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# Incomplete small bowel capsule endoscopy: risk factors and cost-effectiveness of real-time viewing

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**Abstract:**
Aims. International guidelines recommend real-time viewing (RTV) in capsule endoscopy for gastric emptying monitoring, yet it is often overlooked in clinical practice. We aim to assess risk factors for incomplete small bowel capsule endoscopy (SBCE) and evaluate the clinical relevance and cost-effectiveness of RTV implementation.

Methods. We included consecutive SBCEs from 2013 to 2020. RTV was not applied per local protocol. We used multivariate logistic regression to identify risk factors for incomplete SBCE, including prolonged gastric transit time (GTT) and prolonged small bowel transit time (SBTT).

Results. Analysing 858 SBCEs, we observed a completion rate of 94.6%. Prolonged GTT and SBTT were present in 4.9% and 18.2% of complete SBCEs, and in 13% (p=0.03) and 10.8% (p=0.24) of incomplete SBCEs, respectively. Only 0.7% (6 out of 858) had incomplete SBCE with prolonged GTT. In both univariate and multivariate analysis, a modifiable (prolonged GTT [OR 2.9; 95% CI 1.1-7.5]) and two unmodifiable risk factors (inpatient status [OR 2.3; 95% CI 1.1–4.5] and history of incomplete SBCE [OR 4.2; 95% CI 1.3-13.7]) were independently linked to higher incomplete SBCE rates. The pretest completion probability was 90.5% and 95.8% in patients with and without unmodifiable risk factors, respectively (p<0.01). The direct cost of systematic RTV adoption and prokinetics administration would be €5059, aiming to identify and treat each case of prolonged GTT associated with incomplete SBCE.

Conclusions. Modern devices make incomplete SBCE rare, usually not tied to prolonged GTT. In a low-incidence scenario, widespread RTV use brings high costs and uncertain effectiveness.

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## INTRODUCTION

Incomplete small bowel capsule endoscopy (SBCE) refers to small bowel examinations where the device fails to reach the cecum and, therefore, the entire surface of the small bowel is not explored. Available evidence suggests that the inpatient status is associated with SBCE incompleteness.[1,2] Comorbidities, drugs that decrease small-bowel motility, and reduced physical activity may explain the higher SBCE incompleteness among inpatients.[3] Another risk factor for incomplete SBCE is delayed gastric emptying, which may result in gastric capsule retention or in battery depletion.[4–6] In previous studies, prolonged SBCE gastric transit time (GTT) was defined as the failure of the capsule to reach the small bowel within 1 or 2 hours from ingestion.[4–6]

The capsule endoscopy real-time viewing (RTV) allows on-demand real-time monitoring of gastric emptying, thus enabling the prompt administration of prokinetics or the endoscopic delivery of the capsule into the duodenum in case of prolonged GTT to prevent incomplete SBCE examinations. Data from previous studies has suggested that the completion rate of SBCE with RTV and subsequent possible interventions (i.e., drug administration and endoscopic capsule placement) was higher compared to examinations without RTV.[4–7] Therefore, the latest European Society of Gastrointestinal Endoscopy (ESGE) technical review for SBCE recommends the use of the RTV, particularly in patients at risk of delayed gastric emptying who may experience gastric capsule retention and incomplete SBCE.[8] However, this recommendation was based on low-quality evidence. Further, a recent ESGE survey revealed poor implementation of RTV in clinical practice since only 73.2% of European physicians routinely used RTV.[9] In fact, the available studies on SBCE RTV were performed using old-generation endoscopic capsules, with shorter battery life compared to modern devices. A short battery life could negatively affect the completion rate of SBCE, therefore increasing the rationale for the use of RTV. On the contrary, the longer battery life (≥8 hours) of modern capsule endoscopy devices can positively affect the completion rate of SBCE, therefore reducing the need for RTV. Moreover, the routine use of RTV is burdened by costs related to the resources required, such as trained staff, drugs, and dedicated rooms. In case of prolonged

GTT, the costs of peripheral venous catheter placement and prokinetics administration or endoscopically assisted capsule delivery should be added. To the best of our knowledge, there are no large cohort studies evaluating the performance of SBCE without the systematic use of RTV in large cohorts. Moreover, the cost-effectiveness of RTV during SBCE performed with new-generation devices remains unknown. To address this knowledge gap, we aimed to evaluate the risk factors of incomplete SBCE and the cost-effectiveness of the routine use of the RTV during SBCE.

## PATIENTS AND METHODS

### *Patients*

We retrospectively included consecutive SBCEs performed with PillCam SB3 (Medtronic, Minneapolis, USA) in a tertiary referral centre for enteroscopy (Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy) from 2013 to 2020. During this period, RTV was not performed according to local protocol, considering the low level of evidence supporting this practice. Included SBCEs were performed for different indications according to ESGE guidelines, such as suspected, overt or occult small bowel bleeding, Crohn's disease, complicated coeliac disease, suspected neoplasia, and other gastrointestinal symptoms.

Patients were instructed to fast for at least 12 hours and to stop any oral iron supplements 5 days before the procedure. After capsule ingestion, patients were allowed to drink clear liquids 2 hours later and eat food 4 hours later.

Demographic and clinical data were prospectively collected by reviewing medical records. They included patients' age, gender, drugs, and comorbidities that can affect gastric and intestinal transit time (e.g., diabetes, chronic kidney disease, small bowel Crohn's disease, neurological disorders, psychotropic medications), small bowel transit time (SBTT), GTT, history of previous SBCE, and inpatient status. All endoscopic findings were

classified according to the clinical significance, in relation to the indication for the procedure as previously defined in literature.[10] Prolonged GTT was defined when the capsule crossed the pylorus > 2 hours from ingestion, and prolonged SBTT when the cecum was not reached within 6 hours from pylorus crossing.[11,12]

The exclusion criteria were capsule retention, endoscopic delivery of the capsule, and major technical issues (i.e., eating within 2 hours after capsule ingestion or recording issues).

***Cost analysis***

We calculated the direct costs of the routine use of RTV in endoscopy facilities by identifying the time, equipment, and medications needed for the monitoring of a single SBCE. We excluded from our analysis indirect costs of the endoscopic service not directly accountable to the procedure (e.g., administrative and cleaning staff, capsule endoscopy equipment maintenance, patients' time out of work, etc.) and the structural costs of the hospital (e.g., hospital management, human resources, informatics systems, etc.). The direct costs of 1-hour RTV and of the appropriate intervention in case of prolonged GTT were estimated including the cost of a dedicated room[13] and nurse[14], and the administration of metoclopramide through a peripheral venous catheter[15] in case of prolonged GTT (details in Table 1). When different costs were available in the literature for the same element, we considered the most recent ones for our analysis.

***Statistical analysis***

Data related to the patients' clinical and demographic characteristics and technical details of each SBCE were analysed descriptively, producing sums and percentages for the categorical and mean variables, and standard deviations for the continuous variables. Categorical variables were compared with Fisher's exact test or with the $\chi 2$ or McNemar's test, yielding the odds ratio (OR) and its confidence interval. Continuous variables were compared with Student's t-test, in the case of normal distribution, and with the Kruskal–Wallis test or Mann–Whitney U test in the case of non-normal distribution. Both univariate and multivariate logistic regression analyses were built to find significant risk factors associated with incomplete SBCE. Values of $p<0.05$ were

considered statistically significant. All statistical analyses were carried out with IBM SPSS Statistic (release 23; IBM, USA).

***Ethics***

The study was carried out in accordance with the Declaration of Helsinki, adopted in 1964 and incorporating all later amendments. The patients' data were treated confidentially, in compliance with the most recent national and European privacy laws (protocol number 137/2021, Comitato Etico Milano Area 2). The reporting of this study conforms to the STROBE statement (Supplementary Material).[16]

**RESULTS**

A total of 865 SBCEs were performed during the study period at our hospital. We excluded 2 cases for capsule retention, 2 for endoscopic delivery and 3 for major technical issues (i.e., ingested food within a standard gastric transit time of the capsule, major recording issues). The remaining 858 SBCEs were included in the study population (Figure 1). The baseline characteristics of patients are described in Table 2.

Most of the procedures were performed for suspected small bowel bleeding (451 SBCEs, 52.6%), followed by suspected or established complicated coeliac disease (269 SBCEs, 31.4%), other gastrointestinal symptoms (60 SBCEs, 7%), small bowel Crohn's disease (51 SBCEs, 5.9%) and suspected neoplasia (27 SBCEs, 3.1%). The SBCE completion rate was 94.6% and the diagnostic yield was 50%. SBCE technical data are reported in Table 3. Patients with complete and incomplete SBCE did not differ in terms of demographic features and comorbidities (Table 4). Prolonged GTT and prolonged SBTT were found in 46 (5.4%) and 153 (17.8%) procedures, respectively. In patients with incomplete SBCE (n=46), we observed an increased rate of prolonged GTT compared to complete procedures (13% *vs.* 4.9%, p=0.03), while prolonged SBTT was comparable (10.8% *vs.* 18.2%, p=0.24) between the two groups. However, only 6 patients out of 858 (0.7%) had incomplete SBCE and prolonged GTT

(Figure 2). Completion rate, GTT and SBTT were not significantly different between patients with different indications for SBCE. At univariate logistic regression, prolonged GTT, previous incomplete SBCE and inpatient status were associated with a higher rate of incomplete SBCE. Notably, prolonged SBTT was not associated with incomplete SBCE ().  To confirm the described correlation, we built a multivariate analysis including these three significant factors; one modifiable (prolonged GTT [OR 2.9; 95% CI 1.1-7.5, p = 0.03]) and two unmodifiable risk factors (inpatient status [OR 2.3; 95% CI 1.1–4.5, p = 0.01] and history of incomplete SBCE [OR 4.2; 95% CI 1.3-13.7, p = 0.02]) were independently associated with a higher rate of incomplete SBCE (Table 4). Furthermore, we built another multivariate analysis including these three risk factors and other possible confounders (e.g., diabetes, CKD, narcotics, neurological disorders), which confirmed the results of the previous analyses, showing that no confounding factor significantly impacted the correlation between each of the three significant risk factors and SBCE completeness. A total of 189 patients had either one of the two identified unmodifiable risk factors. The pretest probability of SBCE completion was 90.5% and 95.8% in patients with and without unmodifiable risk factors, respectively (p<0.01).

Among the 46 incomplete SBCEs (5.4% of the total), there were 12 examinations (26.1%) with registration lasting <9 hours and 2 (4.3%) with registration lasting <6 hours.

The direct cost for 1-hour real-time monitoring (i.e., dedicated room and nurse) was estimated at €34,87. In case of prolonged GTT, the additional direct cost of €6.53 for metoclopramide injection and peripheral venous catheter should be added (Table 1).

If RTV was systematically performed during the study period, the overall direct cost for RTV would have been equal to €30,030 (i.e., €4290 per year), and those for prokinetics administration in the 46 cases of prolonged GTT would have been equal to €322, with a total of €30,352. Considering that in our cohort only 6 patients with prolonged GTT had an incomplete SBCE, the direct cost for the systematic adoption of RTV to identify and treat with prokinetics each case of prolonged GTT associated with incomplete SBCE would have been equal to €5059.

On the contrary, if RTV had been performed only in patients with pre-test risk factors for incomplete SBCE (previous incomplete SBCE and/or inpatients=189), the direct cost for RTV would have been equal to €6615 (i.e., €945 per year) and that for the administration of prokinetics in the 13 cases with prolonged GTT would have been €91, with a total of €6706. In this sub-group, 2 patients with prolonged GTT had an incomplete SBCE. Therefore, the direct cost for RTV adopted in patients with risk factors for incomplete SBCE to identify and treat with prokinetics each case of prolonged GTT associated with incomplete SBCE would have been equal to €3353. Notably, this second strategy based on a pre-test risk stratification could have saved €23,646 but it could lead to a missed intervention with prokinetics in 4 prolonged GTT associated with incomplete SBCE.

## DISCUSSION

The routine use of the RTV during SBCE and the performance of subsequent interventions, despite being recommended by current guidelines, are debated among experts and not commonly implemented in clinical practice.[8,9]

In our study of consecutive 858 SBCEs, we demonstrated that the rate of complete examinations is extremely high (94.6%), despite the absence of RTV and prokinetics administration. The rate of incomplete SBCE, prolonged GTT and prolonged SBTT did not differ among SBCEs performed for suspected small bowel bleeding, complicated coeliac disease, or other indications. The completion rate of SBCE in our cohort was higher or comparable to previously published studies performed with the use of RTV and prokinetics administration in case of prolonged GTT.[4–6,17] Most of these studies were performed with old-generation SBCE devices,[4–6] with a retrospective design,[6] or in extremely small cohorts.[4,5] To the best of our knowledge, there is a lack of data supporting the effectiveness of this approach when new-generation SBCE devices with longer battery life (from 8 hours to 12 hours) are used.[8,18] This technological improvement can potentially limit the effect of battery depletion on SBCE completeness induced by prolonged GTT and, consequently, the role of RTV may not

be as relevant as previously reported. In fact, the completion rate of our cohort was comparable to that of a recently published Portuguese study of 957 SBCEs (91.1%) performed with modern devices and RTV-guided domperidone administration and/or endoscopic delivery of the capsule in case of prolonged GTT.[17] The data in that study showed that prolonged GTT was not associated with a higher rate of SBCE incompleteness. These findings raise doubts regarding the causal relationship between prolonged GTT and SBCE completeness. Therefore, RTV and the interventions aimed at treating patients with prolonged GTT could not be as effective as thought in increasing the SBCE completion rate and diagnostic yield. These results are consistent with a previous meta-analysis that showed no beneficial effect on SBCE diagnostic yield from prokinetics administration in patients with prolonged GTT detected by RTV, even when associated with an increased completion rate.[19] Furthermore, the use of prokinetics may potentially reduce the SBCE diagnostic yield in a subgroup of patients, considering that a longer SBTT was related to increased detection of significant lesions in suspected small bowel bleeding.[20]

Another remarkable result of this study was the extremely low rate (0.6%) of patients (6/865) with incomplete SBCE and prolonged GTT. Therefore, only one patient in every 144 SBCEs would require prokinetics administration, even if the benefit of this practice on completeness rate and, most importantly, the diagnostic yield of capsule endoscopy performed with modern devices remains still to be convincingly proved.

Our study did not focus on risk factors for prolonged GTT, which was a post-hoc result. Rather, we focused on risk factors that may predict an incomplete SBCE, thereby suggesting the need for a patient-tailored approach for early intervention in case of prolonged GTT based on the use of RTV. In our cohort, there was a low rate of prolonged GTT and a higher rate of prolonged SBTT (5.4% and 17.8%, respectively), with a statistically significant difference between complete and incomplete SBCEs only for GTT. Independent risk factors for incomplete SBCE were inpatient status, prolonged GTT, and previous incomplete SBCE. Among them, the only modifiable risk factor was prolonged GTT, while inpatient status and a history of incomplete SBCE were unmodifiable and had

the advantage of being available a priori. According to this difference, we hypothesised two scenarios: one in which only the patients with at least one pretest risk factor for incomplete SBCE would undergo RTV and selective intervention, compared to another scenario in which RTV was systematically adopted. According to our analyses, 1 in every 14.5 patients with pretest risk factors for incomplete SBCE would benefit from RTV to identify and target early intervention for prolonged GTT, compared to 1 in every 20.1 patients without risk factors.

We also performed a cost-effectiveness analysis to represent the differences in more practical terms.

Considering that the direct cost for 1-hour RTV is equal to €35 and the additional cost of prokinetics administration is €7, we estimated €5059 as the direct cost for the systematic adoption of RTV to identify and treat with prokinetics each case of prolonged GTT associated with incomplete SBCE. Therefore, the potential and largely unproven beneficial effect of RTV on SBCE completeness and diagnostic yield should be weighed against the high costs of its systematic adoption. On the contrary, when adopting RTV only in patients with at least one pretest high-risk feature for incomplete SBCE, this amount would be reduced to €3353. It should be noted that the strategy based on a pretest risk stratification would have saved €3378 per year, when compared to the systematic adoption of RTV. Still, it would also have missed the intervention with prokinetics in 4/6 SBCEs with prolonged GTT associated with incomplete SBCE in an overall cohort of 858 SBCE examinations.

The use of oral rather than intravenous metoclopramide can significantly reduce this cost factor. Nonetheless, the intravenous route of administration is mostly adopted as it is believed to be a more efficient strategy than oral administration based on pharmacokinetic issues.

The implementation of artificial intelligence-assisted RTV is expected to soon be available in many capsule systems, thereby facilitating the adoption of RTV-based strategies. Nonetheless, the direct and indirect costs resulting from the systematic adoption of RTV will only be partially influenced by this technological progress.

In our analysis, we have excluded two cases of capsule endoscopic placement, as they would not allow for gastric transit time evaluation. Furthermore, in a low incidence of incomplete SBCEs setting, the economic impact of capsule endoscopic placement would be negligible; moreover, the cost analysis would vary significantly according to the organization of the endoscopic unit (e.g., on-call endoscopic team, dedicated room). However, a recent multicenter retrospective analysis on a large cohort of adult patients showed that capsule endoscopic placement has very good outcomes in terms of feasibility, safety, and completion rate, specifically with the capsule delivery in the duodenum.[21]

Looking beyond the need for risk stratification, this study identified low battery life as an overlooked risk factor for incomplete SBCE, whose impact could be particularly relevant in high-volume centres. Remarkably, among the incomplete SBCEs observed in our cohort (46/858, 5.4%), we identified a suboptimal registration time in over a quarter of SBCEs (12/46, 26.1%) because of a battery life <9 hours. This time frame stands well below the technical standards of the SB3 system (12 hours). In 2 cases of incomplete SBCE (4.3%), the registration lasted less than 6 hours. To the best of our knowledge, there is no official protocol for monitoring capsule recorder performance and its replacement is currently recommended after evidence of capacity decay in clinical practice, thereby introducing a certain amount of subjectivity and the risk of incomplete SBCE examinations.

The main strength of our study is the high number of SBCEs analysed, which is far higher compared to the studies upon which current guidelines based their recommendation.[4–6] To the best of our knowledge, this is the largest cohort showing the technical outcomes of SBCEs performed with modern devices and without the RTV. We showed that SBCE performed without RTV reached a high completion rate and a diagnostic yield comparable to previous studies, therefore being an effective and more financially, socially and environmentally sustainable examination.[22,23] We identified modifiable pretest risk factors that can significantly affect SBCE completeness and showed an extremely low rate of incomplete SBCEs with a prolonged GTT. Furthermore, we explored the possibility of using the RTV in a limited cohort of patients with a high risk of SBCE incompleteness,

to detect and act on prolonged GTT, the only modifiable risk factor for incomplete SBCE identified by our analysis. Lastly, this is the first direct cost analysis of RTV in SBCE available in the literature.

Our study has some limitations. First, it was a retrospective analysis of data prospectively collected in a single centre. Moreover, the number of SBCEs performed for suspected or known Crohn's disease was relatively small, given that a dedicated type of capsule endoscopy device was often used in this subset of patients. This selection could have potentially influenced our completeness rate, leading to overestimation.

In conclusion, incomplete SBCE occurs only occasionally using modern devices without the RTV and, in most cases, it is not associated with prolonged GTT or prolonged SBTT. The inpatient status, a prolonged GTT and a previous incomplete SBCE are risk factors for incomplete SBCE. The capsule recorder battery life is an overlooked risk factor for incomplete SBCE examinations. According to our direct cost analysis, in a low-incidence scenario for incomplete SBCE, the use of RTV in all patients is burdened by high costs and unproven effectiveness with modern SBCE devices. Further, evidence is required to confirm our results and potentially identify subsets of patients who would significantly benefit from RTV.





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## FIGURES AND TABLES

*Figure 1. Prisma flowchart diagram*

*Figure 2. Rate of small bowel capsule endoscopy (SBCE) completeness and gastric transit time among incomplete examinations*

*Table 1. Direct costs of RTV and prokinetics administration*

| **Invoice** | **Cost** |
|---|---|
| Nurse time (1hxpt) | 24.59 euro/hour[14] |
| Dedicated room (1hxpt) | 10.28 euro/hour[13] |

| | |
|---|---|
| Drug (metoclopramide) (1xpt_pgtt) | 0.38 euro |
| IV catheter (1xpt_pgtt) | 6.15 euro[15] |
| Total | 41.4 euro |

1hxpt = 1-hour RTV per patient; 1hpt_pgtt = 1 per patient with prolonged gastric transit time

*Table 2. Patients' baseline characteristics*

| **Baseline Characteristics** | **SBCE N = 858** |
|---|---|
| Age, median (IQR, years) | 59 (42 – 71) |
| Female, n (%) | 520 (60.6) |
| **Risk factors** | |
| Diabetes, n (%) | 84 (9.8) |
| Narcotics, n (%) | 46 (5.4) |
| End-stage kidney disease, n (%) | 48 (5.6) |
| Neurological disorders, n (%) | 35 (4.1) |
| Crohn's disease, n (%) | 10 (1.2) |
| Previous incomplete SBCE, n (%) | 21 (2.4) |
| Previous SBCE with prolonged gastric transit time, n (%) | 19 (2.2) |
| Previous SBCE with prolonged small bowel transit time, n (%) | 38 (4.4) |
| Inpatient, n (%) | 173 (20.2) |
| Previous incomplete SBCE and/or inpatient, n (%) | 189 (22) |

SBCE = small bowel capsule endoscopy

*Table 3. SBCE technical data*

| **SBCE** | **N = 858** |
|---|---|
| Gastric transit time, mean (±SD) | 00:33:30 (00:47:11) |
| Small bowel transit time, mean (±SD) | 04:39:58 (01:44:39) |
| Prolonged gastric transit time, n (%) | 46 (5.4) |
| Prolonged small bowel transit time, n (%) | 153 (17.8) |
| Incomplete SBCE, n (%) | 46 (5.4) |
| Incomplete SBCE with prolonged gastric transit time, n (%) | 6 (0.7) |
| Diagnostic yield, % | 50 |

SBCE = small bowel capsule endoscopy

*Table 4. Comparison between complete and incomplete SBCE at univariate and multivariate analyses.*

| **Baseline Characteristics** | **Incomplete SBCE**<br>**Patients number = 46** | **Complete SBCE**<br>**Patients number = 812** | **Univariate analysis,**<br>**p-value** | **Multivariate analysis,**<br>**OR (IC95%)** | **Multivariate analysis,**<br>**p-value** |
|---|---|---|---|---|---|
| **Age, mean (±SD)** | 56.3 (18.2) | 59.5 (15.7) | 0.42 | | |
| Female, n (%) | 28 (60.9) | 491 (60.6) | 1 | | |
| **Inpatient°, n (%)** | **17 (36.9)** | **156 (19.2)** | **<0.01*** | **2.3 (1.1-4.5)** | **0.01*** |
| SSBB, n (%) | 26 (56.5) | 425 (52.3) | 0.65 | | |
| Complicated coeliac disease, n (%) | 9 (19.6) | 260 (32) | 0.10 | | |
| Other GI symptoms, n (%) | 5 (10.9) | 55 (6.8) | 0.25 | | |
| SB Crohn's disease, n (%) | 4 (8.7) | 47 (5.8) | 0.34 | | |
| Suspected neoplasia, n (%) | 2 (4.3) | 25 (3.1) | 0.65 | | |
| Diabetes, n (%) | 5 (10.9) | 79 (9.7) | 0.80 | | |
| Narcotics, n (%) | 4 (8.7) | 42 (5.2) | 0.30 | | |
| End-stage kidney disease, n (%) | 1 (2.2) | 47 (5.8) | 0.51 | | |
| Neurological disorders, n (%) | 2 (4.3) | 33 (4.1) | 0.71 | | |
| Small bowel Crohn's disease, n (%) | 1 (2.2) | 9 (1.1) | 0.42 | | |
| **Prolonged gastric transit time, n (%)** | **6 (13)** | **40 (4.9)** | **0.03*** | **2.9 (1.1-7.5)** | **0.03*** |
| Prolonged small bowel transit time, n (%) | 5 (10.8) | 148 (18.2) | 0.24 | | |
| **Previous incomplete SBCE°, n (%)** | **4 (8.7)** | **17 (2.1)** | **0.02*** | **4.2 (1.3-13.7)** | **0.02*** |

The pretest probability of SBCE completion was 90.5% and 95.8% in patients with and without unmodifiable risk factors (°), respectively (p<0.01). SBCE = small bowel capsule endoscopy. SSBB = suspected small bowel bleeding. GI = gastrointestinal. SB = small bowel.