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Title:
Patency capsule – Insights from a nationwide survey in clinical practice

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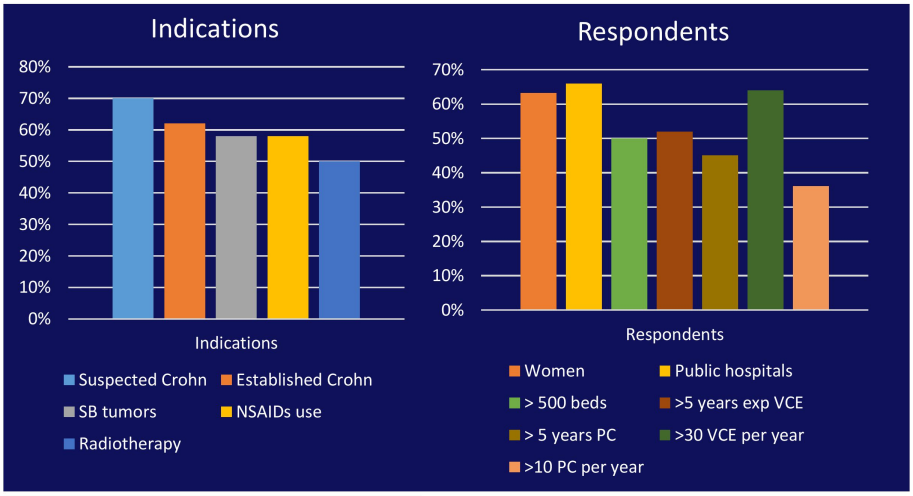
Assessing the Use of Patency Capsule in Preventing Capsule Retention: Insights from a Nationwide Survey in Clinical Practice



Protocols	
VCE reader determines need	34,7%
Isolated IC for PC	33,3%
No preparation	25,3%
Confirmation of PC passage	75%
Rx imaging when not confirmed	93%

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Patency capsule – Insights from a nationwide survey in clinical practice

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Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

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Keywords: Video capsule endoscopy. Small bowel. Capsule retention. Patency capsule. PillCam Patency®. Crohn's disease. Clinical survey. Spain.

List of abbreviations

- **VCE**: Video Capsule Endoscopy
- **SB**: Small Bowel
- **PC**: Patency Capsule
- **NSAIDs**: Non-Steroidal Anti-Inflammatory Drugs
- **IC**: Informed Consent
- **CD**: Crohn's disease
- **CT**: Computed Tomography
- **XR:** Plain abdominal X-Rays
- **MRE**: Magnetic Resonance Enterography
- **US**: Ultrasound
- **PPV**: Positive Predictive Value
- **SEED**: Spanish Society of Digestive Endoscopy
- **SBWG-SEED**: Small Bowel Working Group of the Spanish Society of Digestive Endoscopy
- **SCD**: Suspected Crohn's Disease
- **ESGE:** European Society of Gastrointestinal Endoscopy

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

Summary

This nationwide survey by the Small Bowel Working Group of the Spanish Society of Digestive Endoscopy (SBWG-SEED) assessed the clinical use of the PillCam Patency® capsule (PC) in Spain. Although the PC helps to reduce the risk of video capsule endoscopy (VCE) retention, current guidelines do not provide sufficiently detailed and standardized protocols for its use.

Seventy-five gastroenterologists with VCE experience completed the survey. Most worked in public hospitals (66.2%) and had over five years of experience (52%). The PC was primarily used in high-risk patients, such as those with suspected or confirmed Crohn's disease (CD) (70 and 62% of cases with this indication respectively), small bowel tumors (58%), chronic NSAIDs use (58%), and prior radiation therapy (50%). Prescription responsibility varied, with 48% of decisions made collaboratively.

Pre-procedure preparation was inconsistent: 60% of respondents did not perform specific bowel preparation, and 41% obtained combined consent for PC and VCE. Post-ingestion: 75% confirmed PC passage before VCE and mostly through radiological methods (93%).

Although consensus was found in some answers, clinical practices varied significantly which highlights the need for standardized guidelines to optimize patient management and clinical consistency.

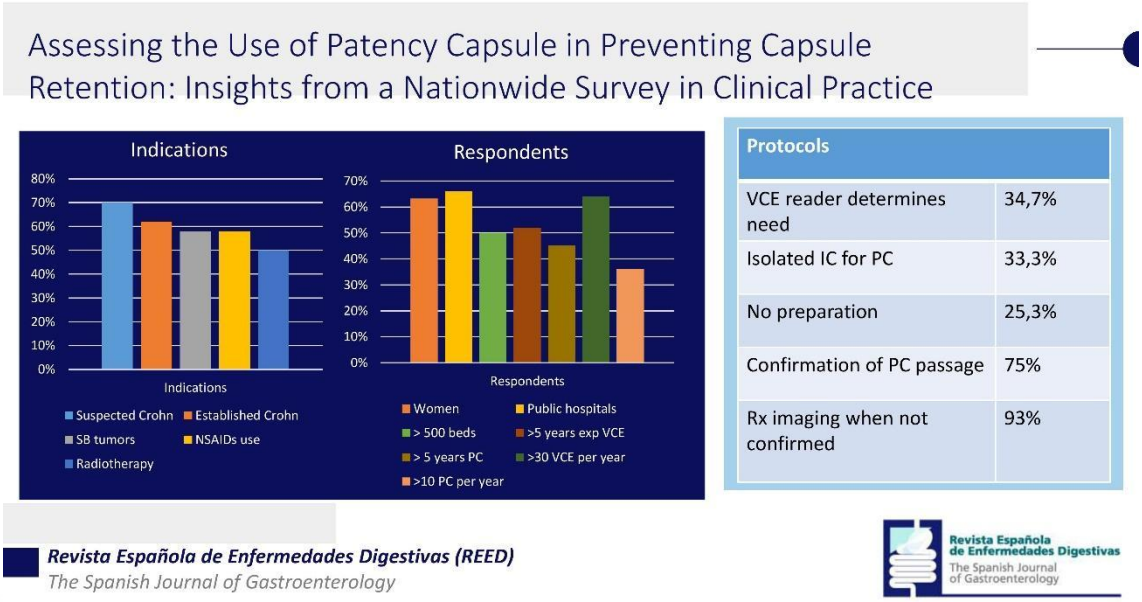
Lay summary

Video capsule endoscopy (VCE) is a non-invasive way to examine the small bowel, helping to diagnose conditions such as obscure bleeding, Crohn's disease (CD), celiac disease, and tumors. However, a major concern is capsule retention, where the VCE gets stuck in the intestine and may be the origin of some complications. To reduce this risk, physicians use the Patency Capsule (PC)—a dissolvable test capsule that ensures the intestine has no strictures, ensuring a safe VCE passage.

The European Society of Gastrointestinal Endoscopy (ESGE) recommends the use of the PC before small-bowel VCE in patients with CD disease to reduce the risk of VCE retention (1). However, detailed and standardized protocols for PC use (including preparation and confirmation of passage) are lacking and have not been previously assessed. The present national survey in 75 gastroenterologists revealed that most physicians use PCs in high-risk patients, especially those with CD or a history of surgery, radiation, or NSAIDs use. While there is strong agreement on using plain abdominal X-Rays (XR) to check if the PC has passed, other practices, such as patient preparation and informed consent (IC), vary between physicians.

The present survey highlights the need for clear guidelines to ensure safer and more consistent use of PC. Standardized protocols may improve patient care and procedure, reducing risks associated with VCE retention.

Visual abstract



Declarations

- The authors declare that they have no conflict of interest related to this article.

- The data supporting the findings of this study are openly available and can be accessed without restriction.

Introduction

Over the last two decades, VCE has transformed small bowel (SB) diagnostics for CD, celiac disease, SB tumors, and polyposis syndromes (1–3). Retention risk ranges from 0.75% in the general population to 21% in CD (4,5), with a recent review reporting 1–6% depending on indications (6). We currently know, after PC global use, that these percentages are much lower (2,3).

The PillCam Patency® capsule (PC; Medtronic, Minneapolis, USA) assesses SB patency before VCE. It has a soluble lactose body with 10% barium sulfate and two plugs dissolving after ~30h. Safe VCE is assumed if the capsule is excreted intact within 30–100h; otherwise, XR or CT is recommended to look for the PC and, thus, indicate or contraindicate the VCE procedure (Images 1-3), (7).

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The Spanish Journal of Gastroenterology

Image 1. PC excretion. Images courtesy of Medtronic, used with permission

Image 2. Plain abdominal X-Ray shows PC in the hypogastrium (circle)

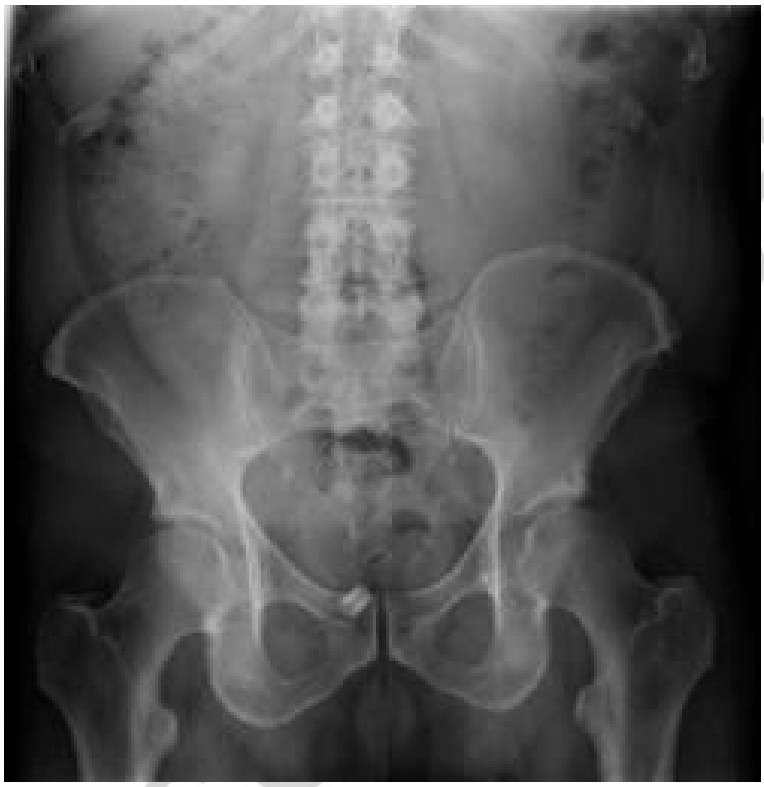
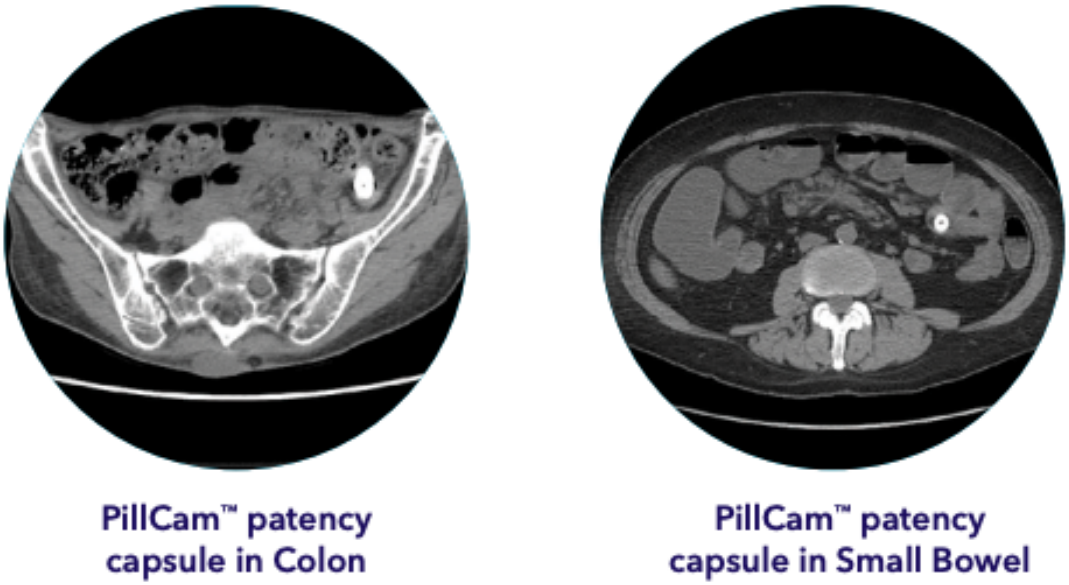


Image 3. Computed Tomography with PC inside bowel (circles). Images courtesy of Medtronic, used with permission



The PC is especially valuable in high-risk patients with suspected SB strictures, including CD, SB tumors, NSAIDs enteropathy, prior surgery, radiation enteritis, or stenosing enteritis, by reducing retention and enabling safer diagnostics (1,8).

PC effectiveness is high, with diagnostic yield 96.7%, sensitivity 83%, specificity 100%, and PPV 96% (9). A systematic review of 402 studies showed a 5.04% retention reduction (5), and a cost-effectiveness analysis indicated that selective PC use in high-risk patients reduces VCE costs to £811, versus £877 without PC and £899 with universal use (10).

Although the ESGE recommends the use of PC in high-risk patients, particularly in CD, standardized and detailed protocols (including preparation, IC, radiological confirmation, and timing) are lacking. To address this, the SBWG-SEED conducted a national survey to assess physician practices and set the need for a global consensus.

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The Spanish Journal of Gastroenterology

Methods

Study Design

This study was designed as a cross-sectional survey to evaluate current clinical practices and experiences related to using the PC. The survey was conducted under the auspices of the SEED and distributed to its members. The survey targeted gastroenterologists familiar with VCE who work in centers with access and relevant experience to PC.

Participants

In 2020, an electronic survey was distributed to SEED members involved in prescribing and interpreting VCE, targeting physicians with VCE/PC experience across Spain. A total of 77 responses were received; two were excluded for incomplete data, yielding 75 participants from both tertiary centers and community hospitals with varying annual VCE and PC

volumes.

Survey

A panel of experts from the SBGW-SEED designed the survey, and it consisted of 34 multiple-choice and open-ended questions structured to cover several key domains, described in table 1. The final section of the survey included open-ended questions that allowed participants to provide additional comments on their experiences with the PC.

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

Table 1. Questions included in the survey.

QUESTIONS INCLUDED IN THE SURVEY

1. Age.	13. Do you provide patients with a post-ingestion recommendation sheet?	25. Do you provide patients with visual aids (e.g., photographs) showing how the PC might be expelled (intact, deformed, fragmented, or showing the internal radiomarker)?
2. Gender.	14. Do you prescribe PC before VCE in patients with suspected Crohn's disease (SCD)?	26. Do you check the condition of the PC expelled by the patient?
3. In what clinical setting do you perform VCE? (e.g., public hospital, private hospital, outpatient clinic).	15. Do you prescribe PC before VCE in patients with established CD?	27. Do you document the excretion time of the PC?
4. What is the total bed capacity of your hospital?	16. Do you prescribe PC before VCE in patients with known or suspected intestinal tumors?	28. When do you assess PC excretion? (select all that apply if assessed multiple times).
5. How many years of experience do you have performing VCE?	17. Do you prescribe PC before VCE in patients with a previous history of abdominal/pelvic radiation therapy?	29. What methods do you use to assess PC excretion? (select all that apply).
6. How many VCE procedures do you perform annually?	18. Do you prescribe PC before VCE in patients with celiac disease and suspected ulcerative jejunitis?	30. What method do you use to confirm PC excretion if the patient has not directly evidenced it?
7. How many PC procedures do you perform annually?	19. Do you prescribe PC before VCE in patients with inherited polyposis	31. Which radiographic projection(s) do you use to evaluate PC excretion? (select

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The Spanish Journal of Gastroenterology

	syndromes?	all that apply).

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de Enfermedades Digestivas
The Spanish Journal
of Gastroenterology

	19. Do you prescribe PC before VCE in patients with inherited polyposis syndromes?	
8. How many years of experience do you have performing PC?	20. Do you prescribe PC before VCE in patients with chronic use of NSAIDs or AAS?	32. If PC excretion is not evident within 30–48 hours and no device is detected using your chosen method (e.g., XR, CT, or others), do you proceed with VCE?
9. Who is responsible for prescribing PC in your practice?	21. Do you prescribe PC before VCE in patients with suspected or confirmed postsurgical intra-abdominal adhesions?	33. If your detection method identifies the PC in the abdomen at 30–48 hours, how do you determine whether it is in the colon or SB? (select all that apply).
10. Do you obtain specific IC for PC administration?	22. For which types of previous gastrointestinal surgery do you prescribe PC? (select all that apply).	34. Do you produce a formal report for PC findings?
11. Do you provide a SB purgative preparation before PC ingestion?	23. When clinical or radiological signs of possible VCE retention are present, do you perform magnetic resonance enterography (MRE) before PC?	35. Please provide any additional comments on aspects not covered in this questionnaire.
12. Do you ask patients to discontinue any medications before PC ingestion?	24. If stenosis is detected on MRE, do you perform PC before proceeding with VCE?	

Statistical Analysis

Survey data were analyzed using descriptive and inferential statistics (mean ± SD for continuous variables, frequencies and/or % for categorical variables and chi-squared

was used for comparisons). Analyses were performed using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, EE. UU.). Primary outcomes were PC use frequency, indications, and passage confirmation methods. Agreement was assessed by response distribution as follows:

	AGREEMENT		
TYPE OF QUESTIONS/ANSWERS	HIGH	MEDIUM	LOW
QUESTIONS WITH 2 ANSWERS (DICHOTOMOUS)	>75%	40-75%	<40%
QUESTIONS WITH 3 ANSWERS	>66%	33-66%	<33%
QUESTIONS WITH >3 ANSWERS/MULTIPLE CHOICE OPTIONS	>50%	25-50%	<25%

Questions with lowest agreement underwent multivariate bimodal logistic regression to identify factors associated with poor agreement. Values of $p < 0.05$ were considered statistically significant.

Results

Demographics

Seventy-five complete responses were analyzed. Most respondents were female (63.2%), aged 31–40 years (50.6%), and worked in public hospitals (66.2%); half (50%) were employed in institutions with >500 beds.

Overall, 52% had >5 years of VCE experience, and 44.6% had >5 years with PC. Annually, 64% performed >30 VCEs and 36.8% >10 PCs.

Answers related to Pre-Procedure Protocols

PC use was indicated by the VCE endoscopist in 34.7% of cases, by the referring physician in 17.3%, and jointly in 48%. Specific IC for PC was obtained by 33.3%, combined IC (PC+VCE) by 41%, and 25.3% did not obtain IC. Most (60%) reported no pre-procedure preparation (laxatives).

Answers related to Indications for Patency Capsule Use

PC was most frequently used in CD: 70% for suspected obstruction and 62% for established disease. Other common indications included suspected SB tumors (58%), chronic NSAIDs use (58%), and prior radiation therapy (50%). Percentages reflect each indication individually.

Answers related to Post-Procedure Monitoring

PC passage was confirmed by clinicians in 75% of cases; in 25%, patient self-report via phone (43.2%) or follow-up visit (57.8%). Radiological tests were used in 93% when visual confirmation was impossible, repeated if needed in 45%; CT or Ultrasound (US) in <10%. If PC was not visualized before 40h, 57% proceeded with VCE, 25.7% repeated the test, and 17.6% contraindicated it.

Agreement Among Physicians

Table 2 shows the level of agreement between respondents. Of 26 survey questions on indications and procedure, 19 (73.1%) showed medium agreement and 7 (26.9%) showed high agreement. Highest agreement was obtained in Q30 (XR for unexcreted PC, 80.9%), and lowest in Q22 (surgery type, 27.2%).

Table 3 shows the multivariate analysis. Multivariate logistic regression of lower-agreement questions (Q15,19,22,28,29) tested possible predictors: center >500 beds (Q4), >10 PCs/year (Q7), >5 years PC experience (Q8), and providing photos (Q25). Centers >500 beds had higher agreement on Q22 (27.2%, p=0.017); >10 PCs/year had higher agreement on Q29 (31.17%, p=0.006). Experience >5 years and providing

photos approached significance for Q29 (p=0.083, 0.076).

Table 2. Level of agreement.

N°	Questions	Answers *n*	Most Voted Answer (%)	Agreement
3	Who indicates PC …	3 Answers	"Both" (46.7%)	MEDIUM
10	Delivery of Informed Consent PC …	3 Answers	"Yes", the same as VCE (40.2%) + a specific one (32.4%) (Total "Yes" 72.6%)	MEDIUM
11	Previous preparation …	>3 Answers	"None", mostly (58.4%)	HIGH
12	Previous medication withdrawal …	>3 Answers	"No", mostly (79.2%)	HIGH
13	Delivery of recommendation sheet post-ingestion of PC …	2 Answers	"Yes", mostly (62.3%)	MEDIUM
14	PC indication in SCD …	>3 Answers	"If there is suggestive clinical suspicion of subocclusion or radiological suspicion of stenosis" (68.8%).	HIGH
15	PC indication in CD …	>3 Answers	"In the presence of suggestive clinical suspicion of subocclusion, radiological suspicion of stenosis or previous surgery" (38.9%).	MEDIUM

16	PC indication in Intestinal Tumor …	>3 Answers	"If there is suggestive clinical suspicion of subocclusion or radiological suspicion of stenosis" (58.4%).	HIGH
17	PC indication in abdominal or pelvic RT …	>3 Answers	"In the presence of suggestive clinical suspicion of subocclusion or radiological suspicion of stenosis" (49.3%).	MEDIUM
18	PC indication in Ulcerative Colitis Yeyunitis …	>3 Answers	"In the presence of suggestive clinical suspicion of subocclusion or radiological suspicion of stenosis" (68.8%).	HIGH
19	PC indication in Intestinal Polyposis Syndrome …	>3 Answers	"In the presence of suggestive clinical suspicion of subocclusion, radiological suspicion of stenosis or previous surgery" (35.0%).	MEDIUM
20	PC indication in chronic NSAIDs Ingestion …	>3 Answers	"If there is suggestive clinical suspicion of subocclusion or radiological suspicion of stenosis" (58.4%).	HIGH
21	PC indication in Adherent Syndrome …	>3 Answers	"In previous clinical suspicion suggestive of subocclusive/occlusive episodes and if there is suspicion of XR stenosis" (45.4%).	MEDIUM
22	In what type of Surgery is	>3 Answers	"Resections of SB or	MEDIUM

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

	PC indicated …		stricturoplasties” (27.2%).	

Revista Española
de Enfermedades Digestivas
The Spanish Journal
of Gastroenterology

	In what type of Surgery is PC indicated …		"Resections of SB or stricturoplasties" (27.2%).	
23	Perform MRE prior to PC in risk of retention …	3 Answers	"No, I perform MRE or PC before VCE indistinctly" (50.6%).	MEDIUM
24	Perform PC prior to VCE if suspicion of stenosis in MRE …	3 Answers	"I always indicate PC before VCE" (58.6%).	MEDIUM
25	Do you show photos of how the PC can be expelled …	2 Answers	"Never" (71.4%).	MEDIUM
26	Do you document the shape of the expelled PC …	2 Answers	Mostly "Yes", the shape of the expelled PC is objectified (72.7%)	MEDIUM
27	Do you document the expulsion time of the PC?	2 Answers	Mostly "Yes", the excretion time of the PC is recorded (70.1%).	MEDIUM
28	When do you check the excretion of the PC?	3 Answers	1st XR control at "30h" (34.2%).	MEDIUM
29	How do you check the excretion of the PC?	3 Answers	"The patient comes to the center to deliver the PC when it is excreted" (31.1%).	MEDIUM
30	What detection technique do you use when the patient has not evidenced the excretion of the PC?	3 Answers	"Simple abdominal XR" (80.9%).	HIGH

31	What XR projection do you use to check the excretion?	>3 Answers	"AP bipedestation XR projection" (44.1%).	MEDIUM
32	If the patient has not evidenced the excretion of the PC at 30-48h, and in the detection test of your choice (XR/CT/others) the device is not objectified, do you administer the VCE?	3 Answers	Mostly "Yes" is administered (54.5%).	MEDIUM
33	If in the technique used for the detection of the PC at 30-48h its presence in the abdomen is objectified, what attitude do you take to know if it is in the colon or SB?	3 Answers	"Repeat abdominal XR" (44.1%).	MEDIUM
34	Do you make a PC 7 report?	2 Answers	Mostly "Yes", a PC report is made (69.7%).	MEDIUM

Table 3. Predictors of survey responses.

Dependent Variables		**Predictors**			
		Question 4	Question 7	Question 8	Question 25
Question 15	OR	1,764	0,64	1,342	1,566
	IC (95%)	0,667-4,67	0,209-1,96	0,455-3,95	0,541-4,53
	p	0,253	0,435	0,594	0,408

Question 19	OR	2,027	1,569	0,782	1,285
	IC (95%)	0,751-5,47	0,499-4,93	0,253-2,42	0,420-3,93
	p	0,163	0,44	0,669	0,66
Question 22	OR	3,581	1,657	1,704	1,073
	IC (95%)	1,252-10,24	0,513-5,36	0,520-5,58	0,344-3,35
	p	**0,017***	0,399	0,379	0,903
Question 28	OR	0,889	0,949	0,648	1,115
	IC (95%)	0,328-2,41	0,297-3,03	0,204-2,06	0,367-3,39
	p	0,817	0,93	0,461	0,847
Question 29	OR	1,026	6,529	0,296	2,974
	IC (95%)	0,339-3,10	1,6909-25,21	0,075-1,17	0,8926-9,91
	p	0,964	**0,006***	**0,083***	**0,076***

Discussion

This is the first European study aiming to provide an overview of current gastroenterologist practices regarding PC performance. The PC is widely regarded as essential, especially in patients with CD and other high-risk conditions. Over half of respondents had extensive PC experience, with primary indications including CD, SB tumors, postoperative SB alterations, and prior radiation therapy (8). These findings align with ESGE recommendations, supporting a selective, risk-based approach (11), and studies show PC has high sensitivity (97%) and specificity (83%) for predicting safe VCE passage (12). Moreover, systematic reviews indicate PC use reduces VCE retention by ~5% (5). On the other hand, PC showed comparable sensitivity, significantly higher specificity, and a significantly lower false-negative rate than cross sectional imaging (13).

One of the main concerns regarding PC, is the lack of global standardize protocols among physicians. To our knowledge, there are not national and/or international guidelines on PC performance. This is probably acting as a negative influence on the real potential of PC. Therefore, we designed this study aiming to assess the agreement of PC use among physicians setting also the need for a future consensus/guideline on the field.

First of all, based on our results, it is not clear who should indicate the PC procedure. In fact, PC use was indicated by the endoscopist in 34.7% of cases, by the referring physician in 17.3%, and jointly in 48%. On one hand, the endoscopist may have more information and experience on PC but, on the other hand, the referring physician has more information regarding the patient and the clinical scenario. So, it seems that the best approach to PC should be discussed jointly.

Survey results show strong consensus on key practices, such as obtaining (IC) and confirming passage of the PC via XR. However, a high variability exists in patient preparation and post-ingestion instructions; 25% did not obtain specific IC for PC, and some did not adjust medications affecting transit times as recommended by some authors (3,14). Medium- and small-sized centers and those performing <10 PCs/year showed less agreement, highlighting the need for standardized guidance.

In fact, some centers omit specific IC despite that rare transient symptomatic retention of PC (1.2%), which usually resolves spontaneously (15), may occur. Although safe, PC can be contraindicated. Contraindications for PC include long-segment stenosis (>10 cm) or >2 pre-stenotic dilatation (12,16). On the other hand, radiological techniques may miss some stenoses, supporting PC as a direct physiological test (17,18) and usually preferred PC over MRE due to its higher sensitivity and PPV (9). So, anyway and based on these previous facts, it seems to be crucial to ask our patients for a specific IC prior PC. This is one of the most important conclusions of our study. Our findings highlight the need to standardize specific IC for the PC, as 25% of respondents did not obtain it, reflecting variability in current practice.

Notably, about 25% of respondents perform VCE without confirming prior PC expulsion before 40h (i.e. visual confirmation). This practice raises concerns regarding patient safety, given the risk of VCE retention, and may also carry medico-legal implications. SB patency should be confirmed with imaging within 30-40h if there is no visual documentation of PC excretion; if undetected, this provides indirect evidence of permeability. XR (upright and lateral) is most widely used, with low-dose CT, tomosynthesis, or US as alternatives when needed. In fact, PC is radiopaque and can be detected in a XR when it is not excreted. However, a carefully examination of the XR is crucial because we may find the PC in the SB or in the colon resulting in different actions. If the PC is still in the small bowel SB, VCE may be contraindicated but if the PC is in the colon, PC may be safely performed (if the patient has a normal colonoscopy), always depending on PC deformation. However, sometimes it is quite difficult to differentiate between SB and colon location. So, it is usually recommended but not worldwide accepted to ask for a lateral XR, ask for the radiologist opinion or wait some hours if doubts persist. Unfortunately, all of these scenarios and ideas are not standardized leading to a suboptimal PC performance as demonstrated by our results and the paper published by Kopylov et al, where, as an example, if the decision to administer VCE had been based on imaging and not PC results, at least 40% of the patients would have been denied the procedure (15).

Hospital level, availability, adherence to local guidelines, and reimbursement policies influence PC use. Most respondents follow the recommended dissolution timing (initial check at 30h, subsequent checks every 24h), although some studies suggest up to 32% of patients can safely proceed with VCE after 72h (19,20). Clinical factors, including age, sex, and other patient-specific variables, may influence PC excretion and its confirmation (21,22) and they should be taken into account but also protocolized.

Summarizing, based on the information obtained by the survey, it seems reasonable to recommend: indicate the PC procedure together with the clinician in high risk patients; use an PC-specific IC or PC-VCE combined IC; no laxatives before PC; confirm PC excretion by physicians before VCE and use XR if there is no visual confirmation.

This study has limitations. Responses may be affected by recall bias, and the 75 participants may not fully represent all professionals performing VCE in Spain, especially those in smaller centers or with lower procedural volumes.

In summary, this SBWG-SEED Patency survey is the first to be conducted worldwide and provides insight into current PC use, demonstrating a high variability in the agreement among physicians regarding its use. This offers a foundation for standardized guidelines to support an effective, safe and cost-effective clinical practice.

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