



Digestive Endoscopy

Capsule endoscopy: Is the software TOP 100 a reliable tool in suspected small bowel bleeding?



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ABSTRACT

Background: Small bowel capsule endoscopy (SBCE) is the reference standard tool for diagnosing small bowel bleeding (SBB). The “TOP 100”, which performs an automatic selection of the 100 images that mostly likely contain abnormalities, emerged as a new functionality of the RAPID Reader[®] software in 2017.

Aim: To compare the concordance of findings between the standard reading (SR) and the use of TOP 100 in suspected SBB.

Methods: Retrospective study, including consecutive patients submitted to SBCE for suspected SBB. Two experienced readers performed SR and reported the most important findings. Another experienced reader, who was blinded to the SR results, reviewed all the SBCE videos using TOP 100 and reported the most important findings. The relevant findings were defined as the presence of high bleeding potential lesions (P2).

Results: 97 patients were included. The TOP 100 detected 81/97(83.5%) of the P2 lesions, in particular 64/67(95.5%) of the angioectasias and 17/30(56.7%) of the ulcers. The TOP 100 identified all sites of active bleeding (n=9).

Conclusion: The TOP 100 identified all sites of active bleeding, as well as the vast majority of significant lesions (83.5%); in particular, it detected over 95% of the angioectasias. Although SR remains the reference standard in the SBCE review, these findings demonstrate that TOP 100 allows for a quick preview reading constituting an important asset in the identification of lesions that may require priority full review and intervention planning.

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1. Introduction

Small bowel bleeding (SBB), defined as bleeding originating distal to the ampulla of Vater and proximal to the ileocecal valve, accounts for approximately 5% of all cases of gastrointestinal bleeding [1,2]. It may be characterized as overt in the presence of melena or hematochezia, or occult defined as the presence of iron deficiency anaemia or positive fecal occult blood test after negative esophagogastroduodenoscopy and colonoscopy [3].

Small bowel capsule endoscopy (SBCE), which emerged in 2001, is the reference standard diagnostic examination in patients with

suspected SBB [4,5] and presents a diagnostic yield that ranges from 38 to 83% [6]. The most common findings include angioectasias, erosions, tumours and ulcers [7].

Although SBCE is a minimally invasive method with high patient acceptability, several limitations have become obvious, including the amount of time required to read each study. Depending on the operator's experience, quality of bowel preparation, intestinal transit time and the frequency of detected abnormalities, it can take approximately 50–120 min to completely read an examination [8–11]. Thus, for indications that may require urgent intervention, particularly in overt SBB, a time-consuming procedure is a major limitation [12].

Complex software approaches to solve the reading time process have been proposed [13]. Rapid Reader[®] (Given Imaging[®], Yokneam, Israel) initially developed two software algorithmic systems that allowed a rapid analysis of SBCE studies to support

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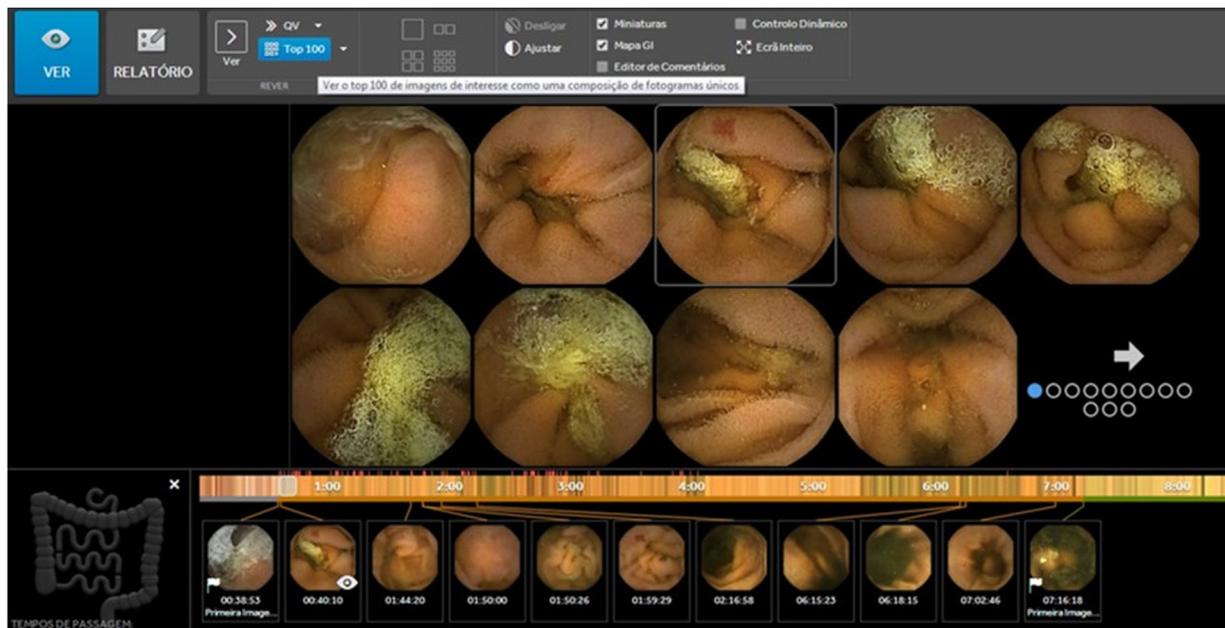


Fig. 1. Angioectasia identified by the TOP 100 software.

medical decision-making. These include “Quickview” (QV), a software that reduces the image quantity by identifying the most distinct ones and hides similar patterns [14,15] and suspected blood indicator (SBI), which selects images with red color pixels that may be consistent with active or potential bleeding [16,17].

In 2017, a new functionality emerged in the Rapid Reader® v9.0, replacing SBI – the “TOP 100”, which performs the automatic selection of the 100 most distinct images that may contain abnormalities. To the best of our knowledge, no study has yet assessed the usefulness of this new tool in clinical practice.

This study aimed to assess the diagnostic yield of the TOP 100 in suspected SBB when compared to standard reading (SR).

2. Methods

We performed a retrospective study in our department between April 2017 and August 2018, including consecutive patients submitted to SBCE for suspected SBB. Suspected SBB was considered in the presence of melena or hematochezia (overt) or iron deficiency anaemia (<12 g/dl for females; <13 g/dl for males) or positive fecal occult blood test (occult) with previous negative esophagogastroduodenoscopy and ileocolonoscopy [2]. Demographic and clinical data were investigated by reviewing medical records.

2.1. SBCE procedure

SBCE were performed using Pill Cam SB3; the patients were on a clear liquid diet for 24 h and fasted for 12 h before SBCE [18]. Patients taking oral iron discontinued the medication at least five days before the SBCE examination. Thirty minutes prior to capsule ingestion we administered 100 mg of simethicone and 10 mg of domperidone per os [19,20]. Patients were allowed to drink clear liquids after 2 h of SBCE ingestion but not to eat until 4 h later [18].

2.2. SBCE review

The recorded digital information was downloaded from the recorder into the computer and the small bowel videos were reviewed in the workstation using the Rapid Reader® software v 9.0 (Given Imaging).

Two experienced readers with more than 500 reviews performed a SR at a maximum speed of 10 frames per second [18] and reported all the relevant findings. Another experienced reader, blinded to the SR results, reviewed all SBCE videos using TOP 100 after selecting the first duodenal and the first cecal landmarks, and reported all the relevant findings, while excluding false positive results – Figs. 1 and 2. All the false positive results selected automatically by the TOP 100 were easily and promptly excluded by the experienced reader during the review process. All the readers were blinded to the patients’ clinical history.

In each study, the relevant findings were defined by Saurin Classification as the presence of lesions with high bleeding potential (P2), namely angioectasias, ulcers or tumours and active bleeding [21]. Lesions with uncertain bleeding potential (P1) included small erosions or red spots [21].

2.3. Statistics

Statistical analysis was performed with SPSS® version 22.0 (IBM, Armonk, New York, USA). The categorical variables were presented as frequencies and percentages, and continuous variables as means and standard deviations.

3. Results

SBCE was performed on a total of 177 patients in our department between April 2017 and August 2018, which included 97 patients with suspected SBB. The remaining patients were excluded because they performed SBCE due to other indications. Mean patient age was 61.5 ± 17.7 years, 57.7% (n=56) were female. SBCE was performed on a majority of patients (90.7%) for suspected occult SBB and 9 (9.3%) for suspected overt SBB. In 4.1% (n=4) of patients, the SBCE did not reach the cecum. The overall diagnostic yield of the SBCE was 51.5%, and angioectasias (35.1%) were P2 lesions more frequently observed followed by ulcers (13.4%). No tumours of the small bowel were observed.

Patients’ demographic and clinical characteristics are detailed in Table 1.

TOP 100 detected 81/97 (83.5%) of P2 lesions when compared to SR, in particular 64/67 (95.5%) of angioectasias and 17/30 (56.7%)



Fig. 2. Active bleeding identified by the TOP 100 software.

Table 1 Demographic and clinical data of patients included in the study.

Variables	
n	97
Female (%)	57.7% (56/97)
Mean age (years)	61.5 ± 17.7
SBCE indication	
Occult	90.7% (88/97)
Overt	9.3% (9/97)
Diagnostic yield of SBCE	51.5% (50/97)
SR findings [% (number of patients)]	
Angioectasias	35.1% (34/97)
Ulcers	13.4% (13/97)
Tumors	0.0% (0/97)
Active bleeding	9.3% (9/97)
Red spots	9.3% (9/97)
Erosions	10.3% (10/97)
Small bowel transit time (min)	305.0 ± 148.0
Mean haemoglobin (g/dl)	9.6 ± 1.8
Mean iron (ug/dl)	33.4 ± 19.8
Mean ferritin (ng/ml)	27.2 ± 47.5
Mean transferrin saturation (%)	9.8 ± 6.5
Comorbidities	
Arterial hypertension	55.7% (54/97)
Dyslipidemia	36.1% (35/97)
Type 2 diabetes	34.0% (35/97)
Ischemic heart disease	14.4% (14/97)
Chronic kidney disease	11.3% (11/97)
Atrial fibrillation	16.5% (16/97)
Aortic stenosis	4.1% (4/97)
Medication	
NSAIDS	5.2% (5/97)
Anti-platelets	25.8% (25/97)
Anti-coagulants	17.5% (17/97)

SBCE: small bowel capsule endoscopy; SR: standard reading; NSAIDS: non steroidal anti-inflammatory drugs.

of ulcers. TOP 100 identified all instances of active bleeding (9/9) – Fig. 3. The 9 patients with active bleeding, the source of bleeding was identified as angioectasias in 6 and in the other 3 no source of bleeding was identified.

P1 lesions were identified by TOP 100 in 54.5% (12/22), 44.4% (4/9) as red spots and 61.5% (8/15) as erosions.

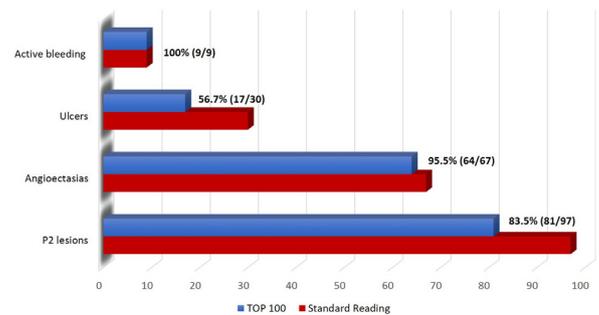


Fig. 3. TOP 100 sensitivity for significant findings.

Concerning per-patient analysis in P2 lesions, we found that of the 34 (35.1%) patients with angioectasias, TOP 100 identified 31 (91.2%) of all cases, and of the 13 (13.4%) patients with ulcers, TOP 100 identified 4 (30.8%) in its entirety.

After excluding patients on whom the SBCE was performed for overt SBB, TOP 100 identified 72/86 (83.7%) of the P2 lesions when compared to SR, which had a count of 56/58 (96.6%) of angioectasias and 16/28 (57.1%) of ulcers.”

All images that were false positives selected by the TOP 100 were easily identified and promptly ignored by the experienced reader.

4. Discussion

SBCE is an essential, validated tool in the investigation of small bowel pathology, namely in suspected SBB [2,18]; however, the burden of video reading time is still a shortcoming [12]. Therefore, the development of an automated software to reduce the reading time is an attractive concept that is still steadily gaining ground [13].

TOP 100 was incorporated in the Rapid Reader® platform in 2017, replacing the previously existing SBI® and QV®, [14,16,17] which consists of a software application that performs automatic selection of 100 images with potential abnormalities.

With this study, we aimed to investigate if TOP 100 would be a useful tool in swift identification of the lesions associated with SBB when compared to SR.

In our series, the diagnostic yield of SBCE for relevant findings was 51.5%, which is in line with previous studies [22,23].

Using the TOP 100 technology, we were able to accurately and efficiently identify 83.5% of the P2 lesions, in particular 95.5% of the angioectasias. In addition, this recent software identified all of the 9 active bleeding and recognized angioectasias as the cause in 6 of the cases.

Further therapeutic or diagnostic intervention could have been planned based on the TOP 100 findings in 34 patients, wherein 91.2% of the patients are ones with angioectasias; however, the source of bleeding could not be identified in 3 patients with active bleeding.

When compared with previous established software applications that intend to reduce the SBCE reading time, SBI presented a lower sensitivity for angioectasias detection that ranged between 12.7–40.6% [16,17], which is quite inferior to our results from TOP 100 (95.5%). However, for active bleeding, a previous study from our centre [16] and a recent meta-analysis [17] that comprised 16 studies showed that SBI was also associated with a high sensitivity (98.8%).

QV[®] was another user-friendly software that reduced the reading time of SBCE review to a couple of minutes (average 11.6 min) [13–15,17], however it displayed an unacceptable miss rate for potentially important lesions and an increased number of software-associated false negatives as the reading speed increased [15,24].

Thus, in comparison to these previous fast reading applications, TOP 100 is an improved upgrade that allows the identification of almost all potential bleeding lesions.

Moreover, when time is a crucial point, TOP 100 is an automatic and immediately available software, instantly allowing, after identification of the proper landmarks, the selection of the 100 most important images.

Finally, regarding lesions with uncertain bleeding potential (P1) the results were not encouraging. We observed that TOP 100 correctly identified P1 lesions in half of the lesions found with SR, in 44.4% with the red spots and 61.5% with the erosions. This lower sensitivity could be due to the small quantities of red pixels or minimal difference from the pattern of frames.

Nevertheless, the low sensitivity in this type of lesions is probably not critical according to a recent study from our centre that showed that the outcome of patients with P1 lesions do not differ significantly from those with no bleeding potential lesions (P0) or normal SBCE [25].

There are some limitations of our study, comprising its retrospective design, which precluded the comparison of the mean reading time of SR versus TOP 100 reading, the small sample size and inclusion of limited cases of overt SBB, making the entire spectrum coverage of possible small bowel findings unlikely.

Nevertheless, the main strength of this study is that for the first time, we support the use of TOP 100 as an initial and quick SBCE screening, accurately assessing for lesions with high potential or active bleeding by allowing an adequate selection of the cases in which SR of the full SBCE video should be a priority and an intervention planned. If not, the clinician can read the complete SBCE at their convenience as per routine-sparing time to a busy gastroenterologist. Even so, our findings support its user-friendly use in beginners, while the learning curve has not yet reached the SBCE-reading expertise level. Multicenter, larger and prospective studies are required to confirm our findings.

In conclusion, regardless of the limitation that the TOP 100 could not be a replacement for SR, we advocate that this powerful software should be employed as a red flag technology alerting the physician to priority cases based on instant recognition of most relevant lesions.

Disclosures

Rosa B. has consulting services agreement with Medtronic.

Conflict of interest

None declared.

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