# Impatto dell'intelligenza artificiale nell'utilizzo della videocapsula





DIGESTIVE ENDOSCOPY UNIT FONDAZIONE POLICLINICO A. GEMELLI IRCCS- ROMA UNIVERSITA' CATTOLICA DEL SACRO CUORE CENTRE FOR ENDOSCOPIC RESEARCH, THERAPEUTICS AND TRAINING (CERTT)



EUROPEAN ENDOSCOPY TRAINING CENTER

- ✓ A typical small bowel CE study collects around 50'000-60'000 images
- ✓ Time of reading is around 30-120 minutes according to reader's experience
- ✓ Pathological findings may be present in one or few more images









SB Capsule Endoscopy





# SB Capsule Endoscopy



Pablo Cortegoso Valdivia. Diagnostics 2022





# Impact of AI on Capsule Endoscopy

#### **Lesion Detection**

# Lesion Characterization Current fields of application in CE for Al Current fields of application in CE for Al Prep evaluation PM evaluation

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## Available technology

	Field of view	Lens	Leds	Image sensor	Transmission	Battery life	Frame/sec	Dimension
PillCam SB3	156	Multielements	4	CMOS	Radiofrequency	9-11,5	AFR(2-6)	11 x 26
MiroCam v2	170	NA	4	CMOS	EFP*	12	3	11 x 24
EndoCapsule	145	NA	4	CCD	Radiofrequency	10	2	11 x 26
OMOM HD	172	Multielements	4	CCD	Radiofrequency	12	AFR (2-10)	11 x 25.4
CapsoCam SV1	360	NA	16	NA	On-board	15	16 (4 per camera)	11 x 31
PillCam Colon 2	172x2	Multielements	4	CMOS	Radiofrequency	10	AFR(4-35)	11 x 31
PillCam Crohn	172x2	Multielements	4	CMOS	Radiofrequency	10	AFR(4-35)	11 x 31
NaviCam	140	Multielements	4	CMOS	Radiofrequency	12	AFR(0.5-12)	11.8 x 27

\* Electric Field Propagation







The morning



Modified by Koulaouzidis A. WJG 2013



#### AI-assisted capsule endoscopy reading in suspected small bowel bleeding: a multicentre prospective study

#### ArtIC Study

ARTificial Intelligence Capsule endoscopy study

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- Multicenter, blinded, prospective, non-inferiority study (AI vs conv reading) in suspected small bowel bleeding
- Consecutive, comparative series of patients
- Primarily: to assess non-inferiority of AI-assisted vs conv reading in the detection of SB lesions\* in a per-patient analysis a real-world setting, using entire, unaltered small bowel capsule endoscopy videos
- Secondarily: accuracy of readers and mean reading time in AI-assisted vs conventional reading



# ArtIC Study – Results (1)

133 pts included in the final analysis (F=73, mean age 66.49 yrs ± 14.4)Completion rate: 84.2%; Adequate SB Cleansing: 70% of pts

#### Out of 133 patients:

- Readers in SM identified P1+P2 lesions in **83** pts (P2 lesions: n=55 pts; P1 lesions: n=28 pts)
- Readers in PSM identified P1+P2 lesions in **98** pts (P2 lesions: n=58 pts; P1 lesions: n=40 pts)
- The Board identified P1+P2 lesions in **105** pts

(P2 lesions: n=65 pts; P1 lesions: n=40 pts)

	Per-patien		
P 51VI VS 51VI	P1+P2 lesions	«P2 only» lesions	
Non inferiority	X p = 0.015	- p = 0.299	Primary aim
Superiority	X p = 0.035	- p = 0.422	



Reading type: SM

%, 95 CI	P2+P1 lesions			P2 lesions			
	SM	PSM	P value	SM	PSM	P value	
Sensitivity	79.0	93.3	0.005	84.6	89.2	0.603	
Specificity	100.0	100.0	1	100.0	100.0	1	
PPV	100.0	100.0	1	100.0	100.0	1	
NPV	56.0	80.0	0.039	87.2	90.7	0.668	
Diagnostic accuracy	83.5	94.7	0.006	92.5	94.7	0.616	

SM

# ArtIC Study – Results (Diagnostic Yield)



Diagnostic Yield (P1+P2) (%)

	Difference (%)	CI	
DY SR vs board	16.5	(95%CI: 5-28%)	$\checkmark$
DY PS vs board	5.7	(95%Cl: -16.2-5.7%)	NS



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# **ArtIC Study – Results**

#### Secondary aims

ProScan sensitivity was 100% at per-patient analysis

At per-lesion analysis, ProScan missed a P2 lesion and a P1 lesion

 $\rightarrow$  Sensitivity:

- → 99.5% for P1+P2 lesions (n=362/364)
- → 99.2% for "P2" lesions (n=122/123)



	Standard Reading	AI-assisted reading	p value	
Mean Reading time +/- SD	00:33:42 ± 00:22:51	00:03:50 ± 00:03:20	< 0.001	
Small Bowel				CE reading 9 5/v
Mean Reading time+/- SD	00:43:32 ± 00:25:52	00:06:00 ± 00:04:41	< 0.001	CL reading 5.54x
All GI tract				
Mean images/video	27504	1366	< 0.001	20x

# OMOM system: SmartScan\_Redundancy

A.I. software for effective lesions identification





Up to 90%

Les





#### SmartScan\_Abnormality Detection

as many as 16 types of abnormalities



Material StateMaterial State

















#### Development and Validation of an Artificial Intelligence Model for Small Bowel Capsule Endoscopy Video Review

- Multicenter, retrospective diagnostic study
- Deep learning neural network used : SmartScan (OMOM Capsule Endoscopy System)
  - Training set: 2927 SBCE examinations from 29 medical centers 17 types of CE structured terminology –CEST
  - Validation set: 2898 SBCE examinations collected from 22 medical centers
- Aim: develop an AI diagnostic model for the automatic diagnosis of 17 types of findings and to test its diagnostic performance

Table I. overall Detection of Financias of conventional Actuality and Shiar tocal Assisted Actuality							
No.	Conventional reading	SmartScan-assisted reading	P value	Combined agreed comparator			
Patients, No. (%)							
2000	2048 (70.7)	2298 (79.3)	< 001	2326 (80.3)			
2090	850 (29.3)	600 (20.7)	<.001	572 (19.7)			
6084	4630 (76.1)	5834 (95.9)	<.001	6084 (100.00)			
	No. - 2898 6084	Conventional reading           No.         Conventional reading           2898         2048 (70.7)           6084         4630 (76.1)	No.         Conventional reading         SmartScan-assisted reading           2898         2048 (70.7)         2298 (79.3)           6084         4630 (76.1)         5834 (95.9)	No.         Conventional reading         SmartScan-assisted reading         P value           2898         2048 (70.7)         2298 (79.3)         <.001			

Table 1 Overall Detection of Findings by Conventional Peading and SmartScan-Assisted Peading



Xie et al. JAMA Network Open. 2022;5(7):e2221992.

#### Development and Validation of an Artificial Intelligence Model for Small Bowel Capsule Endoscopy Video Review

eTable 6. Reading Time and Number of Images by Conventional Reading (CR) and SmartScan Assisted Reading (SSAR)

		CR	SSAR	P value	Difference between two
					readings
SBCE Reading time (min)					
	Mean (SD)	51.42(11.60)	5.37(1.51)		46.05(11.16)
	Med (IQR)	50 (43-58)	5 (4-6)	<0.001 <sup>a</sup>	45 (38-53)
	Med (range)	50 (30-130)	5 (3-12)		45 (25-123)
Number of SBCE Images					
	Mean (SD)	27,910.83(12,882.89)	779.17(337.18)		27,131.66(12,888.95)
	Med (IQR)	26,277 (19,218-35,673)	861 (502-1,044)	<0.001 <sup>b</sup>	25,495 (18,398-34,905)
	Med (range)	26,277 (860.0-81,907)	861 (101-1,554)		25,495 (350-81,789)

a Comparison of reading time between CR and SSAR, non-parametric paired Wilcoxon rank sum test : Z=46.629 , P<0.001

b Comparison of the number of pictures between CR and SSAR, non-parametric paired Wilcoxon rank sum test : Z=46.625, P<0.001

Multicentre prospective study on the diagnostic performance of MiroCam MC2000 double tip small bowel capsule AI scan, first real-world study on all indications.

@ ESGE 2025



242 pts (SSBB, CD, IDA)

	Standard reading	AI reading	
Sensitivity	96.5% (CI 91.2-99%)	<b>95.3%</b> (CI 90.1-98.3%)	NS
Specificity	<b>85.3%</b> (CI 78-90.9%)	96.5% (CI 91.3-99%)	NS
Positive Findings	82.2%	86%	p<0.04
Mean reading time	38.2 (SD 20.96)	18.26 (SD 10.79)	p<0.01





			-				
					Weight	Weight	
Study	Mean		MLN	95%-CI	(fixed)	(random)	
Afonso et al, 2022		- B	95.60	[95.60; 95.60]	0.4%	13.7%	
Ding et al, 2023			89.40	[89.37; 89.43]	0.0%	13.7%	
Giordano et al, 2023		31	92.79	[92.25; 93.34]	0.0%	11.6%	
Saraiva et al, 2021		0	98.50	[98.50; 98.50]	11.1%	13.7%	
Piccireli et al, 2022			93.00	[92.51; 93.49]	0.0%	12.0%	
Spada et al (P1+P2 lesions), 2024		+	78.20	[77.55; 78.85]	0.0%	10.1%	
Spada et al (P2 lesions), 2024		+	87.20	[86.68; 87.72]	0.0%	11.6%	
Mascarenhas et al, 2024		-	97.60	[97.60; 97.60]	88.4%	13.7%	
Fixed effect model			97.69	[97.69; 97.69]	100.0%		
Random effects model		1	91.85	[91.38; 92.33]		100.0%	
Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$							
	-50 0	50					
Pooled accuracy for AI-assisted capsule endo	oscopy.						0
	Study Afonso et al, 2022 Ding et al, 2023 Giordano et al, 2023 Saraiva et al, 2021 Piccireli et al, 2022 Spada et al (P1+P2 lesions), 2024 Spada et al (P2 lesions), 2024 Mascarenhas et al, 2024 Fixed effect model Random effects model Heterogeneity: $I^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ Pooled accuracy for AI-assisted capsule endor	StudyMeanAfonso et al, 2022Ding et al, 2023Ding et al, 2023Giordano et al, 2023Saraiva et al, 2021Piccireli et al, 2022Spada et al (P1+P2 lesions), 2024Spada et al (P2 lesions), 2024Mascarenhas et al, 2024Fixed effect modelRandom effects modelHeterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ -50OPooled accuracy for AI-assisted capsule endoscopy.	StudyMeanAfonso et al, 2022Ding et al, 2023Ding et al, 2023Giordano et al, 2023Saraiva et al, 2021Piccireli et al, 2022Piccireli et al, 2022Spada et al (P1+P2 lesions), 2024Spada et al (P2 lesions), 2024Mascarenhas et al, 2024Fixed effect modelHeterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ -50050Pooled accuracy for AI-assisted capsule endoscopy.	StudyMeanMLNAfonso et al, 202295.60Ding et al, 202392.79Giordano et al, 202392.79Saraiva et al, 202198.50Piccireli et al, 202293.00Spada et al (P1+P2 lesions), 202478.20Spada et al (P2 lesions), 202497.60Mascarenhas et al, 202497.69Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ 97.69Pooled accuracy for AI-assisted capsule endoscopy.90.50	StudyMeanMLN95%-ClAfonso et al, 2022Ding et al, 202395.60[95.60; 95.60]Ding et al, 202395.60[89.37; 89.43]Giordano et al, 202392.79[92.25; 93.34]Saraiva et al, 202198.50[98.50; 98.50]Piccireli et al, 202293.00[92.51; 93.49]Spada et al (P1+P2 lesions), 202497.60[97.69; 97.60]Mascarenhas et al, 202497.60[97.60; 97.60]Fixed effect model97.60[97.69; 97.69]Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ 97.60[97.69; 97.69]-5005050	StudyMeanMLN95%-ClWeight (fixed)Afonso et al, 2022 Ding et al, 2023 Giordano et al, 2023 Saraiva et al, 2021 Piccireli et al, 2022 Spada et al (P1+P2 lesions), 2024 Spada et al (P2 lesions), 2024 Mascarenhas et al, 202495.60[95.60; 95.60] 92.790.4% 92.25; 93.34] 98.50Spada et al (P2 lesions), 2024 Mascarenhas et al, 202490.00[92.51; 93.49] 98.500.0% 98.50Fixed effect model Random effects model Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ $-50$ 97.69[97.69; 97.69] 50100.0% 50Pooled accuracy for AI-assisted capsule endoscopy.100.0% 100.0%100.0% 100.0%100.0% 100.0%	StudyMeanMLN95%-CIWeight (fixed)Weight (random)Afonso et al, 2022 Ding et al, 2023 Giordano et al, 2023 Saraiva et al, 2021 Piccireli et al, 2022 Spada et al (P1+P2 lesions), 2024 Spada et al (P1+P2 lesions), 2024 Spada et al (P2 lesions), 2024 Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ $-50$ 95.60[95.60; 95.60] (95.60; 95.60] 98.50; 98.50; 98.50] (98.50; 98.50; 98.50] (97.60; 97.60]0.0%13.7% (92.25; 93.34] (98.50; 98.50]Fixed effect model Random effects model Heterogeneity: $l^2 = 100\%$ , $\tau^2 < 0.0001$ , $p = 0$ $-50$ 97.69[97.69; 97.69] (97.60; 97.60]100.0% (97.60; 97.60]Pooled accuracy for AI-assisted capsule endoscopy.100.0%

Pablo Cortegoso Pataliva. 198 2025







# Limitations of available evidence

• Very high levels of heterogeneity

#### • Specificity:

- false positives
- risk of unnecessary follow-up investigations
- patient anxiety
- increased workload
- Performance of junior readers? (any potential role as booster?)





### DIAGNOSTIC YIELD OF AI-ASSISTED CAPSULE ENDOSCOPY: A COMPARISON BETWEEN EXPERTS AND TRAINEES IN AN 80-CASE SERIES

Tettoni E.<sup>1</sup>, Piccirelli S.<sup>1</sup>, Ferrari C.<sup>1</sup>, Salvi D.<sup>1</sup>, Pesatori E.V.<sup>1</sup>, Belluardo N.<sup>1</sup>, Marmo C.<sup>2</sup>, Cesaro P.<sup>1</sup>, Spada C.<sup>2</sup>

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#### Al-assisted reading by trainees vs standard reading by expert





# Critical Equation to Remember!!!

# NT + OO = COO

New Technology

Old Organization

Costly Old Organization



# Side intelligent Medical mobile phone Gastroscope

(GICE-1000 Capsule Gastric Endoscopy System)

- Mobile capsule gastroscopy
  - Single-use capsule endoscope
  - Portable recorder (no wearable device)
  - App software (to guide through simple changes in posture)
  - Image analysis software







# **Stomach scanning**







cardia



Upper part of gastric body

Lower part of gastric body





Gastric angle

Gastric antrum

Lesser curvature

胶囊位置示例 胃剖面示例图

胃底

胃体上部

胃体下部

胃窦



pylorus



2 胃剖面示例图 胶囊位置示例 3 贲门 胃体小弯 左半撑位; 右半撑位 左侧卧位 胃角 5 幽门

左-俯位





右半侧位

仰卧位





1/2

\*坦生/0/世/6/亡参考

# **Stomach scanning**

Provide an exclusive position change plan with high coverage, and the examinee can complete the examination under the guidance of a doctor/nurse and guided by their mobile mobile phone position.



# Conclusions

- Capsule endoscopy is a prime candidate for early adoption of AI
- Available systems:
  - Able to differentiate abnormal images from normal images
  - Efficient detection rate
  - Promising performance
  - Rapid reading time
- Prospective studies evaluating the real gain of AI-assisted CE reading on the clinical outcome are needed
- Indications (i.e. Crohn's Disease) need to be evaluated



# AI will not replace endoscopists

but

# those who don't use AI will be replaced by those who use it





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