TRABAJOS ORIGINALES

Predictive factors of an incomplete examination and inadequate small-bowel cleanliness during capsule endoscopy

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ABSTRACT

Aim: the aim of this study was to determine predictive factors for an incomplete capsule endoscopy and an inadequate small-bowel preparation in capsule endoscopy.

Methods: predictive factors for an incomplete capsule endoscopy were evaluated. Therefore, all patients with incomplete examinations performed between June 2009 and February 2016 were retrospectively included and compared with all patients with complete procedures performed between January 2014 and February 2016. Predictive factors of an inadequate small-bowel cleanliness were assessed. Therefore, the subset of patients that underwent capsule endoscopy between January 2014 and February 2016, including incomplete examinations, were evaluated. Small-bowel cleanliness was evaluated according to a quantitative index and a qualitative evaluation scale. Data with regard to patient and capsule endoscopy was analyzed.

Results: 31 incomplete and 122 complete capsule endoscopies were included in the analysis of predictive factors for an incomplete capsule endoscopy. The degree of dependency (OR = 4.67; p = 0.028), performance of a capsule endoscopy in hospitalized patients (OR = 4.04; p = 0.006) and prior abdominal surgery (OR = 3.45; p = 0.012) were independent predictive factors of an incomplete procedure. 130 patients were included in the analysis of predictive factors for an inadequate small-bowel cleanliness. The mean quantitative index value was 7.3 (s.d. ± 2.3); 41.6% and 58.5% of capsule endoscopies were classified as poor-fair and good/excellent respectively, according to the qualitative evaluation. Independent predictive factors for an inadequate preparation according to the quantitative index included male gender (Beta = -0.79; p = 0.028), small-bowel transit time (Beta = -0.007; p < 0.0001) and cardiac disease (Beta = -1.29; p = 0.001). Associated factors according to the qualitative evaluation included male gender (OR = 0.406; p = 0.027) and small-bowel transit time (SBTT) (OR = 0.993; p < 0.0001).

Conclusion: inpatient status, higher degrees of dependency and abdominal surgery are predictive factors for an incomplete capsule endoscopy; male gender and higher small-bowel transit time are predictive factors for an inadequate cleanliness.

Key words: Capsule endoscopy. Small intestine.

INTRODUCTION

Since its introduction in 2001, capsule endoscopy (CE) has revolutionized small bowel imaging as it represents a reliable, safe and noninvasive diagnostic method for the assessment of the entire small-intestinal mucosa (1-7). Moreover, CE has a significantly higher diagnostic yield compared to other methods including push enteroscopy, enteroclysis, computed tomography, magnetic resonance imaging and angiography (3-5,8-12). Therefore, CE currently plays an important role in a wide range of clinical indications, including obscure gastrointestinal bleeding (OGIB), iron-deficiency anemia, known or suspected small-bowel Crohn's disease, small-bowel tumors, polyposis syndromes and celiac disease (1-3,8,10,12-16).

Despite the undeniable advantages of this diagnostic tool, CE has a false negative rate of around 11%, ranging between 0.5% for ulcerative disease and 18.9% for neoplastic disease (17). The diagnostic yield of CE may be hampered by two main factors, an incomplete examination of the entire small-bowel during the recording time of the device and an inadequate enteric cleanliness (2,5,6,11,13-15,18-21). Therefore, it is essential to recognize factors that contribute to

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the limitations of CE in order to adopt specific measures in order to attenuate or obviate them.

The aim of this study was to determine predictive factors for an incomplete small-bowel examination and for an inadequate small-bowel preparation in CE.

METHODS

Patients

The predictive factors for an incomplete CE were evaluated. Therefore, all consecutive patients with incomplete small-bowel examinations during CE, performed since the introduction of the Mirocam® CE system in our department from June 2009 to February 2016, were retrospectively included in the study. These were compared with all consecutive patients with complete CE examinations that underwent CE between January 2014 and February 2016. The rationale for the inclusion of all cases of incomplete CE since the introduction of the Mirocam® CE system was due to the fact that a larger case group may be obtained, thus adding power to the comparative analysis. Furthermore, our CE protocol and the CE system from Mirocam® were not updated within this timeframe.

Only the subset of patients that underwent CE between January 2014 and February 2016 were retrospectively evaluated in order to identify predictive factors for inadequate small-bowel cleanliness in CE.

Patients younger than 18 years of age, those with an ileostomy, patients that had taken prokinetics prior to the procedure, cases with a retained CE in previously undiagnosed small-bowel stenoses and where the CE was directly placed in the duodenum with an upper endoscopy were excluded from the study.

Data with regard to demographics, degree of dependency of patients according to the Karnofsky Scale, past medical and surgical history, medications, CE parameters and the performance regimen (inpatient/outpatient regimen) were analyzed. All patients provided informed consent for the CE examination.

Capsule endoscopies

All CE were performed using the Mirocam® CE system (Mirocam, IntroMedic, Seoul, Korea). This system contains a battery with a life span of 12 hours and records images at a rate of 3 frames per second that are transmitted via human body communication technology to an external recorder.

The CE protocol within our department (22) is as follows: A capsule is ingested with a glass of water at 8 am after a clear liquid diet the day before the procedure and an overnight fast without prior bowel preparation. Real-time views are performed 1 and 2 hours after CE ingestion. 10 mg metoclopramide is administered if the capsule remains in the stomach after 2 hours. Normal daily activities are resumed on an outpatient basis (except for hospitalized patients) as well as the ingestion of an oral light diet 4 hours after CE ingestion. The recorder is removed 12 hours after CE ingestion, or earlier if real-time viewing confirms that the device has already reached the colon.

All CE were reviewed at a fixed rate of 40 frames per second by one of the authors (AP) in order to evaluate the first gastric image, the first duodenal image, the first cecal image or the last small-bowel frame in the case of an incomplete CE. Gastric transit time (GTT) was defined as the time elapsed between the first gastric and duodenal images. Small-bowel transit time (SBTT) was defined as the time elapsed between first duodenal and cecal images and an incomplete examination was defined as the inability of CE to reach the cecum during the recording time.

All CE videos that were included in order to evaluate predictive factors for an inadequate small-bowel preparation were reviewed for small-bowel cleanliness according to two subjective validated scores: the quantitative index (QI) and qualitative evaluation (QE) scales (14). QI grades the level of cleanliness according to five parameters; percentage of mucosa visualized, fluid and debris, bubbles, bile staining and brightness. The score ranges from 0 to 10 and QE is classified as excellent, good, fair and poor (14). In our study, excellent and good were combined and considered as an adequate preparation. Fair and poor were combined and considered as an inadequate preparation. The variables recorded included the indication for CE, degree of cleanliness according to QI and QE scores, GTT, SBTT and incomplete CE.

Statistical analysis

Descriptive statistics were performed with continuous variables presented as the mean and standard deviation. Categorical variables were expressed as proportions. The χ^2 test was used to compare proportions and the student's t-test to compare continuous variables across two groups. Pearson's correlation was used to compare continuous variables and binary logistic regression was used for the multivariate analysis of predictive factors of an incomplete CE and cleanliness in the QE grading scale. Linear regression was used for the same purpose for the QI grading scale. Odds ratios (OR) and 95% confidence intervals (95% CI) were presented when appropriate. Significance was set at $p < 0.05$. Variables with a $p < 0.1$ according to the univariate analyses were entered into the multivariate analyses. The Statistical Package for Social Sciences version 20.0 (IBM Corp., Armonk, New York, USA) was used for data entry and data analysis.

RESULTS

Patients

One hundred and fifty-three patients were included in the analysis of predictive factors for an incomplete CE, corresponding to 31 incomplete CE and 122 complete CE. Seventy-eight patients were male (51%), with a mean age of 56.8 ± 18.0 years. Patient and CE characteristics are detailed in table 1. A total of 484 CE procedures were performed between June 2009 and February 2016 in our department, there was a 6.4% rate of incomplete examinations.

Table 1. *Patient and capsule endoscopy examinations characteristics according to completeness of procedure*

Characteristics	n (%)		Univariate analysis	Multivariate analysis	
	Complete CE (n = 122)	Incomplete CE (n = 31)	p	OR (95% CI)	p
Demography					
Male gender	60 (49.2)	18 (58.1)	0.38		
Mean age (years), mean (S.D.)	56.2 (17.5)	59.0 (20.1)	0.44		
Patient status					
Inpatient/outpatient	15 (12.3)/107 (87.7)	13 (41.9)/18(58.1)	< 0.0001*	4.04 (1.50-10.85)	0.006
Autonomous/dependent	116 (95.1)/6 (4.9)	25 (80.6)/6 (19.4)	0.008*	4.67 (1.19-18.40)	0.028
Past medical and surgical history					
Cardiac disease	38 (31.1)	9 (29.0)	0.82		
Chronic liver disease	5 (4.1)	2 (6.5)	0.63		
Chronic renal disease	9 (7.4)	2 (6.5)	0.86		
Diabetes mellitus	35 (28.7)	9 (29.0)	0.97		
Dyslipidemia	30 (24.6)	6 (19.4)	0.54		
Hypertension	44 (36.1)	10 (32.3)	0.69		
Neurological degenerative disorders	2 (1.6)	0	1.00		
Previous abdominal surgery	23 (18.9)	12 (38.7)	0.04*	3.45 (1.31-9.08)	0.012
Stroke	2 (1.6)	2 (6.5)	0.18		
Thyroid disorders	11 (9.0)	0	0.08*		ns
Medications					
Anticholinergics	3 (2.5)	1 (3.2)	1.00		
Beta blockers	28 (23.0)	6 (19.4)	0.81		
Calcium-channel antagonists	13 (10.7)	3 (9.7)	1.00		
Opioids	0	2 (6.5)	0.04*		ns
CE examination					
Indication for CE:			0.07*		ns
– OGIB	85 (69.7)	27 (87.1)			
– Non-OGIB	37 (30.3)	4 (12.9)			
GTT (minutes), mean (S.D.)	34.8 (34.6)	72.7 (35.0)	0.01*		ns
SBTT (minutes), mean (S.D.)	317.7 (121.1)	-			

CE: capsule endoscopy; CI: confidence interval; GTT: gastric transit time; OGIB: obscure gastrointestinal bleeding; OR: odds ratio; SBTT: small-bowel transit time; ns: non significant; S.D.: standard deviation; *Variables with a p value < 0.01 that were included in the multivariate analysis.

One hundred and thirty patients were included in the analysis of predictive factors for inadequate small-bowel cleanliness. 50.8% (n = 66) were female, with a mean age of 56.4 ± 17.6 years. The mean QI value was 7.3 ± 2.3. 41.6% (n = 54) and 58.5% (n = 76) of CE were classified as poor-fair or good/excellent, respectively, according to the QE analysis. Patient and CE characteristics are summarized in tables 2 and 3.

Predictive factors for incomplete CE examinations

Factors that were significantly associated with an incomplete CE in the univariate analysis included inpatient regimen (p < 0.0001), higher degrees of dependency (p = 0.008), prior abdominal surgery (p = 0.04), opiate use (p = 0.04) and a higher GTT (p = 0.01). The degree of dependency (OR = 4.67; [95% CI, 1.19-18.40], p = 0.028), hospitalized patients (OR = 4.04; [95% CI, 1.50-10.85], p = 0.006) and prior abdominal surgery (OR = 3.45; [95% CI, 1.31-9.08], p = 0.012) were independent predictive factors for an incomplete CE (Table 1) according to the logistic regression analysis.

Predictive factors for inadequate small-bowel cleanliness

Factors that were significantly associated with a worse degree of enteric cleanliness in the QI according to the univariate analysis included male gender (p = 0.005), inpatient regimen (p = 0.012), cardiac disease (p = 0.004), dyslipidemia (p = 0.009), neurological degenerative diseases (p < 0.0001), CE performed for obscure gastrointestinal intestinal bleeding (p = 0.049), older age (Spearman's Rho - r_s = -0.29; p = 0.001) and elevated SBTT (r_s = -4.15;

Table 2. *Patient and capsule endoscopy examinations characteristics according to the degree of small-bowel cleanliness using the Quantitative Index Scale*

Characteristics	Quantitative index Mean (S.D.)	Univariate analysis	Multivariate analysis	
			Beta (95% CI)	p
Demography				
Gender (male/female)	6.73 (2.5)/7.86 (2.1)	p = 0.005*	-0.79 (-1.49;-0.09)	0.028
Mean age (years)		r^2 = -0.29; p = 0.001*		ns
Patient status				
Inpatient/outpatient	5.94 (2.4)/7.5 (2.3)	p = 0.012*		ns
Autonomous/dependent	7.37 (2.3)/6.44 (2.5)	p = 0.25		
Past medical and surgical history				
Cardiac disease (y/n)	6.28 (2.8)/7.8 (2.0)	0.004*	-1.29 (-2.06;-0.53)	0.001
Chronic liver disease (y/n)	5.6 (3.7)/7.4 (2.3)	0.10		
Chronic renal disease (y/n)	6.0 (3.3)/7.4 (2.2)	0.24		
Diabetes mellitus (y/n)	6.7 (2.5)/7.6 (2.2)	0.07*		ns
Dyslipidemia (y/n)	6.4 (2.3)/7.6 (2.3)	0.009*		ns
Hypertension (y/n)	6.8 (2.5)/7.6 (2.2)	0.07*		ns
Neurological degenerative disorders (y/n)	6.0/7.3 (2.3)	< 0.0001*		ns
Previous abdominal surgery (y/n)	6.6 (2.7)/7.5 (2.2)	0.07*		ns
Stroke (y/n)	7.7 (1.2)/7.3 (2.4)	0.79		
Thyroid disorders (y/n)	7.3 (2.2)/7.3 (2.4)	0.96		
Medications				
Anticholinergics (y/n)	8.0 (2.0)/7.3 (2.3)	0.60		
Beta blockers (y/n)	6.8 (3.0)/7.5 (2.1)	0.27		
Calcium-channel antagonists (y/n)	6.6 (2.2)/7.4 (2.3)	0.21		
Opioids (y/n)	7.0/7.3 (2.3)	0.90		
CE examination				
Indication for CE (OGIB/non-OGIB)	7.03 (2.4)/7.9 (2.1)	p = 0.049*		ns
GTT (minutes)		r^2 = -0.13, p = 0.08*		ns
SBTT (minutes)		r^2 = -4.15; p = < 0.0001*	-0.007 (-0.009;-0.004)	< 0.0001

CE: capsule endoscopy; CI: confidence interval; GTT: gastric transit time; OGIB: obscure gastrointestinal bleeding; SB: small-bowel; SBTT: small-bowel transit time; S.D.: standard deviation; y: yes; n: no; *Variables with a p value < 0.01 that were included in the multivariate analysis.

p < 0.0001). Independent predictive factors according to the linear regression included male gender (Beta = -0.79 [95% CI, -1.49 - -0.09], p = 0.028), SBTT (Beta = -0.007 [95% CI, -0.009 - -0.004], p < 0.0001) and cardiac disease (Beta = -1,29 [95% CI, -2.06 - -0.53], p = 0.001) (Table 2). In other words, male gender was associated with a QI classification 0.79 points lower, cardiac disease was 1.29 points lower and a higher SBTT had a QI classification 0.007 x SBTT (minutes) points lower.

With regard to QE, male gender (p = 0.02), older age (p = 0.01) and higher SBTT (p < 0.0001) were significantly associated with an impaired small-bowel cleanliness according to the univariate analysis. Independent predictive factors according to logistic regression included male gender (OR = 0.406; [95% CI, 0.183-0.903], p = 0.027) and SBTT (OR = 0.993; [95% CI, 0.990-0.997], p < 0.0001) (Table 3).

DISCUSSION

The diagnostic yield of CE may be negatively influenced by the presence of bile, bubbles and debris which impair mucosal visualization and also by an incomplete examination of the entire small-bowel (2,5,6,11,13-15,18-21). Incomplete examination and the inability of the CE to reach the cecum within the recording time constitute an important limitation of the technique. Lesions within distal segments of the small-bowel may be missed, resulting in the performance of additional diagnostic procedures and increased costs (3,8,23,24). Previous studies report that 15 to 33% of CE are incomplete (2,3,8,12,17,18,20,24-26). In our study, CE failed to reach the cecum in 6.4% of all procedures. This difference may be secondary to the use of the MiroCam® CE system with a battery life span of 12 hours, instead of the 8 hours as with other previously reported CE systems (3,12).

Table 3. *Patient and capsule endoscopy examinations characteristics according to the degree of small-bowel cleanliness using the Qualitative Evaluation Scale*

Characteristics	n (%)		Univariate analysis	Multivariate analysis	
	Fair-poor SB cleanliness (n = 54)	Excellent-good SB cleanliness (n = 76)	p	OR (95% CI)	p
Demography					
Male gender	33 (61.1)	31 (40.8)	0.02*	0.406 (0.183-0.903)	0.027
Mean age (years), mean (S.D.)	60.9 (17.3)	53.1 (17.2)	0.01*		ns
Patient status					
Inpatient/outpatient	10 (18.5)/44 (81.5)	6 (7.9)/70 (92.1)	0.07*		ns
Autonomous/dependent	49 (90.7)/5 (9.3)	72 (94.7)/4 (5.3)	0.5		
Past medical and surgical history					
Cardiac disease	19 (35.2)	20 (26.3)	0.28		
Chronic liver disease	3 (5.6)	2 (2.6)	0.65		
Chronic renal disease	4 (7.4)	5 (6.6)	1.00		
Diabetes mellitus	19 (35.2)	20 (26.3)	0.28		
Dyslipidemia	17 (31.5)	15 (19.7)	0.13		
Hypertension	23 (42.6)	26 (34.2)	0.33		
Neurological degenerative disorders	2 (3.7)	0	0.17		
Previous abdominal surgery	14 (25.9)	11 (14.5)	0.10		
Stroke	1 (1.9)	2 (2.6)	1.00		
Thyroid disorders	4 (7.4)	7 (9.2)	1.00		
Medications					
Anticholinergics	1 (1.9)	2 (2.6)	1.00		
Beta blockers	12 (22.2)	18 (23.7)	0.84		
Calcium-channel antagonists	7 (13.0)	7 (9.2)	0.50		
Opioids	1 (1.9)	0	0.42		
CE examination					
Indication for CE:			0.93		
– OGIB	38 (70.4)	52 (68.4)			
– Non-OGIB	16 (29.6)	24 (31.6)			
GTT (minutes), mean (S.D.)	41.2 (45.4)	34.3 (33.0)	0.32		
SBTT (minutes), mean (S.D.)	381.5 (138.6)	286.4 (105.8)	< 0.0001*	0.993 (0.990-0.997)	< 0.0001
Positive findings in small-bowel	31 (57.5)	47 (61.8)			
Positive findings in esophagus/stomach/colon	8 (14.9)	6 (7.9)			

CE: capsule endoscopy; CI: confidence interval; GTT: gastric transit time; OGIB: obscure gastrointestinal bleeding; OR: odds ratio; SB: small-bowel; SBTT: small-bowel transit time; S.D.: standard deviation; *Variables with a p value < 0.01 that were included in the multivariate analysis.

In our study, inpatient status, patients with higher degrees of dependency and prior abdominal surgery were independent predictive factors for an incomplete CE. This is consistent with previous reports (2,3,8,23,24,27). In contrast to previous studies, no significant differences in GTT were identified between both groups (2,3,8,23,27). Moreover, advancing age and diabetes mellitus were not associated with a higher risk of an incomplete CE. Although, the results from previous reports are controversial (2,8,27). The identification of risk factors for an incomplete CE is important in order to select patients who may benefit from additional measures to decrease the risk of an incomplete procedure. These measures include performing CE with a device with a longer battery life and the use of frequent real-time views during the procedure with administration of prokinetics or endoscopic introduction of the capsule, as required. Furthermore, endoscopic placement of CE into the duodenum in patients at high risk of an incomplete CE, such as hospitalized patients or patients with previous small-bowel surgery (2,3,8,23,24,28). Currently, there is no consensus regarding the use of prokinetics to decrease the rate of an incomplete CE, as these drugs may decrease the diagnos-

tic yield of CE. Their effect on GTT and SBTT are unclear (3,8,23,27).

In our study, male gender and a higher SBTT were independent predictive factors for inadequate small-bowel cleanliness in CE, for both, QI and QE as well as cardiac disease according to the QI evaluation scale. Data related to predictive factors of an inadequate preparation in CE are lacking and our results may provide important information to fill this gap. In colonoscopy, there is more data with regard to factors that influence the quality of bowel preparation and previous reports concluded that male gender and the presence of co-morbidities may predict a worse bowel preparation (29,30). With regard to cardiac disease, ischemic heart disease, valvular heart disease and cardiac arrhythmias cases were included. Patients with cardiac disease may be more prone to have physical activity constraints and functional limitations to some extent in their daily routine. This could potentially limit the compliance with CE protocol instructions, where patients are advised to walk during the exam.

The inability of air insufflation, aspiration and the presence of uncontrolled movements of CE, mean that small-bowel cleansing should be optimized. This will decrease the number of false negatives and the need for a repeat CE, which may occur in up to 33% of the cases (13,14,27). The usefulness of bowel preparation before CE to improve small-bowel cleanliness remains a controversial issue and an overnight fast remains a widely accepted option (17,23,31). The data are conflicting, due to the heterogeneity of protocols with regard to the type of preparation, dosages and time of administration. A consensus regarding the efficacy, tolerability and best approach for intestinal cleansing before CE is lacking (5,10,11,15,16,18,19,31,32). Nevertheless, small-bowel preparation with 2L of polyethylene glycol before CE seems to improve the quality of mucosa visualization and the diagnostic yield. There are no differences regarding the CE completion rate, GTT and SBTT (12,33,34). In our study, 41.6% (n = 54) of CE were classified as poor-fair, which may be explained by the enteric preparation used (fasting and a liquid diet the day before the procedure). This has led to a review of our protocol with the implementation of simethicone and 2L of polyethylene glycol prior to CE administration.

In conclusion, incomplete examinations and inadequate bowel preparation are two important limitations in CE. Our study showed that inpatient status, patients with higher degrees of dependency and prior abdominal surgery were predictive factors for an incomplete CE. Male gender and a higher SBTT were independent predictive factors for an inadequate small-bowel cleanliness in CE. The identification of these factors may contribute to incorporation of additional measures to decrease the rate of these limitations.

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