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## **A multisystem-compatible deep learning-based algorithm for detection and characterization of angiectasias in small-bowel capsule endoscopy. A proof-of-concept study.**

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### **Disclosure statement**

Xavier Dray, Aymeric Histace and Romain Leenhardt are co-founders and shareholders of Augmented Endoscopy.

Xavier Dray has received lecture fees from Bouchara Recordati, Fujifilm, Medtronic, MSD and Pfizer, and has acted as a consultant for Alfasigma, Boston Scientific, Norgine, and Pentax.

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Mark McAlindon has received research materials from Given Imaging, Jinshan Science, Intromedic, Ankon and has acted as a consultant for Medtronic.

Robert Benamouzig is working for Alfasigma, Medtronic, and Bayer (board)

The others authors do not have disclosures

### **Keywords**

capsule endoscopy; small bowel; artificial intelligence; deep learning; neural networks; algorithms

## Abbreviations

AI: Artificial Intelligence  
CD: crohn's disease  
CE: capsule endoscopy  
DL: deep learning  
GI: gastrointestinal  
GIA: gastrointestinal angiectasia (or angiodysplasia)  
ms: millisecond  
NPV: Negative Predictive Value  
OGIB: obscure gastrointestinal bleeding  
PPV: Positive Predictive Value  
ROI: Region of Interest  
SB: small bowel  
SBCE: small bowel capsule endoscopy  
Se: sensitivity  
Sp: specificity  
TP: True Positive

## Abstract

**Background and aims.** Current artificial intelligence (AI)-based solutions for capsule endoscopy (CE) interpretation are proprietary. We aimed to evaluate an AI solution trained on a specific CE system (Pillcam<sup>®</sup>, Medtronic) for the detection of angiectasias on images captured by a different proprietary system (MiroCam<sup>®</sup>, Intromedic).

**Material and Methods.** An advanced AI solution (Convolutional neural network), previously trained on on Pillcam<sup>®</sup> small bowell images, was evaluated on independent datasets with more than 1200 Pillcam<sup>®</sup> and MiroCam<sup>®</sup> still frames (equally distributed, with or without angiectasias). Images were reviewed by experts before and after AI interpretation.

**Results.** Sensitivity for the diagnosis of angiectasia was 97.4% with Pillcam<sup>®</sup> images and 96.1% with Mirocam<sup>®</sup> images, with specificity of 98.8% and 97.8%, respectively. Performances regarding the delineation of regions of interest and the characterization of angiectasias were similar in both groups (all above 95%). Processing time was significantly shorter with Mirocam<sup>®</sup> (20.7 ms) than with Pillcam<sup>®</sup> images (24.6 ms,  $p < 0.0001$ ), possibly related to technical differences between systems.

**Conclusion.** This proof-of-concept study on still images paves the way for the development of resource-sparing, “universal” CE databases and AI solutions for CE interpretation.

## Introduction

Capsule endoscopy (CE) is recommended for investigating the small bowel (SB) in patients with gastrointestinal (GI) bleeding, iron deficiency anemia, or suspected Crohn's disease, after normal upper GI endoscopy and colonoscopy. (1) Gastroenterologists spend about 30 to 120 min to review and interpret full-length small-bowel capsule endoscopy (SBCE) recordings that encompass a mean number of 50,000 frames. The interpretation of one CE leads to an accuracy decrease of the practitioner, preventing the reading of several capsules. (2,3)

In attempt to relieve physicians from the tedious, time-consuming task of SBCE reading, our team has designed in 2019 a proof-of-concept study where a deep learning (DL)-based artificial intelligence (AI) solution was shown highly sensitive and highly specific to detect gastrointestinal angiectasias (GIA, also known as angiodysplasias), a most common SB vascular lesion. (4) This development was based on datasets of still images captured from one specific third-generation SBCE system. Since then, DL-based solutions have flourished from many academic and industrial research teams. (5,6) These solutions allow a reading time of a full-length SBCE recording in about 2 to 5 minutes. Some solutions are now commercially available (7), but most are proprietary, dedicated to the automated SBCE reading of one specific brand/company. Nevertheless, we believe that, visually speaking, SB findings (and specifically GIA) are very similar, whatever the proprietary CE system used for capture.

The aim of this study was to evaluate a DL-based solution trained on images captured by a specific CE system (namely, Pillcam- SB3, Medtronic, Minneapolis, MN, USA), for the detection of GIA on still images captured not only by the same system, but also by a different one (namely MiroCam, Intromedic, Seoul, South Korea).

## Materials and Methods

Institutional Review Board approval was obtained (Sorbonne University, n°20210209162452, February 9- 2021) for this retrospective, non-interventional study on de-identified images.

### *Initial training and testing, on image datasets built from one specific CE proprietary system*

The initial database and the DL-based prototype AI solution have been described previously. Briefly, de-identified annotated SBCE still frames were extracted from a multicenter (12 French Endoscopy unit) database called CAD-CAP, in which 25,000 still frames were collected from 4166 de-identified, third-generation, SB-CE videos (PillCam<sup>®</sup> SB3 system, Medtronic, Minneapolis, MN, USA). (8)

GIAs were defined as “*clearly demarcated, bright-red, flat lesions, consisting of tortuous and clustered capillary dilatations, within the mucosal layer*” (2) and then reviewed and validated by three senior CE experts with more than 200 readings each (9). Convolutional neural network (CNN)-based approaches were used for DL. The GPU used was a Quadro RTX<sup>®</sup> 3000 (NVIDIA, Santa Clara, CA, USA) with a 6GB RAM.

Dataset A1 with 300 GIA images was used for data augmentation and DL, and dataset A2 with 300 different GIA images was used for testing. Similarly, control datasets were created with 300 normal images each (N1 for DL, N2 for testing). After training on datasets A1 and N1, the DL-based approach demonstrated a 100% sensitivity and a 96% specificity when

tested on datasets A2 and N2, and also precisely located regions of interest (ROI) within images containing GIA. (10)

Since then, this DL-based solution has been refined. It is now able to detect (discriminating still frames encompassing lesions from normal frames), to delineate (box around ROI), to characterize findings (labelling GIA and ulcerations, and displaying a percentage of confidence in the proposed diagnosis), and to score SB video recordings in terms of cleanliness.(11)

### ***Additional testing on image datasets built from two different CE proprietary systems***

In the current study, new frames were extracted, selected, reviewed and validated based on the same methodology as for the initial training/testing datasets. Four additional image datasets (A3, N3, A4, N4) were thus created from different SBCE video recording, independent from the datasets (A1, N1, A2, N2) of the initial study (8). Datasets A3 (with 305 still frames with GIA), and N3 (with 321 normal, control still frames) were created from Pillcam SB3 recordings. Datasets A4 (with 308 still frames with GIA), and N4 (with 321 normal, control still frames) were created from MiroCam1200 recordings.

### ***Diagnostic performances of the AI solution for frame detection, ROI delineation, and characterization.***

All AI outputs were reviewed by three CE experts (1), according to the definitions of true positive (TP) findings in terms of GIA frame detection, delineation of ROI and characterization (*table 1, figure 1*)

The primary endpoint of the study was the sensitivity (Se) of the DL-based algorithm in terms of GIA frame detection, on both A3/N3 (Pillcam) and A4/N4 (MiroCam) datasets. Specificity (Sp), positive (PPV) and negative (NPV) predictive values were calculated as well. Diagnostic performances (TP rate, Se, Sp, PPV, NPV) for ROI delineation and characterization, level (%) of confidence in diagnostic of GIA, and time for processing (calculation plus display on screen), were secondary endpoints

### ***Statistics***

Results were expressed as percentages with 95% confidence intervals (C.I.) for categorical variables and as means  $\pm$  standard deviations (SD) for continuous variables. Fisher's exact test and Student test were used to compare categorical and continuous data between groups, respectively.

### **Results**

TP finding rates were above 95% (**table 2**) for all tasks: GIA frame detection (Pillcam 97.4% vs Mirocam 96.1%,  $p=0.50$ ), delineation of ROI (99.7% for both systems,  $p>0.99$ ) and characterization of GIA (99.7% for both systems,  $p>0.99$ ). The AI solutions also performed well when considering all three tasks combined (Pillcam 96.7% vs Mirocam 95.5%,  $p=0.53$ ).

Similarly, the AI solutions demonstrated high diagnostic performances whatever the dataset used for evaluation (**table 3**): Se of 97.4% with Pillcam images and 96.1% with Mirocam images, Sp of 98.8% and 97.8%, PPV of 98.8% and 97.7%, and NPV of 97.6% and 96.3%, respectively.

The mean percentage of confidence in diagnosing GIA was similar in both groups ( $82.5 \pm 22.9\%$  with Pillcam<sup>®</sup> images vs  $81.6 \pm 24.8\%$  in Mirocam<sup>®</sup> images,  $p = 0.51$ ).

The mean processing time was significantly shorter with Mirocam<sup>®</sup> images ( $20.7 \pm 6.5$  ms) compared to what obtained with Pillcam<sup>®</sup> images ( $24.6 \pm 7.0$  ms,  $p < 0.0001$ ).

## Discussion

To the best of our knowledge, this is the first study where a DL-based AI solution trained on CE specific proprietary image datasets (namely Pillcam<sup>®</sup> SB3) demonstrated excellent diagnostic performances for frame detection, delineation of ROI and characterization of ROI, not only on an independent dataset of GIA images from the same proprietary system (overall, Se of 97.4%, Sp of 98.8%), but also (overall, Se of 96.1%, Sp of 97.8%) on an independent dataset of GIA images captured from a different CE system (namely MiroCam<sup>®</sup>). The system was fast (mean processing time of 20 to 25 ms per image) and displayed a high level of confidence in the diagnostic of GIA (above 80% in most cases).

Our findings with the Pillcam<sup>®</sup> system are similar to that found for AI-based GIA detection by Noya et al. in 2017 (Se of 89%, Sp of 97%) (12) and by our group in 2019 (Se of 100%, Sp of 96%) (8), thus providing some external validity. Current Se for GIA detection of our DL-based solution is slightly lower – but still over 95% – compared to the initial study (100%). This is possibly because the solution has evolved and now addresses more varied and complex tasks (detection, delineation, and characterization of GIA and inflammatory lesions, plus cleanliness evaluation). Diagnostic performances (for all endpoints) were slightly lower when tested on the A4/N4 datasets (MiroCam<sup>®</sup> images) than when tested on the A3/N3 datasets (Pillcam<sup>®</sup> images). We have three main hypotheses for explaining these subtle variations. First, training and testing on images from the same trademark likely makes a difference. Second, technical characteristics between devices such as different fields of view, resolutions (320x320 for MiroCam<sup>®</sup>, 340x340 for Pillcam<sup>®</sup>), contrasts, brightness, blurriness or opacity may also have an impact on performances (table 4)(13). Third, using a convolution process may also explain why the processing time was significantly shorter with MiroCam<sup>®</sup> images than with Pillcam<sup>®</sup> images (in relation with heavier calculations in frames with higher resolution in the latter system). Still, overall, these differences were not statistically significant, and diagnostic performances were all above 95%.

Our study has several strengths. Image datasets were built from several centers across Europe. All images were reviewed (before and after testing) and categorized (for all clinical outcomes) by experts (14) according to well-defined criteria (for GIA definition and for outcome measurements). Still, we must acknowledge several limitations as well. First, the evaluation was retrospective, with potential bias. Among those, GIA were selected to be typical (4) and possibly in a visually clean environment. GIA detection in a real-life setting, in a prospective manner, may be more challenging. Second, the evaluation is based on still frames and not on video recordings which is a source of bias. However, the likelihood for a DL-based solution to capture a GIA is certainly higher when lesions are present on several consecutive frames on a video sequence than once on a single, selected, still frame. Still, another study at the video level would be of interest. Third, only GIA were considered because it is the more common and emblematic lesion seen in SB CE at the stage of a proof-of-concept study. Demonstration of similar results with more varied types of findings is needed.

Overall, these preliminary findings on still images pave the way for a “*killing two birds with one stone*” approach in the development of AI solutions for SBCE interpretation. A similar strategy has been used successfully for DL-based solutions for polyp detection in colonoscopy, developed on a proprietary video database, claimed to work well with all major endoscopy brands (15) and now commercially available (GI Genius, Medtronic). Among advantages, this approach allows building resource-sparing, “universal”, CE databases and AI solutions. Such solutions could be either plug-and-play boxes (as for colonoscopy) or on-line platforms (Software as a Service, SaaS, as proposed with our solution) where CE video recordings from any brand/company could be uploaded and semi-automatically interpreted.

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**Table 1: definitions of true positive findings for various study endpoints**

<b>Outcome</b>	<b>Definition of true positive</b>
<b>GIA frame detection</b>	Any output (box) of the AI solution within a frame containing a GIA, wherever the box is placed, whatever label is displayed (GIA, or not) ( <i>see figures 1A, 1C, 1D and 1F for examples</i> ).
<b>Delineation of ROI</b>	Delineating box covering at least 50% of the GIA, being no larger than twice and no smaller than half the area of the GIA, whatever label is specified (GIA, or not) ( <i>see figures 1A, 1C, and 1D for examples</i> ).
<b>Characterization</b>	“Angiectasia” label is displayed within any frame where a GIA is present (wherever the box is placed) ( <i>see figures 1A and 1D for examples</i> ).

GIA: gastrointestinal angiectasia

**Table 2: True positive findings in images containing angiectasias**

	<b>Pillcam® SB3 A3 dataset (n=305)</b>	<b>Mirocam1200® A4 dataset (n=308)</b>	<b>p</b>
<b>Frame detection</b>	297/305 97.4% <small><sup>95%</sup>C.I.[95.6% ; 99.2%]</small>	296/308 96.1% <small><sup>95%</sup>C.I.[93.9% ; 98.3%]</small>	0.50
<b>Delineation of ROI*</b>	296/297 99.7% <small><sup>95%</sup>C.I.[99.1% ; 100.0%]</small>	295/296 99.7% <small><sup>95%</sup>C.I.[99.1% ; 100.0%]</small>	>0.99
<b>Characterization*</b>	296/297 99.7% <small><sup>95%</sup>C.I.[99.1% ; 100.0%]</small>	295/296 99.7% <small><sup>95%</sup>C.I.[99.1% ; 100.0%]</small>	>0.99
<b>All three combined</b>	295/305 96.7% <small><sup>95%</sup>C.I.[94.7% ; 98.7%]</small>	294/308 95.5% <small><sup>95%</sup>C.I.[93.2% ; 97.8%]</small>	0.53

\* among true positive frame detections only

**Table 3:** Diagnostic performances in terms of detection of frames with angiectasia

	<b>Pillcam® SB3</b> A3/N3 datasets (n=626)	<b>Mirocam1200®</b> A4/N4 datasets (n=629)
<b>Sensitivity</b>	97.4% C.I. <sub>.95%</sub> [96.2% ; 98.7%]	96.1% C.I. <sub>.95%</sub> [94.6% ; 97.6%]
<b>Specificity</b>	98.8% C.I. <sub>.95%</sub> [98.0% ; 99.7%]	97.8% C.I. <sub>.95%</sub> [96.7% ; 99.0%]
<b>PPV</b>	98.7% C.I. <sub>.95%</sub> [97.8% ; 99.6%]	97.7% C.I. <sub>.95%</sub> [96.5% ; 98.9%]
<b>NPV</b>	97.5% C.I. <sub>.95%</sub> [96.3% ; 98.7%]	96,3% C.I. <sub>.95%</sub> [94.8% ;97.8%]
<b>Level of confidence in angiectasia diagnosis*</b>	82.5% ± 22.9%	81.6% ± 24.8%
<b>Calculation time (ms)</b>	24.6 ± 7.0	20.7 ± 6.5

PPV: positive predictive value

NPV: negative predictive value

\* among images with true positive characterisation only

**Table 4:** Main technical differences between Pillcam® SB3 (Medtronic, MN, USA) and MiroCam® (Seoul, South Korean). (6)

	<b>Pillcam® SB3</b>	<b>MiroCam®</b>
<b>Sensor</b>	CMOS	CMOS
<b>Light emitting diodes</b>	4	6
<b>Resolution</b>	340 x 340	320 x 320
<b>Field of view</b>	156°	170°
<b>Capture rate</b>	2 to 6 frames per second (adaptative)	3 frames per second
<b>Transmission</b>	Radiofrequency communication	Human body electrical communication

CMOS: Complementary Metal Oxide Semiconductor

**Figure 1.** Examples of artificial intelligence-based outputs.

- A. Pillcam<sup>®</sup> (Medtronic) image with angiectasia; True positive frame detection, true positive delineation of region of interest, true positive frame characterization.
- B. Pillcam<sup>®</sup> (Medtronic) normal image, false positive frame detection.
- C. Pillcam<sup>®</sup> (Medtronic) image with angiectasia; True positive frame detection, true positive delineation of region of interest, false negative characterization.
- D. Pillcam<sup>®</sup> (Medtronic), false positive frame characterization. A red spot were described by the expert while a angiodysplsia were detected.
- E. Pillcam<sup>®</sup> (Medtronic), false detection and characterization. The angiodysplasia was correctly detected, with good delineation and characterization. However an inflammatory lesion was also detected in the same place.
- F. Mirocam<sup>®</sup>(Intromedic) image with angiectasia; True positive frame detection, true positive delineation of region of interest, true positive frame characterization.
- G. Mirocam<sup>®</sup>(Intromedic) normal image, false positive frame detection.
- H. Mirocam<sup>®</sup>(Intromedic)) image with angiectasia; True positive frame detection, false negative delineation of region of interest (the box is more than twice larger the angiectasia), false negative characterization.
- I. Mirocam<sup>®</sup> (Intromedic), two angiodysplasias were described by the expert while only one were detected
- J. Mirocam<sup>®</sup>(Intromedic) normal image, false positive frame detection. The expert described a bubble, while an angiodysplasia were detected.

