

## Clinical summary

*Medtronic provides the following synopsis of a clinical publication and corresponding discussion points to consider on the TOP100 software tool of the RAPID Reader.*

### **Simplify to improve capsule endoscopy - TOP 100 is a swift and reliable evaluation tool for the small bowel inflammatory activity in Crohn's disease**

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*Scandinavian Journal of Gastroenterology PMID: 1745880*

#### **Takeaway message**

1. TOP100 is shown here to have overall good to excellent agreement with a gastroenterologist experienced in reading SBCE (having reviewed over 500 SBCE previously) performing a classic reading, or CR, specifically with very similar agreement in the first and third tertiles of the small bowel
2. Interobserver agreement was higher in moderate to severe inflammatory activity and all cases of moderate-to-severe inflammatory activity detected by TOP100 were classified likewise by CR
3. TOP100 is estimated to save greater than 30 minutes in read time when for evaluating the presence/ extent of small bowel Crohn's disease activity and calculating LS where applicable
4. Data shows that TOP100 selections remain reliable throughout the small bowel and can be applied in the context of diffuse disease.

#### **Background and aims**

Capsule endoscopy is a recognized method for study of the small bowel (SB), including patients with Crohn's disease (CD). The Lewis score (LS) can be used to assess inflammation activity. TOP100 is a tool of the RAPID Reader® software that assists in the time-consuming capsule reading process by automatically selecting 100 images that will most likely contain abnormalities. The purpose of this study is to evaluate the agreement between TOP100 and CR in determining Lewis Score (LS) in CD.

#### **Study design**

- In this retrospective study including consecutive patients undergoing small bowel capsule endoscopy (SBCE) for suspected or established CD, one experienced reader performed CR and calculated the LS.
- Another experienced reader, blinded to the CR results, reviewed all SBCE videos using TOP100 and calculated the LS.
- Small bowel inflammatory activity was classified by the LS into three stages: no disease or clinically insignificant disease ( $LS < 135$ ); mild disease ( $135 \leq LS < 790$ ); and moderate or severe disease ( $LS \geq 790$ ). Incomplete capsules (those not reaching the cecum within the battery time) were excluded from study analysis.
- Interobserver agreement between the two methods of capsule reading for LS calculation was determined using kappa (k) statistics where negative values correspond to disagreement, a kappa value of zero indicates no agreement better than that which would be expected by chance alone, and positive values correspond to agreement.

## Key data

- 118 SBCE procedures were performed, 3 patients had incomplete SBCE and were excluded from the study leading to a total of 115 patients (n=86, 74.8% female) with a mean patient age of 36.2±12.1 years. A total of 81 (70.4%) of patients had suspected CD and 34 (29.6%) had established CD.
- The overall diagnostic yield of significant inflammatory lesions (erosions, ulcers, and stenoses) by CR and TOP100 was 55.7% and 47.0% (p=.23), respectively.
- SBCE detected significant inflammatory activity (LS ≥ 135) in 55.7% (n=64) patients.
- A comparison of inflammatory activity detected between the TOP100 and CR is reported in the table below.

Inflammatory activity	LS < 135		135 ≤ LS < 90		LS ≥ 790	
Capsule reading	TOP100	CR	TOP100	CR	TOP100	CR
n (%)	53.0%	44.3%	35.7%	42.6%	11.3%	13.0%

- Strong agreement between the two methods of capsule reading (Kappa = 0.83, p<.001) was verified, with an agreement on 89.6% of the cases. Interobserver agreement of capsule reading for LS calculation are presented in the table below.

Capsule reading	K	p-value	95% CI	Interpretation*
CR vs. TOP100	0.83	<.001	0.78-0.87	Excellent
LS				
Insignificant inflammatory activity (LS < 135)	0.83	<.001	0.78-0.88	Excellent
Mild inflammatory activity (135 ≤ LS < 90)	0.78	<.001	0.72-0.84	Good
Moderate-to-severe inflammatory activity (LS ≥ 790)	0.92	<.001	0.86-0.98	Excellent

## Conclusion

While classical review of the entire CE video remains the gold standard, the TOP100 is a useful tool in assisting the reader in prompt calculation of LS, particularly for identifying patients with moderate-to-severe inflammatory disease.

***This concludes the clinical synopsis of this publication***

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