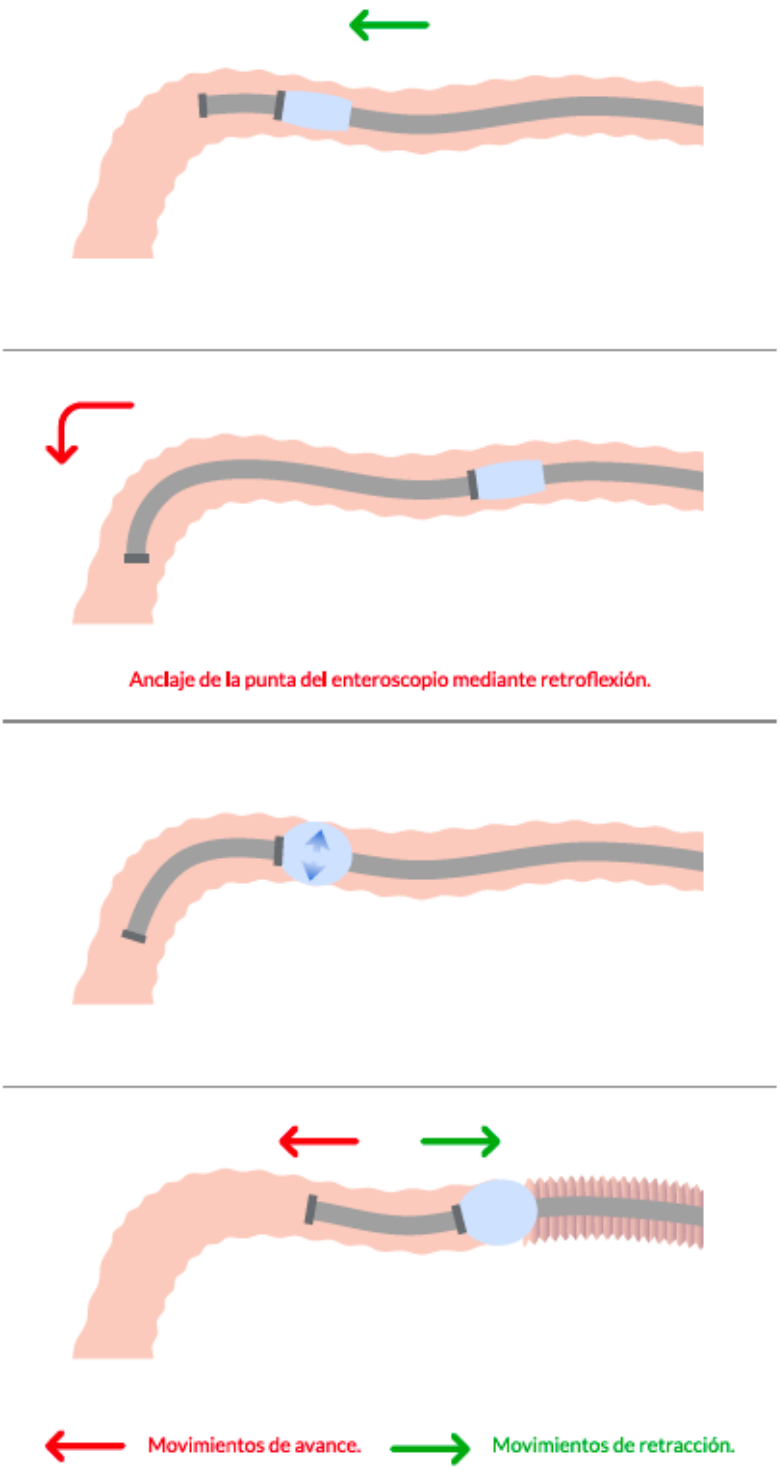


Fig. 19. Detail illustration of the SBE technique (Source: own elaboration).

[No editables]

Anchoring the tip of the enteroscope using retroflexion

Advance movements *Retraction movements*

Table 1. Quality indicators in enteroscopy (in boldface those discussed in the text). Structure, process, and outcome indicators applicable to DAE are detailed. Also detailed are the indicators for gastroscopy and colonoscopy procedures that are also applicable to DAE, as discussed in previous publications (1,2,3,4).

A. Structure
01. Valid informed consent (*)
02. Antithrombotic medication management plan (*)
03. Experienced endoscopist (*)
04. Discharge plan (*)
05. Discharge report quality (*)
06. Disinfection procedure for endoscopic equipment (*)
07. Structural and functional characteristics of an endoscopy unit (*)
B. Process - preprocedure
01. **Appropriate indication** (*)
02. Informed consent form signing (*)
03. Clinical assessment (*)
04. Scheduled sedation (*)
05. Antithrombotic medication management (*)
06. Antibiotic prophylaxis (β)
07. Drug prophylaxis (χ)
08. Fasting instructions for aDAE and preparation instructions for rDAE (χ) (δ)
C. Process - procedure
01. Graphic documentation (*)
02. Sedated patient monitoring (*)
03. Recording of immediate adverse events (*)
04. **Colonic preparation. (□) (□) (for retrograde enteroscopy)**
05. Number and distribution of biopsies for patients with inflammatory bowel disease (α)
06. Biopsy taking (χ) (α)
07. Description and localization of bleeding lesions (χ)
09. Primary endoscopic hemostasis (χ)
10. Estimation of insertion depth (□)
11. Diagnostic impact (□)
12. Therapeutic impact (□)
13. CO_2 use during the procedure (□)
14. Lesion tattooing for subsequent management (□)
15. Tattooing of the point of maximal insertion (□)
16. Choosing the most efficient route
D. Process - postprocedure

01. Patient recovery (*)
02. Discharge information (*)
03. Recording of delayed adverse events (*)
04. Recording of colon preparation quality (α)
05. Withdrawal time (α)
E. Outcome
01. ***Incidence of adverse events*** (*)
02. Perceived quality and patient satisfaction (*)

**General indicators. □: indicators defined for colonoscopy. □: ERCP-specific indicators. □: gastroscopy-specific indicators. □: DAE-specific indicators.*

Table 2. Indications of device-assisted enteroscopy (DAE)

- Lesions identified by CE
- OGIB when CE is unavailable or contraindicated
- Active or massive OGIB
- Histology specimen collection when ileocolonoscopy for suspected CD is negative
- Established CD when treatment is indicated (stenosis without inflammatory signs, with favorable anatomy)
- Suspicion of SB tumors or polypoid lesions on imaging tests
- Hereditary polyposis when polypectomy is indicated
- Refractory celiac disease