Thieme

A comprehensive examination of small-bowel capsule endoscopy in Spanish centers to meet European Society of Gastrointestinal Endoscopy standards

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ABSTRACT

Background and study aims In 2019, the European Society of Gastrointestinal Endoscopy (ESGE) created a working group to develop technical and quality standards for small-bowel capsule endoscopy (SBCE) to improve the daily practice of endoscopy services. They developed 10 quality parameters, which have yet to be tested in a real-life setting. Our study aimed to evaluate the accomplishment of the quality standards in SBCE established by the ESGE in several Spanish centers.

Materials and methods An online survey of 11 multiple-choice questions related to the ESGE performance measures was sent to Spanish centers with experience in SBCE. In order to participate and obtain reliable data, at least 100 questionnaires had to be answered per center because that is the minimum number established by ESGE.

Results 20 centers participated in the study, compiling 2049 SBCEs for the analysis. Only one of 10 performance measures (cecal visualization) reached the minimum standard established by the ESGE. In five of 10 performance measures (Indication, lesion detection rate, terminology, and retention rate) the minimum standard was nearly achieved.

Conclusions Our study is the first multicenter study regarding SBCE quality performance measures in a real setting. Our results show that the minimum standard is hardly reached in most procedures, which calls into question their clinical applicability in real life. We suggest performing similar studies in other countries to evaluate whether there is a need for quality improvement programs or a need to reevaluate the minimum and target values published so far.

Introduction

Small-bowel capsule endoscopy (SBCE) was launched 20 years ago, revolutionizing the study of the small bowel (SB) due to its ability to provide thorough exploration [1, 2, 3]. While guidelines have been established for indications, contraindications, and accuracy parameters [4, 5, 6], a lack of consensus remains concerning quality performance measures.

In 2019 the European Society of Gastrointestinal Endoscopy (ESGE), in association with the United European Gastroenterology, created a working group of experts to develop technical and quality standards for SB endoscopy to enhance daily practice in endoscopy services [7], This initiative followed the example of quality guidelines previously published for other endoscopic procedures. The working group classified the performance measures into two groups: key performance measures (KPMs) and minor performance measures (MPMs), each with corresponding standards (minimum/target) (▶ **Table 1**).

The definitions of the KPMs are as follows. Indication for SBCE, is the proportion of patients who undergo SBCE and have an appropriate indication according to the ESGE guidelines. Cecal visualization is the proportion of patients in whom the cecum/stoma has been visualized. Lesion detection rate is the proportion of SBCEs with positive findings related to the procedure indication. Timing of gastrointestinal bleeding correlates with the proportion of SBCEs performed within 14 days of an overt bleeding episode. Appropriate referral to device-assisted enteroscopy (DAE) is the rate of DAEs recommended according to SBCE findings. Finally, capsule retention rate refers to the proportion of patients in whom a capsule has not been excreted 14 days after ingestion.

The definitions of the MPMs are as follows [7]. Rate of adequate bowel preparation is the rate of patients who have an adequate SB cleansing level. Patient selection is related to the adequate recognition of patients who are at high risk of capsule retention and the rate of patency capsules performed in that specific population. Use of standard terminology is the proportion of capsule reports written using standardized terminology. Reading speed is the number of SBCEs read at the recommended speed of 10 frames per second in single view or 20 frames per second in dual view as recommended by the ESGE technical review [6].

The primary objective of our research was to assess whether SBCE in Spain meets the validated objectives established by ESGE.

Patients and methods

After receiving approval from the ethics committee, we conducted an 11-question online survey (Annex 1) between 2020 and 2021, targeting members of the Spanish Society of Gastrointestinal Endoscopy SBCE working group to assess both KPMs and MPMs. The survey collected information on various aspects, including the type of capsule used, indications for SBCE, timing in cases of gastrointestinal bleeding, utilization of patency capsules, completeness of the procedure, bowel visualization, findings, and referrals for DAE. Neither confidential information nor patient identities were disclosed during the survey. The questionnaire was sent to one gastroenterologist at each center, who was responsible for compiling the necessary data and filling out the survey. All but one gastroenterologist responsible for questionnaire fulfillment were experienced capsule readers; since there is no official accreditation in Spain, the expertise is described as more than 5 years of expertise and with > 100 SBCEs read per year [8].

We requested information on the last consecutive 100 SBCEs performed at each center to avoid selection bias. To ensure accuracy and consistency, CE specialists, who might have been different from the individuals responsible for reading and generating the SBCE reports, supervised or compiled this information. These CE specialists had full access to patient clinical history and the SBCE reading program.

We accepted data from various SBCE trademarks to ensure inclusivity in our study, 18 of 20 centers used SB3 or PillCam Crohn depending on the indication. The two remaining centers used Olympus SBCEs.

▶ **Table 1** Summary of performance measures.*

Domains	Performance measure (minimum/target)	
	KPM	MPM
Pre-procedure	Indication for SBCE (≥ 95%)	Rate of adequate bowel prep (≥ 95%)
		Patient selection (≥ 95%)
Completeness of procedure	Cecal visualization (≥ 80%/≥ 95%)	NA
Identification of pathology	Lesion detection rate (≥ 50%)	Use of standard terminology (≥ 90%)
	Timing of gastrointestinal bleeding (≥ 90%)	Reading speed (≥ 90%/≥ 95%)
Management of pathology	Appropriate referral to DAE (≥ 75%/≥ 90%)	NA
complications	Capsule retention rate (< 2%)	NA

* For easy reading, when the minimum and target are equal, we have included only one.
Adapted from *Spada C* et al. Performance measures for small-bowel endoscopy: A European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative [7].
KPM, key performance measure; MPM, minor performance measure; SBCE, small-bowel capsule endoscopy; DAE, device-assisted enteroscopy.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) program version 20. As all the variables were qualitative and their results were described using frequencies and percentages.

Results

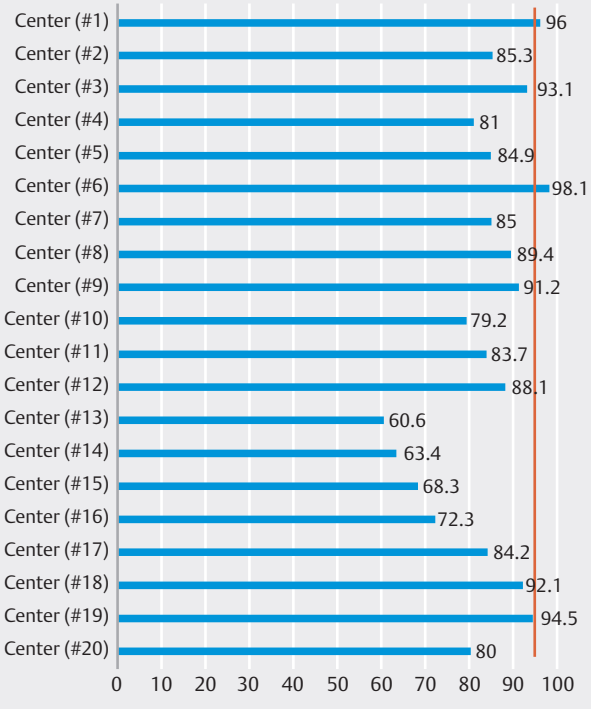
Our study involved 20 medical centers, contributing a total of 2049 questionnaires, each corresponding to a single SBCE procedure. We analyzed achievement of the performance measures and present our findings here.

Indication for SBCE

Our results show that, at a national level, 91.2% of the procedures (1880/2049) were performed in accordance with ESGE guidelines. However, the recommended minimum standard is 95%, and only six of the 20 hospitals in our study achieved this threshold. The indications for SBCE were anemia (45%), Crohn's disease (17.8%), small-bowel tumor (0.9%), abnormal radiological imaging (1.7%), obscure bleeding (21.8%), celiac disease (1.6%), polyposis syndrome (2.6%), and other indications (8.2%).

Rate of adequate bowel preparation

Bowel preparation for SBCE is a topic of debate worldwide and among the 20 hospitals in our study as well. Therefore, different approaches have been used. According to our study, 83.6% of procedures (1713/2049) had adequate preparation. It is worth mentioning that only 10% of the hospitals (2 of 20) met the minimum standard (▶ **Fig. 1**), and interestingly, those two hospitals did not use any purgative before the procedure.



▶ **Fig. 1** Rate of adequate bowel preparation. The red line shows the ESGE minimum/target standard (the name of each center has been codified in order to protect their privacy).

Patient selection

Among our patients, 27.7% (568/2049) were identified as having a potential risk of capsule retention, indicating that they should have received or been offered a patency capsule before SBCE. However, only 48.59% of these patients were actually offered the capsule.

In the individualized analysis by center, only 5% of the centers (1/20) met the ESGE standard (≥ 95% compliance with offering the patency capsule).

Cecal visualization

The performance measure achievement is represented in ▶ **Fig. 2**.

Lesion detection rate

Lesion detection rate (LDR) is defined as the number of SBCE whose findings are related to the indication. In our study, the global LDR was 48.27% (989/2049); 11 of 20 hospitals achieved a LDR > 50% (threshold recommended by ESGE). Despite this study being designed to analyze small-bowel abnormalities, findings outside the SB were also reported, 1.4% (28/2049) in the esophagus or stomach and 1.6% (33/2049) in the colon. Of the SBCEs, 42.9% (880/2049) were reported as normal. The LDR, according to indication, were anemia (49.35%), obscure gastrointestinal bleeding (OGIB)(62.4%), Crohn´s disease (56.16%), celiac disease (25%), small-bowel tumor (47.3%), and polyposis syndrome (54.7%). Findings related to indication are listed in ▶ **Table 2**.

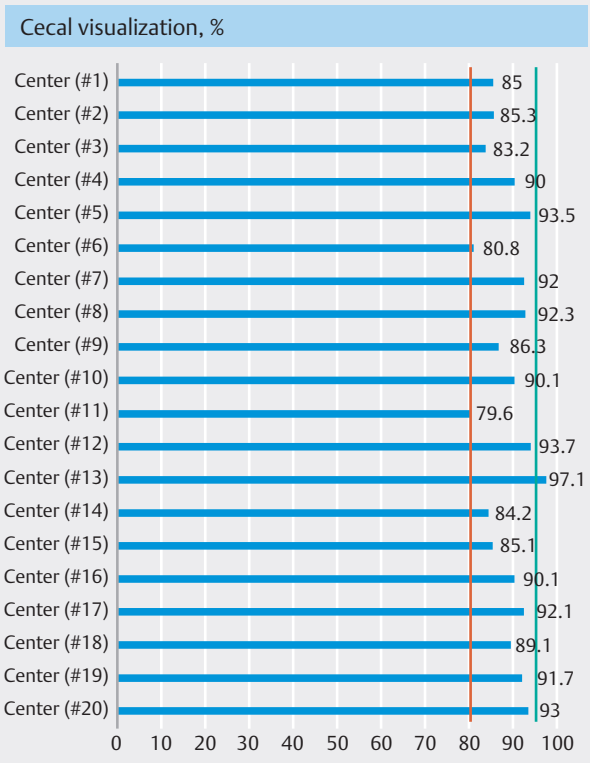
Different findings were considered significant depending on the indication; the findings accepted as positive finding for "anemia" or "OGIB" were nonsteroidal anti-inflammatory drugs, enteropathy, SB tumor, P1/P2 lesions (according to Saurin classification [9]), Meckel´s diverticulum or metastasis. When analyzing "celiac disease" not only bowel atrophy was accepted as a related finding but also lesions compatible with lymphoproliferative disease, because it is a described complication of non-treated celiac disease. Lastly, for "polyposis syndrome," both polyps and tumors were included.

Timing of gastrointestinal bleeding < 14 days

Of the SBCEs, 75.3% (360/478) were performed within 14 days after the bleeding episode, not reaching the minimum standard established (≥ 90%). In the per-center analysis, only six of them achieved the suggested threshold.

Use of standard terminology

Standardized reporting is crucial for communication among healthcare professionals; Thus, the use of standardized terminology is recommended. In our study, 88.6% of the gastroenterologists stated that they used standard terminology in the reports, coming close to the recommended threshold of > 90% set by the ESGE. Furthermore, 75% of the centers (15/20) reached the stipulated level.



▶ **Fig. 2** Percentage of SBCEs reaching the cecum (the name of each center has been codified in order to protect their privacy). The red line corresponds to the minimum (80%) and the green line corresponds to the target standard (95%).

Reading speed

Reading speed may impact the effective interpretation of SBCE results. In our study, 87% of the procedures (1782/2049) were read at the recommended speed, meeting both the minimum and target standards. Fourteen of 20 and 13 of 20 centers achieved the minimum and target goals, respectively.

Appropriate referral to DAE

Early identification and appropriate referral for DAE are critical for patients with positive SBCE results. Of the positive SBCEs, 47.2% (415/879) were properly referred to DAE; however, only three hospitals in our study achieved the target of more than 75% DAE referrals.

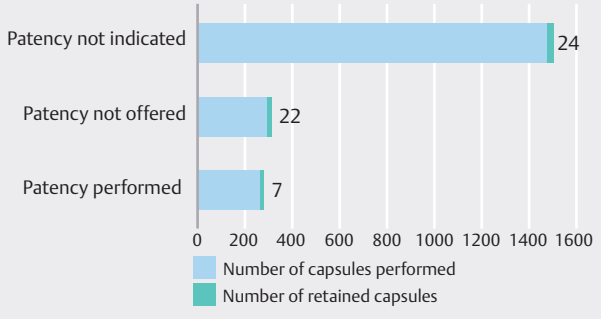
Capsule retention rate

Capsule retention is a significant concern in SBCE procedures. In our study, the capsule retention rate was 2.6% (53/2049), slightly above the minimum standards set by the ESGE guidelines. Eight of 20 hospitals achieved the standard established by the ESGE (< 2%). ▶ **Fig. 3** summarizes the relationship between capsule retention and the identification of patients who were at high risk of this event.

▶ **Table 2** Findings according to each indication.

Findings	Indication								
	Anemia	OGIB	Crohn disease	Celiac disease	Sb tumor	Polyposis syndrome	Abnormal imaging	Other	Total
Normal	434	139	139	16	9	20	18	105	**880**
Retention	5	5	1	0	0	0	0	0	**11**
Extra SB findings	29	20	1	0	0	0	0	11	**61**
Mass	24	20	3	1	9	29	5	4	**95**
Suspected Whipple	0	0	0	0	0	0	0	2	**2**
NSAID enteropathy	3	3	0	0	0	0	1	3	**10**
Atrophic enteropathy	7	2	1	7	0	0	0	5	**22**
Portal hypertension related enteropathy	5	1	0	0	0	0	0	0	**6**
Crohn disease	35	15	204	0	1	0	4	15	**274**
Anastomosis stenosis/ erosion	2	3	0	0	0	1	0	0	**6**
P1/P2	367	230	12	1	0	3	4	17	**634**
Invagination	1	0	3	0	0	0	0	0	**4**
Meckel diverticulum	1	1	0	0	0	0	0	0	**2**
Duodenum diverticulum	1	4	0	0	0	0	1	1	**7**
Incomplete (no retention)	1	0	0	0	0	0	1	0	**2**
Actinic lesions	1	0	0	0	0	0	0	0	**1**
Graft versus host disease	0	0	0	0	0	0	0	2	**2**
Unspecific erosive enteritis	7	2	1	2	0	0	0	2	**30**
Total	**930**	**447**	**365**	**32**	**19**	**53**	**34**	**169**	**2049**

OGIB, obscure gastrointestinal bleeding; SB, small bowel; NSAID, nonsteroidal anti-inflammatory drug



▶ **Fig. 3** Relation between capsule retention and identification of patients who were at high risk of this event. Patency not indicated refers to patency that was not indicated. Patency not offered refers to that patency was indicated but not offered and, therefore, not performed. Patency performed refers to patients for whom patency was indicated and performed.

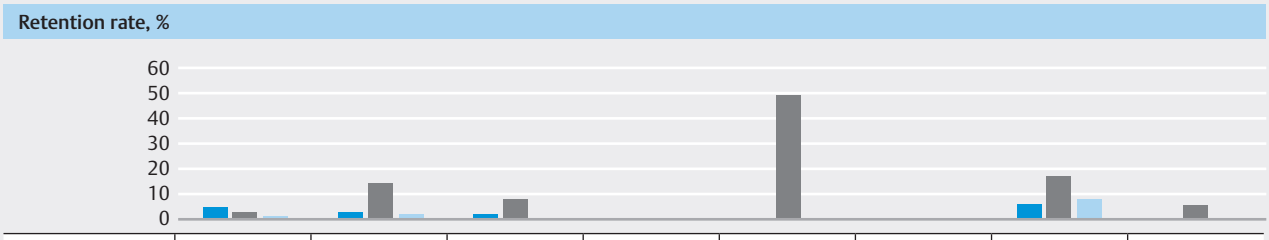
Indication, patency capsule use, and retention rate

Crohn's disease

Of patients referred for SBCE due to Crohn's disease, 59% (217/365) were selected as being at high-risk of retention. However, a patency capsule (PC) was offered and used in only 142 of 217 of these patients (65%) (patency performed). Thus, in 75 of 217 (35%), there was an indication for a PC but it was not offered to the patient (named as "patency not offered"). The retention rate in the "patency performed" group was 2.1% (3/142) while it was 8% (6/75) in the "patency not offered" group. No patients previously identified as low-risk had SBCE retention and they were classified as "patency not indicated"

OGIB

The retention rate in this group was 3.6% (16/447). Patency was used in 35 patients, with only one capsule retention (2.9%) in this subgroup. Forty-seven patients were identified as potential



	Anemia	Obscure GI bleeding	Crohn disease	Celiac disease	ID tumor	Polyposic syndrome	Abnormal radiological imaging	Other
Patency	4.3	1.9	2.1	0	0	0	6.7	0
No patency	3.2	14.9	8	0	50	0	16.7	5.9
Not indicated	1.8	2.2	0	0	0	0	7.7	0

▶ **Fig. 4** Subanalysis of the retention rate based on each indication. Patency refers to high-risk retention patients who were offered patency before SBCE. No patency refers to high-risk retention patients to whom patency was not offered. Not indicated refers to patients with low-risk of retention who did not have an indication of patency.

candidates for patency; nevertheless, it was not offered and 14.9% of these patients (7/47) experienced capsule retention.

Anemia

In this subgroup, 18.26% (171/930) had risk of SBCE retention, but patency was performed in only 45 of 171 patients (26.31%). The retention rate was two of 46 (4.3%).

Further information is shown in ▶ **Fig. 4**.

Discussion

Quality standards are not designed to punish those who do not achieve them, but rather, to create a culture of continuous improvement. For this reason, we decided to analyze SBCE quality performance in Spain according to ESGE guidelines [7]. However, it is also important to challenge these standards, because they are the first quality performance measurements for capsule endoscopy described in the literature. Their design and definition may have been biased by expert opinions, local practices, and limited evidence, and in some cases, they may lack a robust foundation in scientific literature. Therefore, it becomes necessary to question the guidelines, seek further evidence-based research, and prove their feasibility in a real-life context.

Our analysis revealed that the minimum standard was reached in only one performance measure, namely cecal visualization. In fact, Rondonotti et al [10, 11], who compared Italian center performance according to the latest ESGE technical review recommendations and SBCE performance measures [6, 7] showed that in Italy, more than 80% of centers reached the minimum standard in four of 10 suggested measures: Indication for SBCE, LDR, cecal visualization, and capsule retention rate. Although our results in terms of quality did not reach the minimum standard, they were close to it in five of the performance measures: cecal visualization, LDR, use of standard terminology, reading speed, and complications.

CE diagnostic yield is influenced not only by timing but also by cleansing level. Intestinal cleansing is controversial [12, 13, 14, 15]. Although the latest ESGE recommendations include the use of pre-procedure laxatives [6], the absence of a universal cleansing scale hinders uniform data analysis, leading us not to require the classification of a specific scale when filling in the questionnaire. In fact, due to the ambiguous opinions in the literature [6, 12, 13, 14, 15] we did not inquire about the use of different laxative protocols. Actually, the two centers in our study that achieved the minimum standard in "rate of adequate bowel preparation" did not use any purgative preparation before the procedure.

However, despite the results regarding cleansing quality, our LDR is similar to the one previously reported by Rondonotti et al [11], with more than 50% of the centers meeting the minimum standard. Taking into account these two measurements (rate of adequate cleansing level and rate of positive findings), we believe that the ESGE standard regarding adequate preparation should be reviewed, and the threshold probably needs to be lower.

Another quality issue is "reading speed," which should be set at ≤ 10 fps [6, 7]. In our country, the minimum standard (90%) was reached in 88.6% of the SBCEs, near the suggested threshold [7]. In fact, this was achieved by 14 of 20 participating centers. According to our results, this quality measurement can be easily achieved across all centers. We know that our survey has a retrospective design, and thus, it may be difficult to know the average reading speed of each center. However, some time before this study we conducted a survey regarding the performance of the ESGE technical review [6] recommendations. Since then, the working group has been aware of the speed we should read at. Nevertheless, both the retrospective design and the self-reported questionnaire may have led to some bias regarding reading speed and the results should be viewed with caution.

OBIG was the indication for 478 of 2049 procedures. Previous guidelines [4] suggest that CE should be performed within 14 days after a bleeding episode, whereas the recent 2022 ESGE guideline update reduces the time to the immediate 48 hours after the event [5]. In our study, 75.3% (360/478) achieved the 2015 recommendation. Comparing our results with the ESGE minimum standard (set at 90%), we did not reach the minimum standard [7]. Thirty percent of the participating centers (6/20) had at least 90% of their procedures with an OGIB indication performed in the initial 14 days. These data are in agreement with the results published by Rondonotti et al [11], who considered that the low number of Italian centers (30%) reaching the minimum standard in "timing of SBCE for overt bleeding" was the consequence of long waiting lists in health systems and the absence of gastroenterologists for initial evaluation of patients with gastrointestinal bleeding. In our opinion, the results from our study may have been influenced by the same problems because it is sometimes difficult to perform CE close to the bleeding episode due to capsule work overload. Besides, it has been widely proven that shortening the timing between bleeding and the procedure improves the diagnostic yield [5, 16, 17, 18, 19, 20].

In our opinion, performing CE as soon as possible is so important that endoscopy units should try to prioritize these patients. However, in the near future, the widespread incorporation of artificial intelligence in capsule reading will open new opportunities to improve such standards. Until then, as Rondonotti et al suggest [11], involving gastroenterologists in the initial management of patients with gastrointestinal bleeding could allow for establishing initial contact and faster access to endoscopy, and in particular, to SBCE. Somehow, drawing up a protocol might be an accessible strategy in order to spread the use of the SBCE and its indications, reaching not only gastroenterologists but also colleagues dedicated to different areas. Therefore, after analyzing the data from multiple centers, timing in SBCE when OGIB is the indication appears to be a global problem. Trying to improve it may consequently increase the diagnostic yield and therapeutic efficiency.

For us, one of the most important quality standards is the one regarding the rate of DAE referrals, following the indications in Spada C, et al [7]. According to ESGE [7], at least 75% of patients with positive findings should be referred to DAE; however, this has not been the case in our country, where only 47% of cases were appropriately referred. In fact, only three of 20 hospitals met the 75% recommended referral rate to DAE.

Notwithstanding, SBCE is a reliable diagnostic procedure, and it is also considered noninvasive; however, there are complications that cannot be overlooked [21, 22, 23, 24, 25, 26], such as capsule retention. Consequently, ESGE recommends identifying high-risk retention patients [5, 6, 7] in order to provide PC. Even though in our study, patency was only offered to 48% of the high-risk retention patients and 5% of the centers offered patency to > 95% of their high-risk patients, the global retention rate was 2.6%, which is similar to the retention rate published in the literature [11, 21, 22, 25]. However, we obtained an 8% retention rate in "high-risk" retention patients with established Crohn's disease who were not offered PC, in agreement with the retention rate reported by Rezapour M et al [22]. That also differs from results from the recent metanalysis by Pasha et al [27] in which patients with diagnosed with Crohn's disease had a 4.63% retention rate.

We believe that our survey has some limitations. First, the study was designed to be observational and descriptive and the data were compiled retrospectively, but included 100 consecutive patients, to avoid any selection bias. Second, the questionnaire was self-reported, increasing the risk of bias. Moreover, 20 different centers participated in this study, but in some centers, more than one professional was in charge of compiling the data. Unfortunately, that increased the difficulty of the data collection, which can be difficult per se for some parameters, such as reading speed, because it does not appear in the reports. Besides, it seems difficult to verify the adequacy of timing between bleeding and SBCE administration, which would have required an in-depth search in each patient medical record, because this information is not usually included in the final report.

Conclusions

Our analysis of the ESGE quality performance measures regarding SBCE in a real-life setting is the first to be performed. The main strength of our study was its multicentric approach, and it can be assumed that it offers a global and realistic vision of quality standards achievement in Spain. Our data concludes indicate that the minimum standard for MPMs and KPMs is hardly reached during most of the procedures.

These results, which agree with the Italian study by Rondonotti et al, call into question the clinical applicability of some of the standards. It seems that although they are not reached in most of the procedures, the clinical results fundamentally represented by "diagnostic yield and capsule retention" are not far from being achieved. Therefore, we believe that more national and international studies should be performed, preferably with a prospective design, to obtain reliable data that could be used in the future to adjust the thresholds in keeping with experience in daily clinical practice.

Conflict of Interest

I Fernández-Urien provided advisory and received speaker honoraria from Medtronic. B González-Suárez received speaker honoraria from Olympus, Medtronic and Norgine. C Carretero provided advisory and received speaker honoraria from Medtronic. The remaining authors have no conflict of interest to declare.

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