Single-centre experience on use of videocapsule endoscopy for obscure gastrointestinal bleeding in 120 consecutive patients

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Abstract

Background and study aims : **Capsule endoscopy (CE) has become first choice for evaluation of the small bowel in case of obscure gastrointestinal bleeding (OGIB). The influence of clinical factors on CE diagnostic yield remains controversial and little is known about the exact impact of CE on management and outcome.**

We aimed to identify the ideal candidates for CE examination in daily practice by reviewing our own data and the available literature.

Patients and methods: **We retrospectively analyzed data of 120 consecutive patients with OGIB (33 overt – 87 occult) that underwent CE in a single centre.**

Results : **Complete evaluation of the small bowel was achieved in 82,5%, with only one case of capsule retention. The overall diagnostic yield was 47,5% and no difference was noted in the overt versus the occult group. Only the presence of cardiovascular comorbidity was associated with a statistically significant increase in diagnostic yield (p = 0,041). Arterio-venous malformation (AVM) was diagnosed most frequently in 68,4% of positive studies. Specific management alterations were made in 22 patients (18,3%) following CE, mostly guided by a positive result (91%) (p = 0,0001).**

Conclusion : **In daily practice it remains very difficult to predict pathology detection rate on CE as well as to estimate the impact on further management and outcome in the individual patient. Diagnostic yield is significantly higher in patients with cardiovascular comorbidity than in those without.** (Acta gastroenterol. belg., **2011**, 74, **400-406**).

Key words : capsule endoscopy, obscure gastrointestinal bleeding, arterio-venous malformation, small bowel endoscopy.

Introduction

Obscure gastrointestinal bleeding (OGIB) is encountered in 5% of all gastrointestinal bleeds. The term obscure is used because conventional upper and lower gastrointestinal endoscopy have failed to show the origin of recurrent or persistent bleeding, which is suspected somewhere inside the small bowel. OGIB can be overt when melaena or haematoschezia occur or can be occult, when iron deficiency anaemia and/or positive faecal blood testing are present.

The diagnostic and therapeutic approach of OGIB remains challenging, since classical radiology (small bowel follow-through and computed tomography) and push-enteroscopy lack sensitivity in detecting bleeding lesions in the small bowel. The introduction of capsule endoscopy (CE) in 2001 has offered a non-invasive way of visualising mucosa throughout the entire small bowel and has been shown superior to other diagnostic modalities in detecting the source of bleeding. This is illustrated by a sensitivity, specificity and positive and negative predictive values of 95%, 75%, 95% and 86%, respectively, when compared to intraoperative enteroscopy as golden standard (1,2,3). A similar diagnostic accuracy is found in double balloon enteroscopy (DBE), but only when an antegrade and retrograde approach are combined (4,5). Despite its non-invasive character and potent diagnostic capabilities, CE has several drawbacks. It has some intrinsic technical limitations that can lead to incomplete small bowel visualization and subsequently missed lesions (5,6). In general, the exact location of a lesion in the small bowel can only be roughly estimated and finally, capsule endoscopy lacks any option to take biopsy samples or perform therapeutic interventions. CE is, however, commonly recommended as first line investigation in case of OGIB to direct further investigations and/or therapy.

We report data on 120 consecutive capsule endoscopies carried out for the indication of OGIB in a single centre. Our aim was thriple : First to analyse whether we could confirm certain hypothesis on the predictability of a positive finding on CE in our study population. Secondly we wanted to check that our CE diagnoses were consistent with the available literature and thirdly to evaluate how CE seems to influence decision making in daily practice.

Patients and methods

Patients

One hundred and twenty consecutive patients, presenting with OGIB, underwent CE at the community hospital of Bonheiden (Belgium) between July 2008 and March 2010. All patients had undergone upper and lower endoscopy shortly before, which was unable to identify a potential bleeding source. Since nearly half of the patients with occult obscure bleeding were referred from neighbouring hospitals, there was no standardised diagnostic work up prior to CE. As a consequence, time between first presentation and CE examination varied

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Submission date : 06/03/2011
Acceptance date : 16/06/2011

broadly. Data of the 120 cases were extracted from their electronical medical records and were analysed retrospectively.

Collected clinical data included : age, gender, type of OGIB (occult vs. overt), technical/radiological examinations prior to CE, time-delay to CE (overt), use of anticoagulant medication and/or non-steroidal anti-inflammatory drugs (NSAID), comorbidity, lowest haemoglobin value noted, in- or outpatient status at time of CE and further management following CE.

A history of a cerebrovascular accident, coronary artery disease or known peripheral arterial disease, as well as severe valvular heart disease and/or congestive heart failure were considered as *cardiovascular* comorbidity. Patients with known preterminal renal impairment or who were under renal replacement therapy had *nephrological* comorbidity. *Pneumological* comorbidity included presence of relevant obstructive and/or restrictive lung disease. *Hepatological* comorbidity was noted when liver cirrhosis had been diagnosed. Any known haematological disorder, which could be a co-factor in the occurrence of anaemia, was considered as *haematological* comorbidity. A history of inflammatory mediated *reumatological* disease was taken in to account and finally the presence of active *oncological* comorbidity was recorded.

Capsule endoscopy specifications

The EndoCapsule-system from Olympus (Japan) was used in this study (1). The capsule was swallowed with a glass of water after an overnight fast of at least twelve hours. No purgative bowel preparation was given nor were prokinetics administered. Progression of the capsule through the pylorus into the small bowel was monitored regularly with the "real-time viewer" enabling interpretation of endoscopic images, transmitted by the capsule, in real-time. If passage of the capsule did not occur 60 to 90 minutes after ingestion, it was entered into the small bowel endoscopically.

A single gastroenterologist with extensive experience in the field of enteroscopy interpreted all collected videos. CE related data included : completion rate, complication rate, positive findings with their location in time and/or place and the small bowel transit time. Diagnostic lesions ("positive findings") covered the presence of arterio-venous malformation (AVM), ulcers, large and/or multiple erosions, tumours, hypertensive enteropathy and active bleeding or blood clots in the small bowel.

Statistical analysis

Chi squared tests (χ^2) were used to compare diagnostic yield between groups. Yates' correction was applied where necessary. A p-value of $< 0{,}05$ was regarded as statistically significant.

Results

Patient baseline characteristics

The baseline characteristics of all 120 patients are presented in table 1.

Capsule endoscopy findings

The capsule reached the caecum during the life span of the battery in 99 patients, which reflects a complete examination of the small bowel in 82,5%. In one case

Table 1. – **Patients baseline characteristics**

	Total	**Occult**	**Overt**
number of patients n (%)	120 (100%)	87 (72,5%)	33 (27,5%)
gender M/F n (%)	M 54 (45%) F 66 (55%)	M 33 (37,9%) F 54 (62,1%)	M 21 (63,6%) F 12 (36,4%)
age mean (range) in years	62,7 (13-84)	60,7 (13-84)	67,9 (38-82)
lowest Hb mean (range) in g/dl	8,8 (3,1-13,9)	9,3 (4,4-13,9)	7,7 (3,1-12,7)
examinations prior to CE n (%)			
abdominal CT	40 (33,3%)	22 (25,3%)	18 (54,5%)
abdominal US	8 (6,66%)	6 (6,9%)	2 (6%)
small bowel transit	11 (9,2%)	9 (10,3%)	2 (6%)
enteroscopy	2 (1,7%)	0 (0%)	2 (6%)
arteriography	2 (1,7%)	0 (0%)	2 (6%)
Meckel-scintigraphy	2 (1,7%)	1 (1,1%)	1 (3%)
patient status n (%)			
outpatient	88 (73,3%)	73 (83,9%)	15 (45,5%)
inpatient	32 (26,7%)	14 (16,1%)	18 (54,5%)
external referral	50 (41,7%)	45 (51,7%)	5 (15,2%)
endoscopic capsule introduction n (%)	10 (8,33%)	8 (9,2%)	2 (6,1%)
small bowel transit time mean (range) in minutes	301 (97-529)	298 (97-529)	311 (175-398)

M : male, F : female, Hb : haemoglobin, CE : capsule endoscopy, CT : computed tomography, US : ultrasound.

Table 2. — **Capsule endoscopy findings in relation to presentation characteristics**

Type of lesion/disorder	Total N (%)	Occult N	Overt N	Active bleeding on CE N	Age (mean) in years
Small bowel AVM	39 (68,4)	32	7	5	63,2
Small bowel ulcer eci	4 (7,0)	2	2	2	59
Small bowel erosions eci	2 (3,5)	2	0	1	79
Small bowel diverticulum	1 (1,8)	0	1	1	67
Small bowel bleeding eci	2 (3,5)	0	2	2	80
Stomach bleeding eci	1 (1,8)	1	0	1	59
Erosive antritis	1 (1,8)	1	0	1	54
Watermelon stomach (gastric antral vascular ectasia)	2 (3,5)	2	0	0	70,5
Heterotopic pancreatic tissue	1 (1,8)	0	1	0	66
Small bowel ulcerative stenosis (NSAID)	1 (1,8)	0	1	1	81
Hypertensive enteropathy	1 (1,8)	1	0	0	71
Small bowel leiomyosarcoma	1 (1,8)	0	1	1	64
Small bowel submucosal mass	1 (1,8)	1	0	0	81
Haemobilia (liver metastasis)	1 (1,8)	0	1	1	81
Colon AVM	1 (1,8)	0	1	0	77
Crohn's disease	1 (1,8)	1	0	0	31
Total positive findings	**60**	**43**	**17**	**16**	

CE : capsule endoscopy, eci : e causa ignota, NSAID : non-steroidal anti-inflammatory drug, AVM : arterio-venous malformation.

(0,83%) capsule retention was seen during imaging at a stenotic site in the small bowel (probably NSAID induced). However spontaneous passage and capsule evacuation occurred later on, so no surgery was needed.

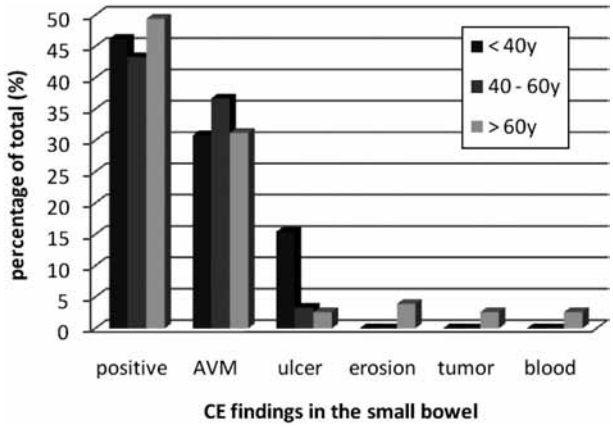
A total of 57 patients had positive findings on CE, representing an overall diagnostic yield of 47,5%. Three patients had two different types of diagnostic lesions leading to a total of 60 positive findings. 10% of these findings were found within range of conventional esophagogastroduodenoscopy and 1,67% within range of classical ileocolonoscopy. The remaining 88,3% of positive findings was in fact localized in the small intestine.

Small bowel AVM was, by far, the most diagnosed anomaly, being found in 39 cases (68,4%). In 51,3% of cases these vascular lesions were noticed within one hour after passage through the pylorus.

In second place came ulcerative lesions in the small intestine, present in 5 cases (8,77%). One of these patients had known Crohn's disease that was clinically in remission at the time of CE. All diagnostic lesions are described in table 2. We saw no remarkable difference in the actual type of positive finding between different age groups (Fig. 1).

Several factors, possibly influencing the rate of diagnostic lesions found at CE are summarised in table 3.

The diagnostic yield of CE was similar (p = 0,893) in the occult versus the overt bleeding group. No significant difference was seen, when looking at different age groups and the chance of CE positivity (p = 0,850). There was a trend towards a higher yield for CE in the presence of severe anaemia (cut-off 8,0 g/dl) (p = 0,056).

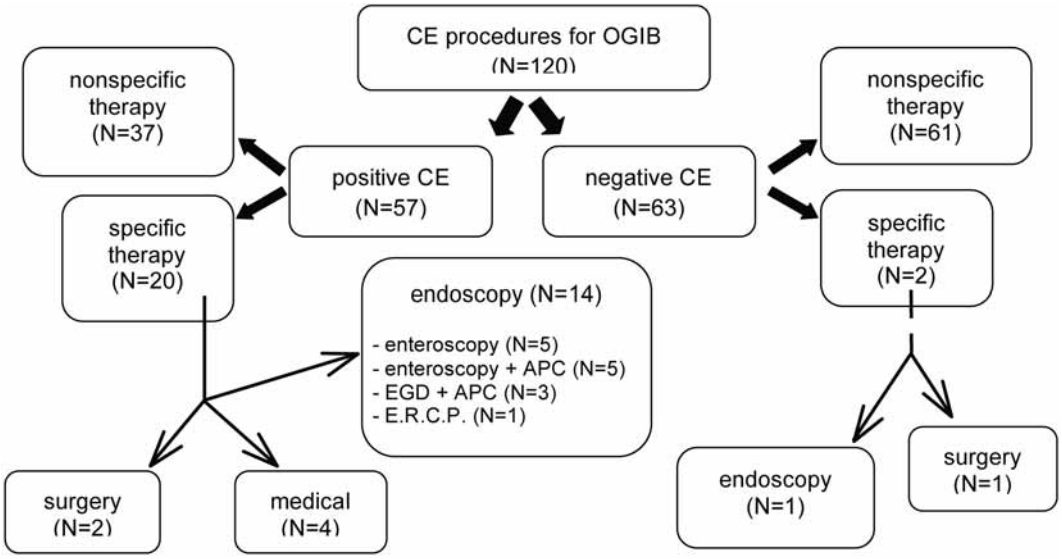


CE : capsule endoscopy, AVM : arterio-venous malformation.

Fig. 1. — Small bowel findings in relation to age (years)

In the overt bleeding group the mean time delay between presentation and video capsule examination was 12,94 days (ranging from 1 day up to 50 days). Our data did not show statistical difference in the diagnostic yield, whether CE was done in the first 14 days following presentation or even within the first 7 days, when compared with CE after a delay of more than 2 weeks (p = 0,728).

Presence of relevant comorbidity resulted in a significantly higher diagnostic yield (p = 0,05), however the number of associated comorbidities had no additional predictive value. When looking at the different subgroups of comorbidity ; only cardiovascular comorbidity was associated with significantly higher rate of a positive CE result (p = 0.041).



OGIB : obscure gastrointestinal bleeding, APC : argon plasma coagulation, EGD : esophagogastroduodenoscopy, ERCP : endoscopic retrograde cholangiopancreaticography.

Fig. 2. — Management alteration after capsule endoscopy (CE)

Further analysis on the influence of risk medication, such as anticoagulant therapy or NSAID's showed no significant difference in positive CE whether patients were on such therapy or not (p = 0,665). No specific class of these drugs was found to be associated with a higher diagnostic yield, nor did their combination seem of importance on that matter.

Management alteration

Capsule endoscopy was followed by two possible therapeutic approaches (7). Non-specific management was used when no further investigations were planned and therefore no etiological therapy was applied. Patients in this group (N = 98) received iron substitution and red blood cell transfusion where appropriate and were submitted to conventional follow up (watchful waiting).

In 22 out of 120 patients (18,3%) CE findings lead to a specific alteration in management, most frequently a form of targeted endoscopy, whether diagnostic or therapeutic (e.g. in case of argon plasma coagulation). These specific measures after CE are described in figure 2. A positive CE result induced specific alterations in therapy more frequently than negative results (p = 0,0001).

Discussion

This article presents a fairly large patient cohort that underwent capsule endoscopy for evaluation of obscure gastrointestinal bleeding. Since its introduction, CE has been used for a broad spectrum of small bowel disorders, such as Crohn's disease, celiac disease, hereditary polyposis syndromes and many others (8). Main indication, however, remains OGIB and since July 2008 this is the only indication in Belgium in which CE is reimbursed. Since then the number of patients referred for CE has risen, but diagnostic yield has significantly decreased (9).

In this study 47,5% of patients had one or more relevant abnormalities noted on CE. This result is very similar to other studies, although the reported diagnostic yield seems to vary from 30 to up to 92%, depending on the population studied and the definition of a "positive finding" used (4,5,7,10,11). For the moment there is no real consensus on defining a true positive finding on CE, which makes comparison between different cohorts difficult. In our opinion the presence of fresh blood in the small bowel without a visible lesion responsible for the bleeding, contributes to the diagnostic yield, since it offers confirmation that bleeding indeed arises from within the small bowel and can direct further targeted diagnostic and/or therapeutic approaches.

The caecum was reached during the life span of the battery in 82,5% of patients, which also corresponds well to other reports (1,12). Use of the real-time viewer periprocedurally made it possible to monitor progression of the capsule to the small bowel within a certain time frame. If the capsule remained in the stomach after 60 to 90 minutes, it was carried through the pylorus endoscopically. Capsule retention, usually at the site of lesions, is the most common complication and occurs in 1-2% of cases (12). We encountered only one case of capsule retention (0,83%), in which the capsule was retained for the duration of image registration at a stenotic ulcerative site in the small bowel, strongly suggestive for NSAID induced enteropathy. However no surgery was necessary as spontaneous passage occurred later on. No purgative bowel preparation or prokinetic medication was administered. Although there is evidence that bowel preparation might benefit CE diagnostic

yield, so far no consensus on the use or regimen of such a preparation has been reported (1).

Although it is well known that CE has a rather low negative predictive value for lesions in the upper and lower digestive tract (7), experience has shown that a substantial proportion of diagnostic lesions on CE is indeed found within the reach of conventional upper and lower endoscopy. In our patients 10% of lesions were within the reach of an esophagogastroduodenoscopy, compared to 2,8-9,4% in previous reports (10,13). Only one diagnostic lesion (1,7%) was seen within the range of a standard ileocolonoscopy, compared to 2,3% in other studies (10). In their recent guidelines, The American Society for Gastrointestinal Endoscopy (ASGE) recommends repeating upper and/or lower endoscopy before CE when there is clinical suspicion of a missed lesion in that area and/or when previous examination quality was thought to be suboptimal (13). However the role of repeat colonoscopy is less clear than that of repeat upper GI endoscopy.

As in most published series in Western world countries, we found small bowel AVM to be the most frequent diagnosis (68,4%), followed by small bowel ulcerations (8,77%), small bowel tumours (5,3%) and erosions (3,5%). AVM lesions seem proportionally less import in Southeast Asian countries, where ulcerative and erosive lesions are much more common (14,15). Sidhu *et al*. noticed around half of AVM localizations were encountered within one hour of small bowel entrance (duodenum and proximal jejunum) (10). These proximal vascular lesions are more likely reachable by standard push-enteroscopy. We observed a similar result with 51,3% of AVM's in that area. AVM is thought to be a phenomenon encountered mainly in elderly patients. However in our data we found no significant difference in pathology between different age groups (Fig. 1).

Several authors have made efforts in the past to identify factors that can predict the probability of pathology detection during CE. The presence of overt bleeding, when compared to occult bleeding, seemed to increase the diagnostic yield (11,14). In the subgroup with overt bleeding, it was stated that a shorter time interval between presentation and CE also resulted in higher yield (3,16). Some of these assumptions made are becoming increasingly controversial as recent large series fail to confirm such associations (7,10). In our data no significant difference in diagnostic yield was found between the occult and overt group, nor did timing of CE within 7 days, between 7 to 14 days or after 14 days influence yield in the overt group. The fact that our study population mainly consisted of occult obscure bleeding has to be taken into account. However some confusion in terminology might, at least partly, explain these discrepancies. One can indeed assume that investigation with CE during "ongoing" overt bleeding (synonyms "massive" or "active" overt bleeding) has a higher chance of finding anomalies in the small bowel, especially when presence of blood without a visible bleeding focus is included as a positive finding. Apostolopoulos *et al*. found blood in the small bowel to be present in 91,9% of their patients with active overt bleeding (17). In approximately 60% the actual bleeding focus was obvious and in around 30% the bleeding location could be specified, but not the aetiology. Similar findings were reported by Carey *et al*. (11). On the other hand no difference in diagnostic yield was seen between a massive overt bleeding group versus a chronic recurrent overt bleeding group in a large series of 309 cases with overt obscure bleeding (4). In our opinion these inconsistent results make it very difficult to give recommendations on optimal timing of capsule endoscopy.

Equally conflicting statements on the influence of patient age, comorbidity and medication intake on CE diagnostic yield have been reported. Since most studies are conducted retrospectively the intake of NSAID is probably underestimated and the definition of relevant comorbidity is not consistent between different authors. We could not confirm that diagnostic yield is significantly increasing with age in contrary to some previous reports (4,10,11,18). On univariate logistic regression Sidhu *et al*. noted warfarin intake and cardiovascular, renal or liver disease were significant factors that predicted higher CE yield (10). After multivariate analysis, only liver comorbidity and warfarin intake remained significant. In our own results only the presence of cardiovascular comorbidity was associated with a significantly higher diagnostic yield ($p = 0,04$). Presence of other comorbidity types or the number of present comorbidities seemed of little influence, as did medication intake (table 3). It should be noted however, that the number of subjects in some of the subgroups could be too small to detect significant differences. Haemoglobin under 8,0 g/dl showed a trend towards higher yield on CE, however the p-value did not reach statistical significance ($p = 0,056$).

Besides being able to predict the result of CE in certain subgroups of patients with OGIB, one would actually like to know the exact impact of CE findings on management and outcome afterwards. Unfortunately most authors report only changes in management after CE, but data on outcome are very scarce. This study lacks data on haemoglobin measurement and transfusion requirements after CE and follow up duration was too variable to draw any conclusions. Carey *et al*. collected follow up data on 260 patients with OGIB for a mean duration of 9,6 months (range 1-31). They concluded that CE improved outcome in terms of re-hospitalization, transfusion needs and gastrointestinal bleeding related procedures (11). After a median follow up of 19 months (range 12-31) of 49 patients with OGIB, Lai *et al*. reported a significantly lower rebleeding rate after negative CE compared to positive CE, 5,6% and 48,4% respectively ($p = 0,03$) (19). Interestingly, in that study, almost two thirds of patients with positive CE did not undergo any further interventions for various reasons. In a retrospective study Hindryckx *et al*. followed their

Table 3. — **Capsule endoscopy (CE) diagnostic yield according to clinical characteristics**

Factor	Positive CE N (%)	P value
1. presentation		
occult (N = 87)	41 (47,1%)	P = 0,893
overt (N = 33)	16 (48,5%)	
2. lowest hemoglobin (Hb) in g/dl		
Hb < 8,0 (N = 52)	29 (55,7%)	P = 0,056
Hb ≥ 8,0 (N = 68)	26 (38,2%)	
3. age (y)		
age < 40 (N = 13)	6 (46,2%)	P = 0.850
40 ≤ age ≤ 60 (N = 30)	13 (43.3%)	
age > 60 (N = 77)	38 (49.4%)	
4. medication		
4.1. medication type		*P = 0,760**
aspirin low dose (N = 33)	13 (39,4%)	P = 0,592
warfarin (N = 14)	9 (64,3%)	P = 0,206
clopidogrel or ticlopidine (N = 20)	11 (55,0%)	P = 0,459
non-steroidal anti-inflammatory drug (N = 13)	4 (30,8%)	P = 0,343
low molecular weight heparin (N = 4)	3 (75,0%)	P = 0,530*
aspirin plus extended release dipyridamole (N = 3)	1 (33,3%)	P = 0,847*
systemic corticosteroids (N = 2)	1 (50,0%)	P = 0,554*
4.2. risk medication intake		
present (N = 67)	33 (49,3%)	P = 0,665
absent (N = 53)	24 (45,3%)	
4.3. number of medication types		
no risk drug (N = 53)	24 (45,3%)	P = 0,401
1 risk drug (N = 48)	26 (54,2%)	
>1 risk drug (N = 19)	7 (36,8%)	
5. comorbidity		
5.1. comorbidity type		*P = 0,591**
cardiovascular (N = 60)	34 (56,7%)	P = 0,041
nephrological (N = 16)	4 (25,0%)	P = 0,368
pneumological (N = 13)	6 (46,2%)	P = 0,557
hepatological (N = 11)	5 (45,5%)	P = 0,869*
hematological (N = 4)	2 (50,0%)	P = 0,975*
reumatological (N = 5)	2 (40,0%)	P = 0,716*
oncological (N = 2)	2 (100,0%)	P = 0,297*
5.2. comorbidity presence		
present (N = 69)	38 (55,1%)	P = 0,053
absent (N = 51)	19 (37,3%)	
5.3. number of associated comorbidity types		
no comorbidity (N = 51)	19 (37.3%)	
1 comorbidity type (N = 39)	24 (61,5%)	P = 0,226*
2 comorbidity types (N = 23)	11 (47,8%)	
> 2 comorbidity types (N = 7)	3 (42,9%)	
6. timing CE in overt OGIB in days (d) or hours (h)		
CE ≤ 7d of presentation (N = 12)	7 (58,3%)	P = 0,728*
7d < CE ≤ 14 d of presentation (N = 14)	5 (35,7%)	
CE > 14 d of presentation (N = 7)	4 (57,1%)	
CE ≤ 48 h of presentation (“ongoing”) (N = 2)	2 (100%)	P = 0,439*
CE > 48 h of presentation (N = 31)	14 (45,2%)	

*Yates correction on chi square calculation.

patients with OGIB for a mean duration of 635 days after CE (7). Favourable outcome was noted in 66,3% of cases and did not seem to be influenced by CE result, despite the fact that the management strategy in the positive group was totally different from the negative group.

CE can influence management in a direct or indirect manner. Direct impact of CE results in guiding further diagnostic and/or therapeutic approach (e.g. performing DBE). This type of specific management is most frequently triggered by a positive CE result (7). The indirect impact of CE is less obvious and mainly consists of watchful waiting, providing iron substitution and transfusion where appropriate. The high negative predictive value of CE – rebleeding in only 6 to 11% of cases after a negative result (13) – prevents unnecessary further investigations, especially in elderly fragile patients. In this study no standardized diagnostic or therapeutic protocol was applied after CE. In twenty-two patients (18,3%)

CE guided further specific management (Fig. 2) : endoscopy with or without therapeutic intervention in 14 cases (70%), surgery in 2 (10%) and medical therapy changes in 4 patients (20%). Specific management changes were made after a positive CE result in 20 cases (91%) and after negative result in only 2 patients (p = 0,0001).

We acknowledge several limitations in the current study. In first place it is a retrospective, single centre study with a limited number of subjects. Secondly a single gastroenterologist, who was not blinded for clinical information concerning these cases, performed CE interpretation. Finally it is regrettable that follow up was too heterogeneous to use in terms of patient outcome. This was in large part due to the proportion of referrals from other hospitals, in which follow up was less clear. However we feel that our data represent daily practice very accurately.

Conclusion

Recommendation to use CE for OGIB after negative initial upper and lower endoscopy is based on its non-invasive character, its diagnostic superiority and its excellent negative predictive value. However the most cost-effective use and timing of CE remains to be further investigated. CE is used, in daily practice, to guide a further diagnostic and/or therapeutic approach with for example enteroscopy. A negative result on the other hand aids in supporting a conservative approach. This study adds to the inconsistent data published on factors that predict an increased diagnostic yield in CE, so that it seems impossible to make recommendations on ideal patient selection in daily practice. We found no increase in diagnostic yield in the overt obscure bleeding group when compared to the occult group. Outcome data are scarce in literature and are to be interpreted in function of the studied population and the definitions used.

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