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Can we predict an incomplete capsule endoscopy? Results of a multivariate analysis using a logistic regression model

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Abstract:

Background and aims: Small bowel capsule endoscopy (SBCE) does not reach the cecum within the battery lifetime in approximately 15-35% of patients. Incomplete examinations result in diagnostic delays and increase the economic burden. To date, risk factors for incomplete examinations have been described with contradictory results. The aims of this study were to analyze rate and identify risk factors for incomplete examinations, excluding capsule retentions, in a large cohort of patients. Methods: Data from 1894 consecutive SBCE examinations performed from January 2009 to December 2015 were analyzed. Variables recorded included demographics, past medical and surgical history, biochemical parameters and procedure characteristics. The rate of incomplete examinations, excluding capsule retentions, was calculated and a multivariate analysis using a logistic regression model was performed in order to evaluate predictive factors. Results: The incidence of incomplete examinations, excluding capsule retentions, was 10.1% (187 incomplete procedures). The multivariate analysis showed that age >65 years, gastric transit time >41 minutes

and SB transit time >286 minutes are predictive factors for incomplete examinations, increasing the probability of this event by 199% (OR:1.99; CI95%:1.34-2.95), 260% (OR:2.60; CI95%:1.72-3.93) and 352% (OR:3.52; CI95%:2.26-5.48), respectively. Conclusions: Age >65 years, gastric transit time >41 minutes and SB transit time >286 minutes are predicting factors for incomplete examinations excluding capsule retentions. Both age and gastric transit time events are known before procedure ending. Therefore, pharmacologic or endoscopic measures may be taken into account to avoid incomplete examinations.

Introduction:

The development of endoscopy represented a remarkable breakthrough in gastroenterology, since it allows real-time imaging of the gastrointestinal tract and the possibility of histological study through biopsy sampling. Nevertheless, the study of the small intestine remained almost inaccessible until the appearance of capsule endoscopy (CE) in 2000. Since its introduction by Iddan et al. [1], CE has demonstrated to be a simple, effective and safe procedure which has also proved to be superior to other diagnostic modalities [2-8]. In fact, it is currently considered as a first line tool for small bowel (SB) examination. There have been major advances in its technical elements and video-processing systems from the first prototype to the currently available device. However, CE has still some limitations. It is unable to take mucosal biopsies for histological examination, ~~nor~~ lumen water instillation, air insufflation or intestinal fluids aspiration as in conventional endoscopy. This results in false positives and false negatives, unclear examinations and incomplete procedures. The latter is defined as the studies in which the cecum is not reached within the battery lifetime. As a result, some lesions may be missed in the non-visualized segments even though the capsule can be properly excreted with the feces. An incomplete CE not only increases the economic burden of diagnosis (cost of the capsule and used resources), but also prevents the patients from receiving on time the appropriate treatment. According to published series, the rate of incomplete examinations is usually 15-35% [9-19]. To date, some studies [10,12,14,19] have evaluated the influence of individual factors or relations between certain characteristics of the patients with the presence of incomplete

procedures. However, these studies show contradictory results from which no firm conclusions can be drawn. This study has been built on the hypothesis that we may be able to optimize CE procedures by avoiding incomplete examinations with a plan of action (such as giving prokinetics, endoscopy-guided CE introduction or just procedure contraindication) if we could predict the presence of incomplete procedures before capsule ingestion or at the beginning of the examination. The aim of this study as a primary endpoint was to analyze the incidence of incomplete SBCE examinations in a large cohort of patients who underwent SBCE at a single institution. Secondary endpoints were to analyze characteristics and predictive factors, if any, of incomplete examinations excluding capsule retentions.

Patients and methods:

This study is a retrospective analysis of 1894 consecutive SBCE examinations performed at our Institution from January 2009 to December 2015. All examinations were performed with the PillCam SB2 and PillCam SB3 capsules (Given Imaging Ltd, Yoqneam, Israel) that offer a battery life of 9-10 hours approximately. Moreover, all examinations were addressed to examine the SB and not colon. Patients with capsule retention, defined as absence of excretion for more than 15 days, were excluded from the analysis. Variables recorded included demographics (age, sex, anthropometric parameters), past medical and surgical history (abdominal), biochemical parameters (hemoglobin, MCV, iron, ferritin, leukocytes, creatinine, urea) and procedure characteristics (indication, gastric and intestinal transit times, complete examination, use of prokinetics and ingestion protocol). Esophageal transit time (ETt) was defined as the time between first esophageal and gastric images, gastric transit time (GTt) was defined as the time between first gastric and duodenal images and SB transit time (SBTt) was defined as the time between first duodenal and cecal images.

CE procedure:

All procedures were performed following an established protocol for both, outpatients and inpatients: the day before the study, at dinner, only clear liquids were allowed and after 22:00h, the patient started fasting. Necessary medications were taken with some

water. The following morning, the patients presented at our Unit and after introducing their registration data on the computer software, we proceeded to place the sensors in the abdominal wall or in a belt adjusted to the patient waist. The recorder was set on the shoulder strap. The capsule was swallowed usually in right supine position in order to examine the esophagus. If the patient did not tolerate this position, it was changed to supine or standing position. Complete fasting was maintained for two hours following the ingestion of the capsule and then it was allowed to drink liquids except for milk. After five hours of ingestion, the patient was allowed to eat a very light meal and after completing the procedure, started his usual diet. Patients were instructed to contact our Unit in case of abdominal pain, nausea or vomiting during the technique. After 10 hours of ingestion, the patient came to our Unit for withdrawal and delivery of the system. Patients were asked to check if the capsule was excreted or not. It most cases it happens spontaneously during the first 72 hours but in case of not having done so or not having sureness, patients were instructed to contact his doctor, who usually indicated an abdominal X-ray to confirm the location of the device. After downloading the data of the recorder in the computer, the images were reviewed by trained gastroenterologists with the program RAPID Reader.

Statistical analysis:

The Statistical Package for Social Sciences version 20.0 (IBM Corp. Armonk, New York, USA) was used for data collection and analysis. Variables such as demographics (age, sex, anthropometric parameters), past medical and surgical (abdominal) history, biochemical parameters (hemoglobin, MCV, iron, ferritin, leukocytes, creatinine, urea) and procedure characteristics (indication, gastric and intestinal transit times, complete examination, use of prokinetics and ingestion protocol) were recorded in order to perform the univariate analysis. Multivariate analysis was then performed using a logistic regression model. An “event variable” that indicates whether the test has been complete and thus able to visualize the cecum or, in the contrary, has been incomplete because it did not progress to that location, was created. Initially, a descriptive study of the quantitative and qualitative variables was carried out. Then, incidence of incomplete procedures was calculated. Patients with capsule retention were excluded

from the analysis. Subsequently, the association between each variable and the dependent variable, in our case the "event variable", was studied using a univariate analysis. We opted for a multivariate analysis using a logistic regression model with a backwards predictive approach. In order to perform this evaluation, all the variables that showed an association between them and the dependent variable were included in the model. A p value of less than 0.05 was considered statistically significant. Finally, we investigated the values of gastric and SB transit times in every predicting factor in order to focus on future patients´ management options or posibilities.

Ethics:

The Institutional Review Board approved data collection and their use for the present study purpose.

Results:

During the study period, a total of 1894 SBCE procedures were included in the study: 1659 (87.6%) were complete procedures, 187 (9.9%) were incomplete procedures and 48 (2.5%) were capsule retentions.

Table 1 and Table 2 shows patients´ and procedures´ general characteristics and results of the univariate analysis.

Incidence of incomplete examinations and univariate analysis:

After excluding capsule retentions, a total of 1846 procedures were finally taken into account for incidence analysis which was 10.1%.

On the other hand, in the univariate analysis (**Table 1 and Table 2**), the following variables showed a statistically significant association ($p<0.05$) with the possibility of having an incomplete CE procedure and were included in the multivariate analysis: age (>65 years), gender (female), indication (OGIB-overt), setting (inpatient), abdominal surgery, cardiopathy, ingestion protocol (right supine position), creatinine levels (>1.7),

haemoglobin levels (<12 gr/dL), GTt (>41 minutes) and SBTt (>286 minutes).

Multivariate analysis:

Final results of the multivariate analysis are shown in **Table 3**.

Once adjusted the effect of all variables included in the logistic regression model the analysis showed that age older than 65 years, GTt higher than 41 minutes and SBTt higher than 286 minutes are predictive factors for incomplete CE examinations increasing the probability of this event by 199% (OR: 1.99; CI95%: 1.34-2.95), 260% (OR: 2.60; CI95%: 1.72-3.93) and 352% (OR: 3.52; CI95%: 2.26-5.48), respectively.

Transit times analysis in independent predictive factors:

Patients older than 65 years had a GTt significantly shorter than those < 65 years (35.1 vs 46.3 minutes; $p<0.05$) and a SBTt significantly longer (243.3 vs 229.6 minutes; $p<0.05$). Patients with GTt > 41 minutes had significantly shorter SBTt respect to those with ≤ 41 (217.8 vs 238.6 minutes; $p<0.05$). Finally, patients with SBTt > 286 minutes had significantly shorter GTt respect to those with ≤ 286 minutes (31.4 vs 38.7 minutes; $p<0.05$).

Discussion:

Since its introduction in 2001, CE has revolutionized the approach to SB diseases. CE is a minimally invasive, effective and safe technique. Moreover, it has been proven to be superior to other diagnostic modalities for SB examination such as SB follow-through, CT scan and MRI [8]. Thus, CE is currently considered as a first-line procedure for the visualization of the SB. However, CE has some limitations such as incomplete procedures which occur when the capsule does not reach the cecum before battery-life expiration. The term “incomplete examination” has been confusing over the years since, if literally used, it should include both capsule transit delays and capsule retentions. Incomplete examinations may be classified in 2 categories: 1) capsule

delays defined as those procedures where the capsule is excreted without the need of therapeutic interventions before 14 days [20] and 2) capsule retentions defined as those procedures where the capsule is excreted after 14 days or before if therapeutic interventions are needed [20]. As in our study, scientific literature uses frequently the term "incomplete examinations" referring to capsule delays and not retentions. The importance of incomplete procedures is that they may result in false negative examinations. In fact, in those scenarios where the CE does not reach the cecum, lesions located at distal segments are missed resulting in an economic burden due to repeated diagnostic procedures and, consequently, diagnosis delays. To date, the incidence of incomplete procedures is a well-known topic. Most of articles report an incidence of incomplete procedures ranging from 10% to 35% [9-19]. In a recent article, the ESGE quality improvement committee recommends as a standard of care a minimum of 80% of complete examinations [21]. In order to become auditable, complete examinations should be documented in a written report as well as by photo-documentation (cecum images). If the minimum standard is not reached, an analysis of those factors influencing completion rate should be performed on a service level and for each individual reader. After evaluation and adjustment, a close monitoring should be performed with a further audit within 12 months and/or for a sample of 100 procedures [21]. The incidence of incomplete examinations, excluding patients with capsule retentions, in our study was 10.1% that meets the ESGE quality criteria. Although some patients were under therapy under prokinetics drugs, it did not affect incidence values and was not demonstrated to be a predictor of incomplete examinations. Our large sample size is a strong argument to extrapolate our results to the general population. Some researchers have investigated those factors that may be related or predict incomplete procedures [10,12,14,19,20,22-28]. These investigations could be helpful since it would give us the opportunity to evaluate the use of alternative methods such as prokinetic drugs, protocol ingestions or endoscopic interventions in those patients at risk of incomplete examinations. On the other hand, they could also guide those Institutions with suboptimal parameters in terms of quality performance to improve their standards. Unfortunately, they show contradictory results from which no firm conclusions can ~~cannot~~ be drawn. Ponte et al. [19], in a recent study, concluded

that degree of dependency, hospitalized patients and prior abdominal surgery were independent predictive factors of an incomplete CE procedure. On the other hand, several authors demonstrated in their respective studies the negative impact of hospitalization in CE performance [22-25]. In the Korean Capsule Endoscopy Registry [26] (2,914 patients), the overall incomplete rate was 33% and was higher in the elderly and in those patients with poor bowel preparation. Höög et al. [20], concluded that older age, male gender, suspected and known Crohn's disease were risk factors for an incomplete examination. Lee et al, in one of the most complete studies on the field concluded that independent risk factors for an incomplete CE procedure include prior history of bowel obstruction and procedures performed for gastrointestinal bleeding [14]. However, in this study, patients with a prior history of abdominal surgery, those taking opiate medications and hospitalized patients did not show statistical significance [14]. Diabetes Mellitus was also considered a risk factor for incomplete examinations by Triantafyllou et al [27]. Westerhof et al., concluded that previous small-bowel surgery, hospitalization, moderate or poor bowel cleansing, and a long gastric transit time were identified as independent risk factors for incomplete CE procedures [12]. Nevertheless, other authors such as Niv et al. [28] or Selby et al. [10], concluded that demographic and clinical parameters cannot predict prolonged gastric transit time or incomplete examinations. Summarizing, it seems that, excepting for hospitalized patients as mentioned in the ESGE technical review in 2018 [29], there are not clear factors that may influence the rate of complete examinations. In addition, most of these studies have been performed in small sample sizes, which may reduce their impact, and with this information it is difficult to give solid recommendations. Our study aimed to shed some light in the current darkness and evaluate those possible predicting factors of incomplete CE examinations in a large study population. In the univariate analysis, age, gender, procedure indication, hospitalization, personal history of surgery and/or cardiopathy, ingestion protocol, creatinine, haemoglobin and GTt as well as SBTt were significantly related to incomplete procedures. The multivariate analysis revealed that only age > 65 years, GTt > 41 minutes and SBTt > 286 minutes were independent predictive factors for incomplete procedures. Those patients older than 65 years have a 199% increased risk of incomplete CE respect to younger

patients. Since patients´ age is easily predictable before CE examinations and, as demonstrated by our results, shows longer SBTt, it could be recommended to administer prokinetic agents. The target of the prokinetic agent in these cases should be to decrease the SBTt. On the other hand, patients with GTt longer than 41 minutes had a 260% increased risk of incomplete examinations. Surprisingly, they showed shorter SBTt than patients with GTt < 42 minutes. Anyway, it should also be recommended to use prokinetic agents but focused only on the gastric motility. However, GTt are not predictable before CE. So, we may use the real time viewer system after 41 minutes of capsule ingestion and if the capsule remains in the stomach, then prokinetic agents should be given. If prokinetic drugs are not effective, then the endoscopic approach is recommended. Patients with SBTt transit times longer than 286 minutes had a 352% increased risk of incomplete CE procedures. They showed GTt shorter than those patients with SB transit times < 287 minutes. Since SBTt are not predictable, it is again difficult to make any recommendation. Based on these and previous results, it seems that the real problem are transit times more than patients´ features. Future efforts should be made in analysing those factors that may predict long transit times and thus, support the idea of prokinetic drugs pre-medication and/or endoscopic management. In the meanwhile, patients older than 65 years should receive prokinetic agents with demonstrated effect in the SB such as prucalopride [30] or just physical activity [31], and patients with GTt longer than 41 minutes should receive prokinetic agents with demonstrated effect in the stomach such as erythromycin/domperidone [32,33] or just left supine position [34]. However, it should be demonstrated by future studies. This study has some limitations. On one hand, it is a retrospective study which means that some data may be missing such as type of surgery or type of prokinetics. On the other hand, we believe that a second group of incomplete examinations including capsule retentions would be interesting. Nevertheless, we believe that the large number of patients included in the analysis minimize the negative impact of the study design and gives strength to our conclusions. In summary, the incidence of incomplete examinations at our Institution is within the limits of the standards recommended by the ESGE quality improvement committee (10,1%). Age higher than 65 years, GTt longer than 41 minutes and SBTt

longer than 286 minutes are predicting factors for incomplete examinations. The presence of these factors, alone or together, prior to capsule examination could be an indication for prokinetic agents pre-medication, endoscopic actions or physical manoeuvres during capsule endoscopy ingestion.

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Table 1 Patients´ general characteristics

Variable	**Categorization**	**Overall n (%)**	**Complete n (%)**	**Incomplete n (%)**	**LR Chi^2 (p value)**
Gender			797 (87.8)	111 (12.2)	7.90

	Male	908 (47.9)			(<0.05)
	Female	986 (52.1)	904 (91.7)	82 (8.3)	
Age	<65	1134 (59.8)	1041 (91.8)	93 (8.2)	11.98 (<0.05)
	≥65	760 (40.2)	660 (86.8)	100 (13.2)	
BMI	<18.5	50 (3.2)	45 (90.0)	5 (10.0)	1.68 (0.641)
	18.5 – 24.9	584 (37.1)	537 (92.0)	47 (8.0)	
	25 – 30	651 (41.4)	586 (90.0)	35 (10.0)	
	>30	288 (18.3)	259 (89.9)	29 (10.1)	
Diabetes	No	1543 (83.0)	1389 (90.0)	154 (10.0)	0.17 (0.677)
	Type I	51 (2.7)	45 (88.2)	6 (11.8)	
		266	239 (89.8)	27 (10.2)	

	Type II	(14.3)			

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		266 (14.3)			
Abdominal Surgery	No	1179 (63.4)	1074 (91.1)	105 (8.9)	4.20 (<0.05)
	Yes	681 (36.6)	600 (88.1)	81 (11.9)	
Cirrhosis	No	1803 (96.8)	1624 (90.1)	179 (9.9)	1.58 (0.209)
	Yes	59 (3.2)	50 (84.7)	9 (15.3)	
Hypothyroidism	No	1737 (93.3)	1561 (89.9)	176 (10.1)	0.847 (<0.05)
	Yes	125 (6.7)	113 (90.4)	12 (9.6)	
Nephropathy	No	1750 (94.0)	1576 (90.1)	174 (9.9)	0.380 (0.77)
	Yes	111 (6.0)	97 (87.4)	14 (12.6)	
Cardiopathy	No	1433 (77.1)	1304 (91.0)	129 (9.0)	6.66 (<0.05)
	Yes	425 (22.9)	368 (86.6)	57 (13.4)	

Haemoglobin (gr/dL)	<12	909 (49.7)	796 (87.6)	113 (12.4)	13.45 (<0.05)
	12-13.99	446 (24.4)	406 (91.0)	40 (9.0)	
	≥14	475 (26.0)	444 (93.5)	31 (6.5)	
Leucocytes (mil/mm³)	<4000	79 (4.3)	68 (86.1)	11 (13.9)	3.48 (0.17)
	4000 – 12000	1643 (90.4)	1487 (90.5)	156 (9.5)	
	>12000	96 (5.3)	83 (86.5)	13 (13.5)	
Creatinine (mg/dL)	≤1.7	1668 (93.9)	1509 (90.5)	159 (9.5)	3.86 (<0.05)
	>1.7	109 (6.1)	91 (83.5)	18 (16.5)	

Table 2 Procedures´ general characteristics

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Variable	Categorization	Overall n (%)	Complete n (%)	Incomplete n (%)	LR Chi^2 (p value)
Indication	Iron Deficiency Anemia*	480 (25.5)	426 (88.8)	54 (11.2)	17.58 (<0.05)
	Obscure GI Bleeding - Occult	325 (17.2)	294 (90.5)	31 (9.5)	
	Obscure GI Bleeding - Overt	233 (12.4)	196 (84.1)	37 (15.9)	
	IBD	351 (18.6)	315 (89.7)	36 (10.3)	
	Chronic Diarrhea	135 (7.2)	125 (92.6)	10 (7.4)	
	Abdominal Pain	170 (9.0)	160 (94.1)	10 (5.9)	
	Tumor	26 (1.4)	25 (96.2)	1 (3.8)	
	Celiac disease	43 (2.3)	41 (95.3)	2 (4.7)	
	Malabsorption	13 (0.7)	12 (92.3)	1 (7.7)	
	Other	110 (5.8)	102 (92.7)	8 (7.3)	
Setting	Inpatient	449 (23.9)	382 (85.1)	67 (14.9)	13.95 (<0.05)

	Outpatient	1432 (76.1)	1309 (91.4)	123 (8.6)	
Ingestion	Standing	480 (31.4)	414 (86.2)	66 (13.8)	16.12 (<0.05)
	Supine	47 (3.1)	41 (87.2)	6 (12.8)	
	Right Supine	999 (65.3)	927 (92.8)	72 (7.2)	
	CE Release System	5 (0.3)	5 (100)	0 (0)	
Erythromycin	No	1771 (95.9)	1595 (90.1)	176 (9.9)	0.04 (0.838)
	Yes	75 (4.1)	67 (89.3)	8 (10.7)	
ETt	≤90 seconds	1280 (75.7)	1153 (90.1)	127 (9.9)	1.46 (0.22)
	>90 seconds	410 (24.3)	377 (92.0)	33 (8.0)	
GTt	≤41 minutes	1280 (75.7)	1153 (90.1)	127 (9.9)	31.00 (<0.05)

	>41 minutes	410 (24.3)	377 (92.0)	33 (8.0)	
SBTt	≤286 minutes	1323 (75.5)	1281 (96.8)	42 (3.2)	32.15 (<0.05)
	>286 minutes	430 (24.5)	357 (83.0)	73 17. 0)	

*Defined as Hb < 13 gr/dL in man and < 12 gr/dL in women, evidence of iron deficiency and no bleeding source outside the GI tract.

Table 3 Multivariate Analysis

Variable	**Categorization**	**OR**	**SE**	**z**	**p**	**IC95%**
Age	>65 years	1.99	0.39	3.46	0.001	1.34-2.95
GTt	>41 minutes	2.60	0.54	4.56	<0.0001	1.72-3.93
SBTt	>286 minutes	3.52	0.79	5.60	<0.0001	2.26-5.48