

Supplementary material

Appendix 1.

SECTION A: CENTRE'S FEATURES

Notes:

- **Please provide only one set of answers for each Centre**
- Please provide only one answer per question, unless differently specified
- SBCE: small bowel capsule endoscopy
- Answers to questions marked with "*" are **mandatory**
-

1*) Centre location (Region): _____

2*) The Centre is a:

- University Hospital and/or Research Hospital and/or IRCCS
- Public Hospital
- Private Hospital (Part of the state-run health care - "Privato convenzionato")
- Private Hospital (Outside the state-run health care - "Privato non convenzionato")
- Other (please specify): _____

3*) The majority (>80%) of patients undergoing SBCE at your Centre were:

- 1-18 years old
- >18 years old

4) Which SBCE platform was available in your Centre in the last five years (more than one answer possible)

- PillCam (Medtronic Italia S.p.A., Milano, Italy) (including SB capsule, Colon capsule and SBCrohn capsule)
- Mirocam (Intromedic Co. Ltd., Seoul, Korea)
- OMOM (Jinshan Science and Technology Company, Chongqing, China)
- Capsocam (Capso-Vision, Saratoga, California, USA Capsocam)
- Endocapsule (Olympus Co., Shinjuku, Tokyo, Japan)
- Other (please specify): _____

5) Capsule endoscopy is available in you Centre since (year): _____

6*) How many SBCEs have been performed in your Centre in the last 5 years?

2014: _____

2015: _____

2016: _____

2017: _____

2018: _____

(Please provide a numerical answer for each year; if capsule endoscopy was unavailable at your Centre please write "unavailable" in the corresponding year)

7) How many gastroenterologists are involved in SBCE reading in your Centre? _____

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8) Are there fellows in training actively involved (e.g. as pre-readers or readers) in the capsule reading process?

- Yes
- No

9*) The most SBCE-experienced reader from your Centre has evaluated:

- 1-10 SBCE examinations
- 11-25 SBCE examinations
- 26-50 SBCE examinations
- 51-75 SBCE examinations
- 76-100 SBCE examinations
- >100 SBCE examinations

10*) Is SBCE reimbursed in your Centre?

- Yes
- No

11*) Is SBCE routinely (i.e. more than 80% of SBCEs) performed on a full open-access basis?

- Yes
- No (there is a SBCE-dedicated gastroenterologist which checks the patients' clinical history, indications, possible contraindications etc., before performing SBCE)

12*) Is Patency Capsule available in your Centre?

- Yes
- No
-

13) Is Patency Capsule reimbursed in your Centre?

- Yes
- No

14*) Is Device Assisted Enteroscopy (DAE) available in your Centre?

- Yes
- No

**→PLEASE PROCEED TO “SECTION B”:
Quality assurance in Capsule Endoscopy**

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SECTION B: QUALITY ASSURANCE IN CAPSULE ENDOSCOPY

Notes:

- **Please provide only one set of answers for each Centre**
 - Please provide only one answer per question, unless differently specified
- 1) Do you routinely monitor performance measures (e.g. adenoma detection rate, cecal intubation rate, complication rate) in endoscopy (i.e. in upper and lower endoscopy and/or in EUS and/or in ERCP)?
 - Yes
 - No
 - 2) If yes, at which level do you monitor the performance measures in endoscopy (i.e. in upper and lower endoscopy and/or in EUS and/or in ERCP)?
 - Service level
 - Physician level
 - 3) Do you monitor the performance measures in SBCE?
 - Yes
 - No

Note: If “YES” please answer questions 4, 5, 6 and 7; If “NO”: go to question 7

- 4) At which level do you monitor the performance measures in SBCE?
 - Service level
 - Physician level
- 5) How often do you monitor performance measure for SBCE?
 - Annually
 - Every 6 months
 - Every 100 SBCEs
 - Other (please specify): _____
- 6) Which parameters you routinely monitor for SBCE (more than one answer is possible)?
 - Indication (i.e. rate of patients referred for established clinical indications)
 - Complication rate
 - Diagnostic yield (i.e. rate of positive SBCE)
 - Completion rate (i.e. rate of SBCEs with complete small bowel visualization)
 - Device Assisted Enteroscopy (DAE) referral rate
 - Other (specify): _____
 - Other (specify): _____
 - Other (specify): _____
 - Other (specify): _____
- 7) For a SBCE quality assurance program, which parameters would you suggest to measure:
 - Indication (e.g. rate of patients referred for established clinical indications)
 - Complication rate
 - Diagnostic yield (i.e. rate of positive SBCE)
 - Completion rate (i.e. rate of SBCEs with complete small bowel visualization)
 - Device-assisted enteroscopy referral rate

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- Other (specify): _____
- Other (specify): _____
- Other (specify): _____
- Other (specify): _____

→ PLEASE PROCEED TO “SECTION C”: Performance measures for small bowel endoscopy

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SECTION C: PERFORMANCE MEASURES FOR SBCE

Notes:

- **Please provide only one set of answers for each Centre**
- **Please refer ONLY to capsule endoscopies performed between 01/2018 and 12/2018 (as reported in SECTION A, question 6)**
- Please provide only one answer per question, unless differently specified
- SBCE: small bowel capsule endoscopy
- Answers to questions marked with "*" are **mandatory**

Domain: pre-SBCE procedure

1*) Which was the rate of SBCEs performed for the following indications in the timeframe 01 January 2018-31 December 2018?:

- Abnormal radiological imaging: _____
- Chronic abdominal pain: _____
- Chronic diarrhea: _____
- Crohn's disease (known or suspected): _____
- Suspected small bowel bleeding/unexplained iron deficiency anemia: _____
- Small bowel tumors: _____
- Inherited polyposis syndromes: _____
- Patients with complicated and/or refractory celiac disease: _____
- Patients with non-complicated celiac disease (e.g. at time of diagnosis, during clinical follow-up etc.): _____
- Other (specify): _____

(please provide a rate for each indication; the sum has to be 100%)

2) Which was the rate of SBCE with "adequate" bowel prep in the timeframe 01 January 2018-31 December 2018? (Note: emergency SBCEs, patients with active bleeding and patients with previous small bowel resections are excluded from this calculation)

- <35%
- 35-54%
- 55-74%
- 75-94%
- ≥95%

3) Which was the rate of patients referred for SBCE, which were defined at high risk for capsule retention (i.e. (i.e. known Crohn's, symptoms of obstruction, long term NSAID use, abdomino-pelvic radiation), receiving Patency Capsule before SBCE in the timeframe 01 January 2018-31 December 2018?)

- <35%
- 35-54%
- 55-74%
- 75-94%
- ≥95%

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Domain: Completeness of the procedure

4*) Which was the rate of procedures in which the caecum/colon or stoma bag (in patients who have had ileo-colonic resection or other relevant surgery) have been reached during capsule recording time in the timeframe 01 January 2018-31 December 2018?

- <50%
- 50-64%
- 65-79%
- 80-94%
- ≥95%

Domain: Identification of pathology

5*) Which was the overall diagnostic yield (rate of procedures in which a diagnosis or a finding considered significant according to the indication) in the timeframe 01 January 2018-31 December 2018?

- <40%
- 40-49%
- 50-59%
- 60-69%
- ≥70%

6*) In patients with overt small bowel bleeding which was the rate of procedures performed within 14 days (from the bleeding episode) in the timeframe 01 January 2018-31 December 2018:

- <30%
- 30-49%
- 50-69%
- 70-89%
- ≥90%

7*) Which was the rate of SBCE reports (for SBCEs performed in the timeframe 01 January 2018-31 December 2018) including all the following items: patient demographics, details of capsule used, indication, examination characteristics, findings, recommendations and complications, a detailed description of lumen, content, mucosal appearances and any lesions identified **according to standard terminology?**

- <30%
- 30-49%
- 50-69%
- 70-89%
- ≥90%

8*) Which was the rate of SBCEs, performed in the timeframe 01 January 2018-31 December 2018, in which the reading was performed with the following settings: speed is up to 10fps in single view or 20 fps in dual/multi view?

- <80%
- 80-84%
- 85-89%

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- 90-94%
- $\geq 95\%$

Domain: Management of pathology

9*) Which was the rate of positive SBCE referred to Device-Assisted-Enteroscopy in the timeframe 01 January 2018-31 December 2018?

- <75%
- 75-79%
- 80-84%
- 85-89%
- $\geq 90\%$

Domain: Complications

10*) Which was the rate of patients in which retention (defined as capsule was retained for > 15 days and/or requiring additional intervention) occurred after SBCE in the timeframe 01 January 2018-31 December 2018?

- $\leq 1.0\%$
- 1.1-2.0%
- 2.1-3.0%
- 3.1-4.0%
- >4.0%

OPTIONAL:

If you are willing to be involved in further data collections/studies and to be included as co-author whether the collected data will be published[§], please provide your name and the e-mail address.

Name/surname: _____

Email address: _____

[§]If the data will be presented and/or published, the Centre and the physicians participating in the data collection **will be kept completely anonymous** and it will be not possible to identify any of them.

→ PLEASE PROCEED TO "SECTION D": Section D (optional), it collects practical/procedural data.

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SECTION D: PRACTICAL/PROCEDURAL DATA

Notes:

- **Please provide only one set of answers for each Centre**
- Please provide only one answer per question, unless differently specified
- SBCE: small bowel capsule endoscopy

1) In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer laxatives in patients undergoing SBCE?

- Yes: _____
- No: _____

Note: If "YES" please answer all the following questions; If "NO": go to question 4.

2) In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of patients receiving laxatives) administer:

- PEG-based laxatives (low volume schedule): _____
- PEG-based laxatives (high volume schedule): _____
- Other (specify): _____

3) In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of patients) administer laxatives:

- Only the day before the procedure
- Partially the day before the procedure and partially the day of the procedure (before capsule ingestion)
- Partially the day before the procedure and partially the day of the procedure (at time of capsule ingestion)
- Partially the day before the procedure and partially the day of the procedure (after capsule ingestion)
- Only the day of the procedure, before capsule ingestion
- Only the day of the procedure, at time of capsule ingestion
- Only the day of the procedure, after capsule ingestion
- Other: please specify: _____

4) In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer prokinetics in patients undergoing SBCE?

- Yes: _____
- No: _____

5) In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer anti-foaming agents in patients undergoing SBCE?

- Yes: _____
- No: _____

6) In the timeframe 01 January 2018-31 December 2018, did you routinely report (in more than 80% of examinations) the small bowel cleansing?

- By means of a published standardized scale
- By means of an internal non validated scale

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- I do not routinely report small bowel cleansing

7) In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the “Saurin classification” in the report of patients referred to SBCE for suspected small bowel bleeding?

- Yes: _____
- No: _____

8) In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the value of the “Lewis score” in the report of patients referred to SBCE for known or suspected Crohn disease?

- Yes: _____
- No: _____

9) In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the value of the “SPICE score” in the report of patients in which a mass or bulging was detected?

- Yes: _____
- No: _____

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Appendix 2.

Administrative Region	Inhabitants 01/01/2019	N. of centres performing SBCE participating in the data collection	N. of centres performing DAE participating in the data collection
Lombardia*	10.060.574	34	10
Lazio	5.879.082	6	4
Campania	5.801.692	9	2
Sicilia	4.999.891	0	0
Veneto*	4.905.854	4	2
Emilia-Romagna*	4.459.477	5	5
Piemonte*	4.356.406	8	2
Puglia*	4.029.053	4	2
Toscana	3.729.641	1	0
Calabria	1.947.131	2	2
Sardegna	1.639.591	2	2
Liguria	1.550.640	4	0
Marche*	1.525.271	1	0
Abruzzo	1.311.580	4	1
Friuli-Venezia Giulia*	1.215.220	3	2
Trentino-Alto Adige*	1.072.276	1	1
Umbria*	882.015	2	0
Basilicata*	562.869	1	0
Molise	305.617	0	0
Valle d'Aosta*	125.666	0	0
Tot.	60.359.546	91	35

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Appendix 3.

Section D, Question 1. In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer laxatives in patients undergoing SBCE?

- Yes: 83 (91.2%)
- No: 9 (8.8%)

Section D, Question 2. In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of patients receiving laxatives) administer:

- PEG-Based laxatives (low volume schedule): 69 (85.2%)
- PEG-based laxatives (high volume schedule): 10 (12.3%)
- Other: 2 (Magnesium-citrate based laxatives) (0.5%)

Section D, Question 3. In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of patients) administer laxatives:

- Only the day before the procedure: 55 (67.9%)
- Partially the day before the procedure and partially the day of the procedure (before capsule ingestion): 20 (24.7%)
- Partially the day before the procedure and partially the day of the procedure (at time of capsule ingestion): 0 (0.0%)
- Partially the day before the procedure and partially the day of the procedure (after capsule ingestion): 2 (2.5%)
- Only the day of the procedure, before capsule ingestion: 3 (3.7%)
- Only the day of the procedure, at time of capsule ingestion: 0 (0.0%)
- Only the day of the procedure, after capsule ingestion: 1 (1.2%)
- Other: 0

Section D, Question 4. In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer prokinetics in patients undergoing SBCE?

- Yes: 85 (94.4%)
- No: 5 (5.6%)

Section D, Question 5. In the timeframe 01 January 2018-31 December 2018 did you routinely (in more than 80% of examinations) administer anti-foaming agents in patients undergoing SBCE?

- Yes: 24 (26.4%)
- No: 67 (73.6%)

Section D, Question 6. In the timeframe 01 January 2018-31 December 2018, did you routinely report (in more than 80% of examinations) the small bowel cleansing?

- By means of a published standardized scale: 22 (24.1%)
- By means of an internal non validated scale: 49 (53.8%)
- I do not routinely report small bowel cleansing: 20 (22.1%)

Section D, Question 7. In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the "Saurin classification" in the report of patients referred to SBCE for suspected small bowel bleeding?

- Yes: 11 (12.2%)
- No: 79 (87.3%)

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Section D, Question 8. In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the value of the “Lewis score” in the report of patients referred to SBCE for known or suspected Crohn disease?

- Yes: 26 (28.9%)
- No: 64 (71.1%)

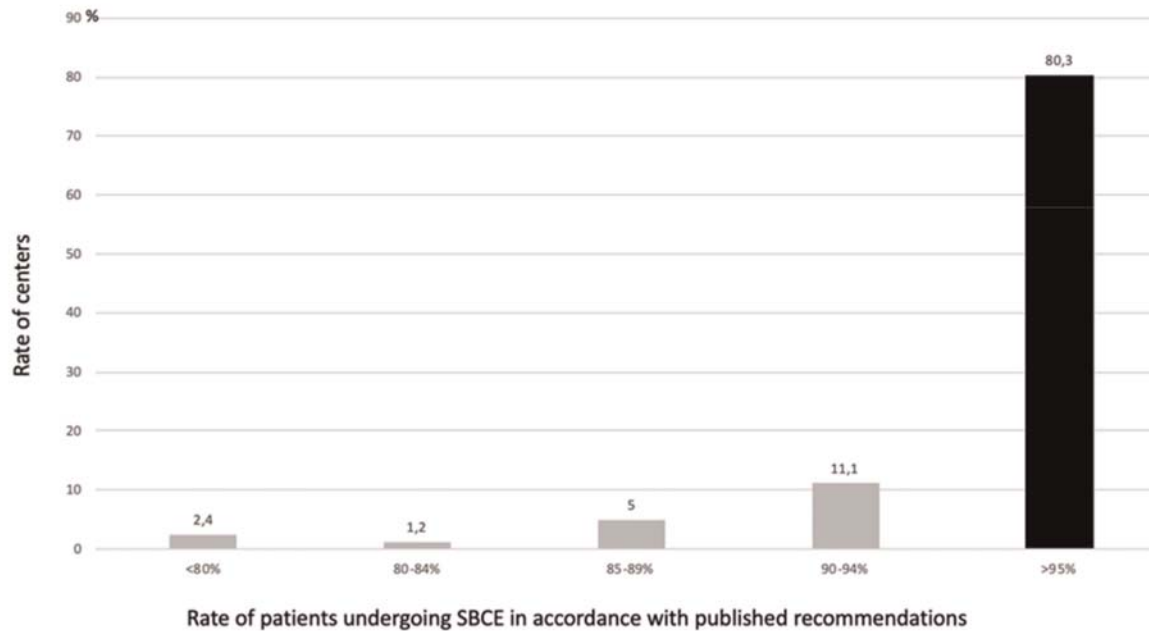
Section D, Question 9. In the timeframe 01 January 2018-31 December 2018, did you routinely (in more than 80% of examinations) included the value of the “SPICE score” in the report of patients in which a mass or bulging was detected?

- Yes: 12 (13.3%)
- No: 78 (86.3%)

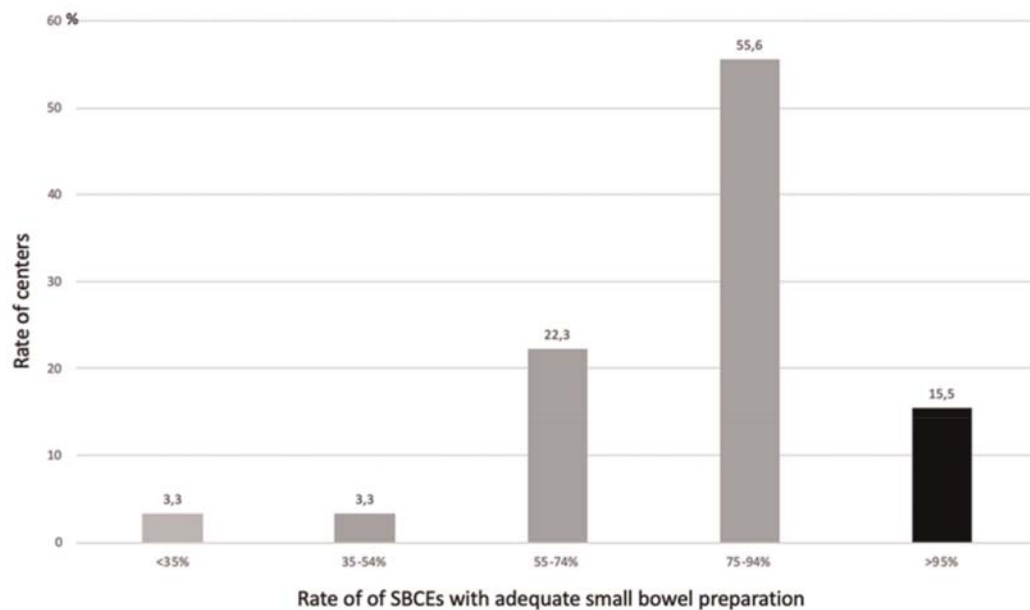
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Appendix 4.

Indication for SBCE

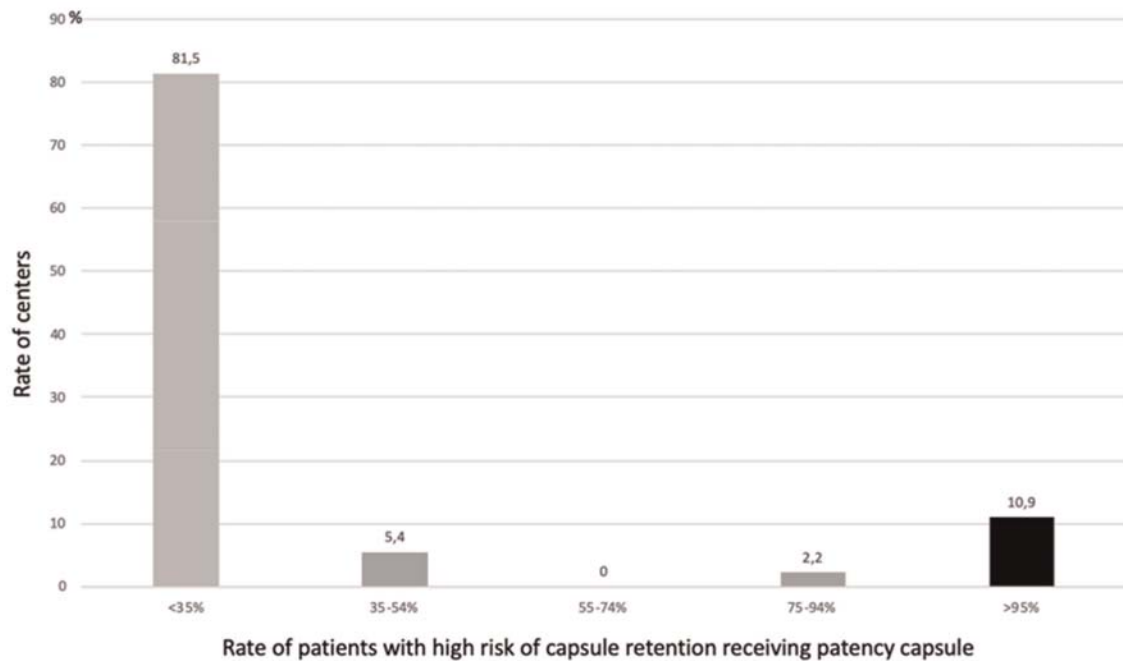


Adequate bowel preparation

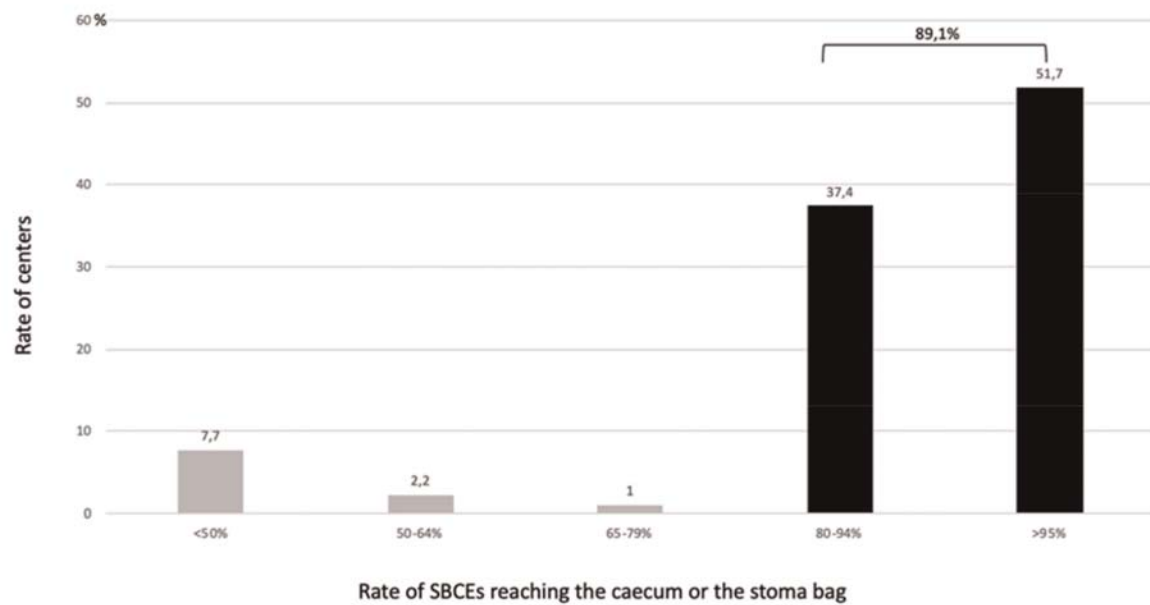


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Patient selection

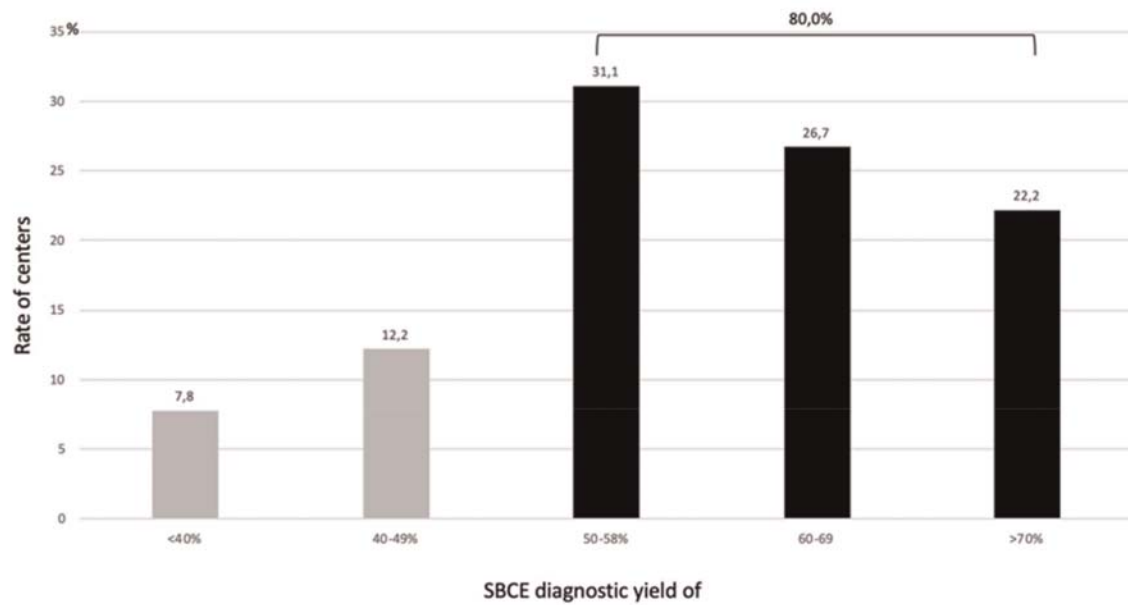


Caecal or stoma visualization

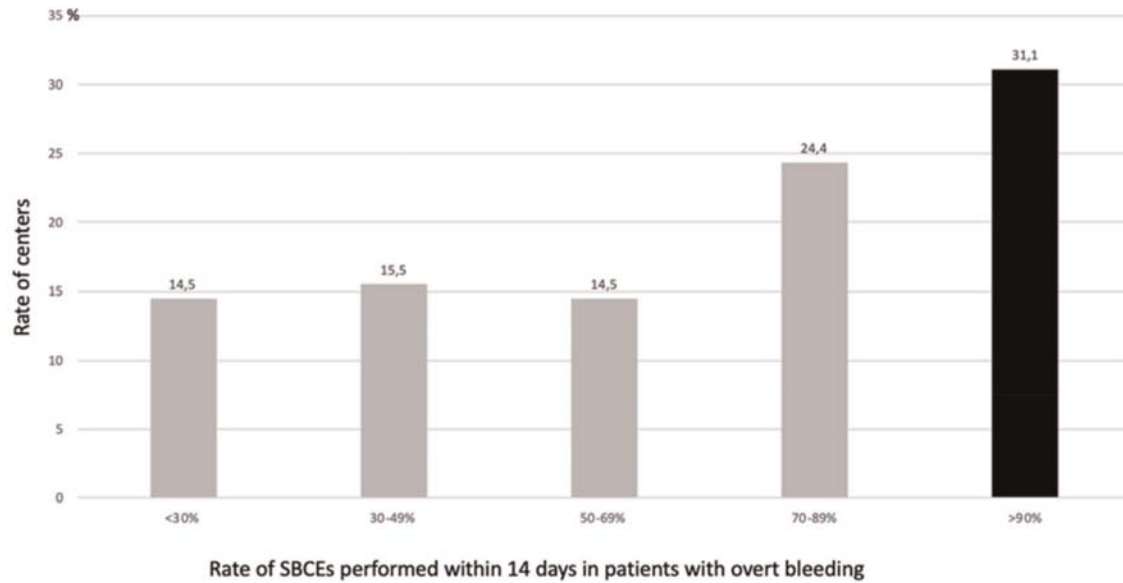


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Lesion detection rate

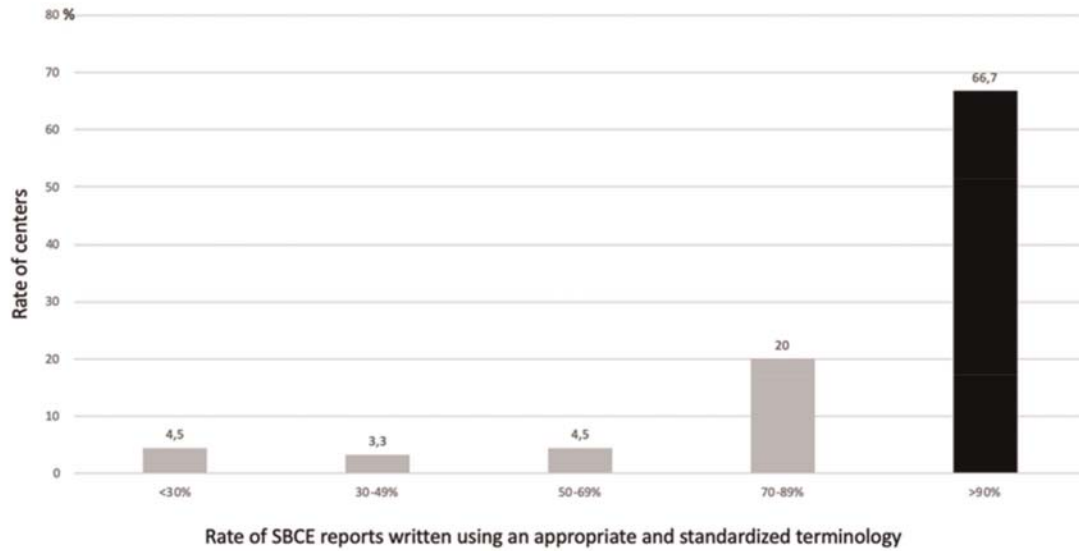


Timing of SBCE for overt bleeding

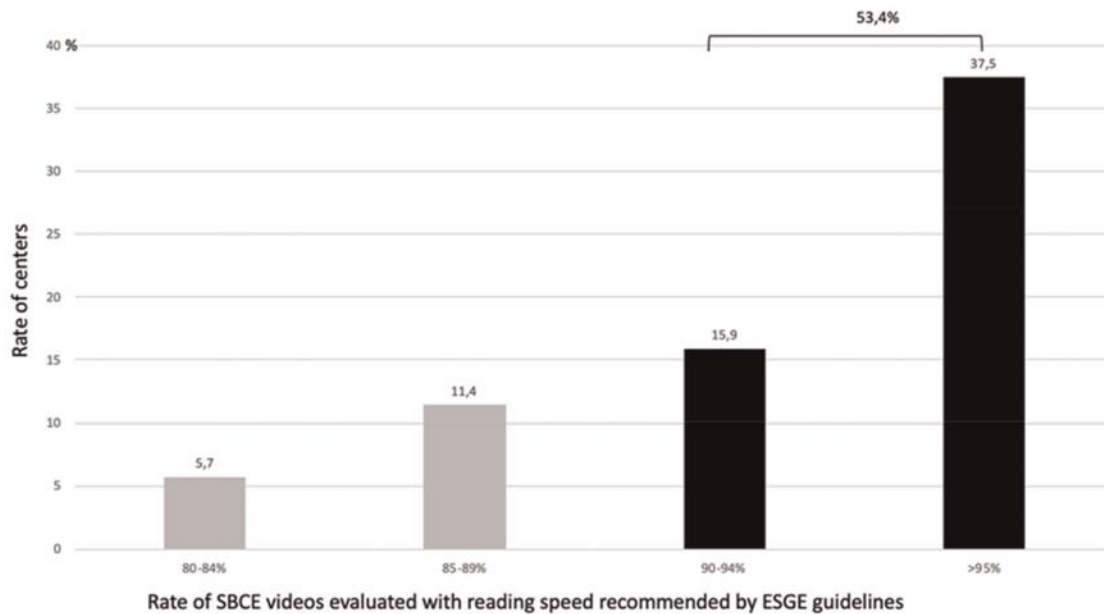


Use of standard terminology

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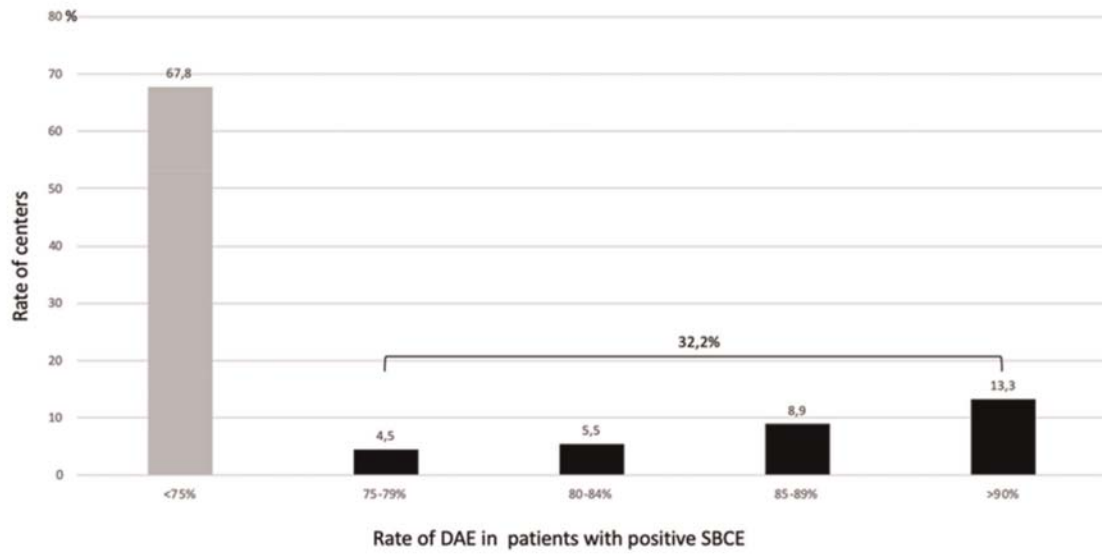


Reading speed of SBCE



Appropriate referral for DAE

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Capsule retention rate

