



VIII CONGRESSO NAZIONALE GISCoR

WORKSHOP SCREENING CCR REGIONE LAZIO

GISCoR  
Gruppo  
Italiano  
Screening  
Colorettale

ROMA, 3 E 4 OTTOBRE 2013  
Auditorium Antonianum, Viale Manzoni 1

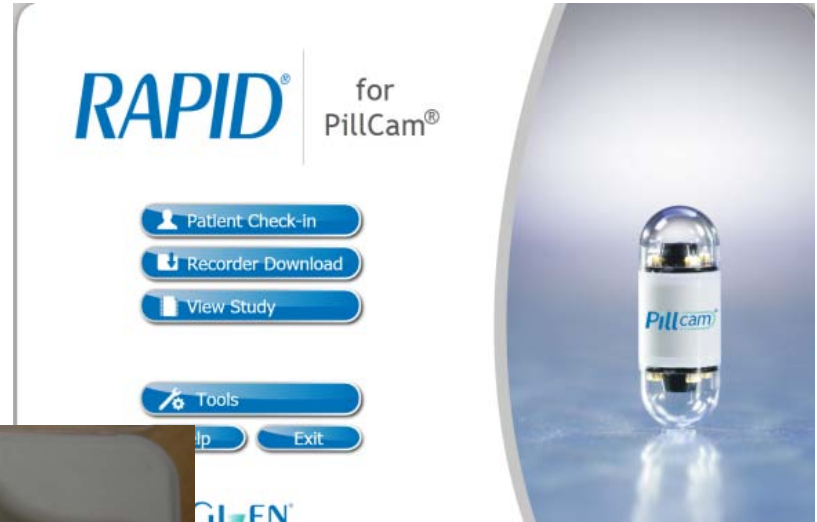
# La video capsula: a che punto siamo?

Cristiano Spada

Digestive Endoscopy Unit  
European Endoscopy Training Centre  
Catholic University  
Rome, Italy



# PillCam Colon Capsule 2



# PillCam Colon Capsule 2

- **Dimension and optics**

- Diameter: 11.6 mm
- Length: 31.5 mm
- Advanced optics enhance image quality and lesion detection

- **Adaptive Frame Rate**

- 35 images / sec when capsule in motion
- 4 images / sec when capsule is virtually stationary
  - Enhance colon coverage
  - Conserve battery energy
  - Optimize video length

- **Wider viewing angle**

- 172° from each side to broaden the screened area
- Nearly 360° coverage of the colon



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07 Oct 09

11

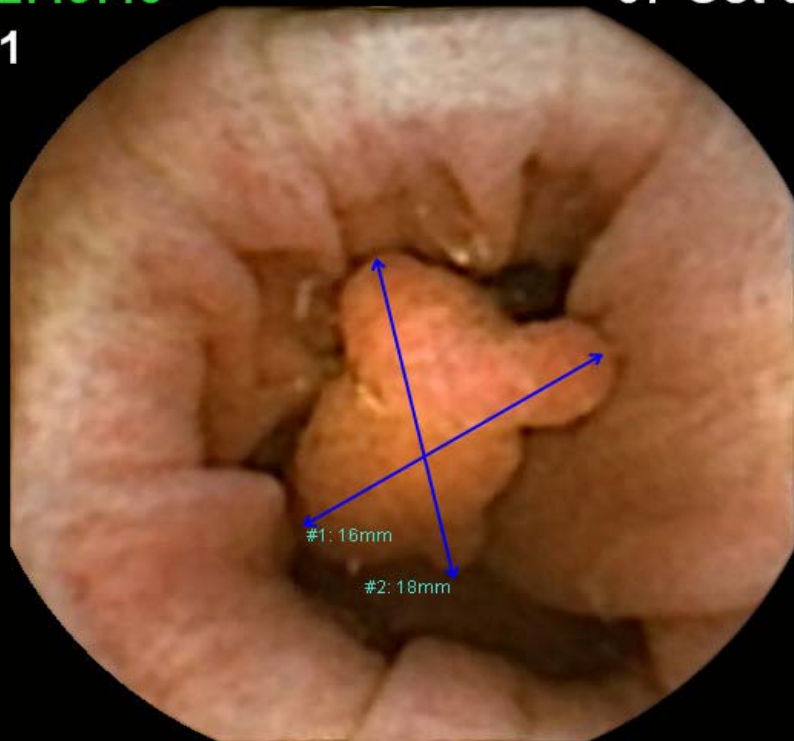


PillCam<sup>®</sup> COLON

02:49:40

07 Oct 09

11



PillCam® COLON

Grid

/10/2009

:38:04

F:13

N

EH-71

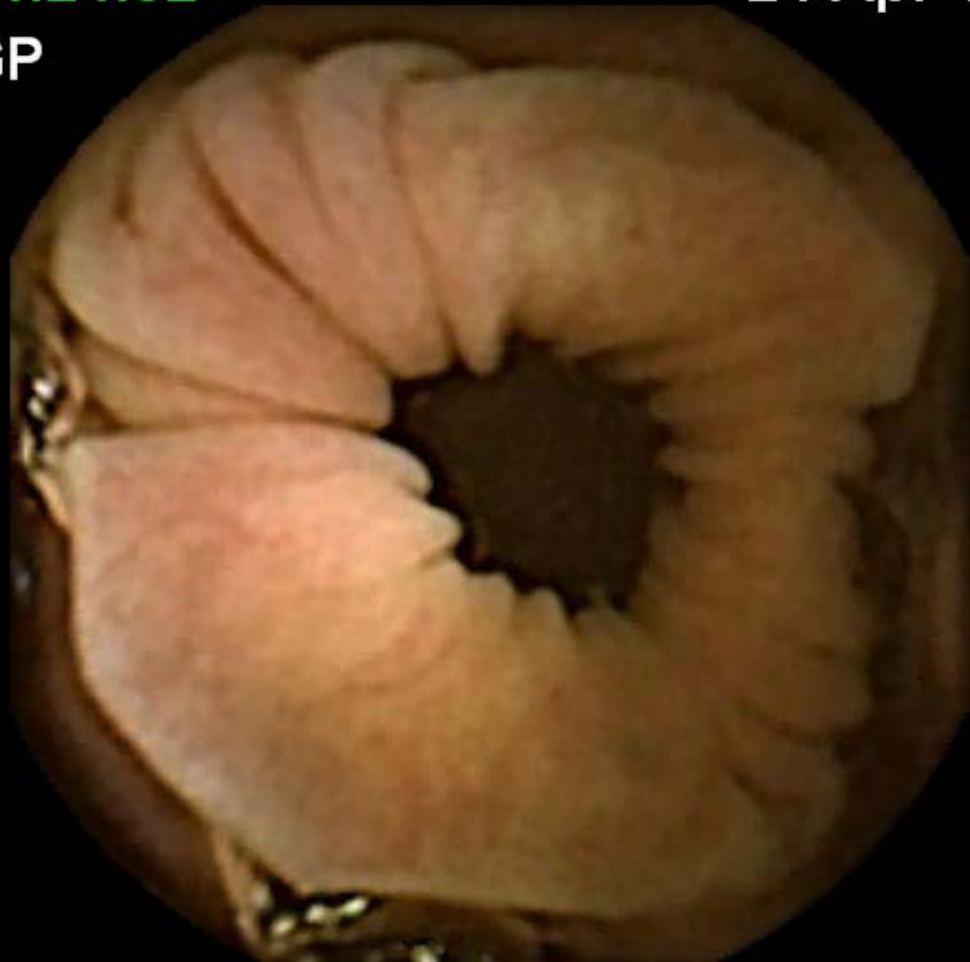
petruzzello, Lucio

esecuzione dell'esame con ENDOBASE

04:24:32

24 Apr 12

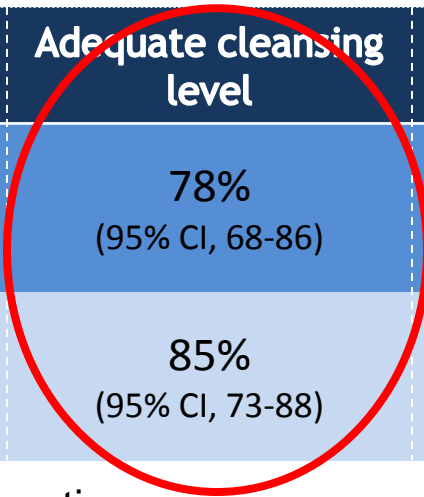
GP



PillCam<sup>®</sup> COLON 2

# Cleansing level

	# pts	Adequate cleansing level	Excretion rate *	Sensitivity ** (95% CI)	Specificity** (95% CI)
Eliakim Endoscopy 2009	98	78% (95% CI, 68-86)	81%	88% (56-98%)	89% (86-90%)
Spada GIE 2011	109	85% (95% CI, 73-88)	81%	88% (76-99%)	95% (90-100%)



\*within 8 hours post ingestion

\*\* for polyps ≥ 10 mm

# Preparation

	Schedule	Intake
Day -1	All Day	Clear Liquid Diet
	Evening (7-9 pm)	2 L PEG
Exam Day	Morning (7-9 am)	2 L PEG
	~ 10 am (~1h after last intake of PEG)	Capsule Ingestion*
	1 <sup>st</sup> Boost <i>after small bowel detection</i>	30 ml NaP + 1 L water
	2 <sup>nd</sup> Boost ** <i>3 hrs after 1<sup>st</sup> Boost</i>	25 ml NaP + 0.5 L water
	Suppository ** <i>2 hrs after 2<sup>nd</sup> Boost</i>	10 mg Bisacodyl

- **Boosters** → to improve CCE excretion rate (EL 4, RG D)
- **NaP-based boosters should be used** (EL 1+, RG B)
- Low dose NaP boosters → adequate CCE excretion rate and should be preferred over higher NaP doses (EL 4, RG D)



# Excretion rate

	# pts	Adequate cleansing level	Excretion rate *	Sensitivity ** (95% CI)	Specificity** (95% CI)
Eliakim Endoscopy 2009	98	78% (95% CI, 68-86)	81%	88% (56-98%)	89% (86-90%)
Spada GIE 2011	109	85% (95% CI, 73-88)	81%	88% (76-99%)	95% (90-100%)

\*within 8 hours post ingestion  
 \*\* for polyps ≥ 10 mm

88% → 8 hours and above post ingestion

# News from DDW 2013

	# pts	Adequate cleansing level (95% CI)	Excretion rate
Rex DDW 2013	884	80% (76-83)	91%*

\* within 10 hours post ingestion

# Accuracy

	# pts	Adequate cleansing level	Excretion rate *	Sensitivity ** (95% CI)	Specificity** (95% CI)
Eliakim Endoscopy 2009	98	78% (95% CI, 68-86)	81%	89% (70-97%)	76% (72-78%)
Spada GIE 2011	109	85% (95% CI, 73-88)	81%	84% (74-95%)	64% (52-76%)

\*within 8 hours post ingestion

\*\* for polyps  $\geq$  6 mm

# Accuracy

	# pts	Adequate cleansing level	Excretion rate *	Sensitivity ** (95% CI)	Specificity** (95% CI)
Eliakim Endoscopy 2009	98	78% (95% CI, 68-86)	81%	88% (56-98%)	89% (86-90%)
Spada GIE 2011	109	81% (95% CI, 73-88)	81%	88% (76-99%)	95% (90-100%)

\*within 8 hours post ingestion

\*\* for polyps  $\geq 10$  mm

# News from DDW 2013

	# pts	Adequate cleansing level (95% CI)	Excretion rate
Rex DDW 2013	884	80% (76-83)	91%*

\* within 10 hours post ingestion

<i>For adenoma</i>	<i>Sensitivity (95% CI)</i>	<i>Specificity (95% CI)</i>
<b>≥ 6 mm</b>	88% (82-93%)	82% (80-83%)
<b>≥ 10 mm</b>	92% (82-97%)	95% (94-95%)



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**10/10 CRC** CCE-detected  
in CCE-2 studies



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- Prep
- Indication
- Procedure

# Prospective multicenter evaluation of colon capsule examination indicated by colonoscopy failure or anesthesia contraindication

M. Pioche<sup>1</sup>, A. de Leusse<sup>1</sup>, B. Filoche<sup>2</sup>, P. A. Dalbiès<sup>3</sup>, P. Adenis Lamarre<sup>4</sup>, P. Jacob<sup>5</sup>, J. L. Gaudin<sup>6</sup>, P. Coulom<sup>7</sup>, J. C. Letard<sup>8</sup>, E. Borotto<sup>9</sup>, A. Duriez<sup>10</sup>, J.-M. Chabaud<sup>11</sup>, D. Crampon<sup>12</sup>, R. Gincul<sup>1</sup>, P. Levy<sup>13</sup>, E. ben-Soussan<sup>14</sup>, M. Garret<sup>15</sup>, J. Lapuelle<sup>6</sup>, J. C. Saurin<sup>1</sup>

*Endoscopy* 2012

## Colon capsule endoscopy is feasible to perform after incomplete colonoscopy and guides further workup in clinical practice

Konstantinos Triantafyllou, MD, PhD,<sup>1</sup> Nikos Viazis, MD, PhD,<sup>2</sup> Panagiotis Tsibouris, MD, PhD,<sup>3</sup> Georgios Zacharakis, MD,<sup>2</sup> Chryssostomos Kalantzis, MD, PhD,<sup>3</sup> Demetrios G. Karamanolis, MD, PhD,<sup>2</sup> Spiros D. Ladas, MD, PhD<sup>4</sup>

*GIE, in press*





1<sup>st</sup> International Colon Capsule  
Expert Meeting  
Consensus Conference  
17-18 February 2011  
Tarquinia, Italy



# Colon capsule endoscopy: European Society of Gastrointestinal Endoscopy Guideline

C. Spada<sup>1</sup>, C. Hassan<sup>1</sup>, J. P. Galmiche<sup>2</sup>, H. Neuhaus<sup>3</sup>, J. Stein<sup>6</sup>, G. Gay<sup>7</sup>, M. Pennazio<sup>8</sup>, D. K. Rex<sup>9</sup>, R. Benamouzig<sup>10</sup>, R. de Franchis<sup>11</sup>, M. ... C. Fraser<sup>14</sup>, F. Hagenmuller<sup>15</sup>, J. M. Herrerias<sup>16</sup>, M. Keuchel<sup>17</sup>, F. Macrae<sup>18</sup>, ... Quintero<sup>21</sup>, M. E. Riccioni<sup>1</sup>, E. Rondonotti<sup>22</sup>, R. Marmo<sup>23</sup>, J. J. Sung<sup>24</sup>, ... A. Van Gossum<sup>12</sup>, G. Costamagna<sup>1</sup>

Endoscopy 2012

No comparative data between CCE vs radiology are available

- CCE is a safe tool for colon mucosa visualization in patients with incomplete colonoscopy without stenosis (EL 3, R ...).

# Methods



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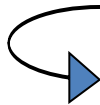
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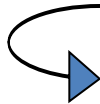
- CTC was performed after capsule excretion or latest at 10-12 hours post ingestion

- Complete CCE and CTC



Colonic segments not explored by first CC were visualized

- Efficacy analysis

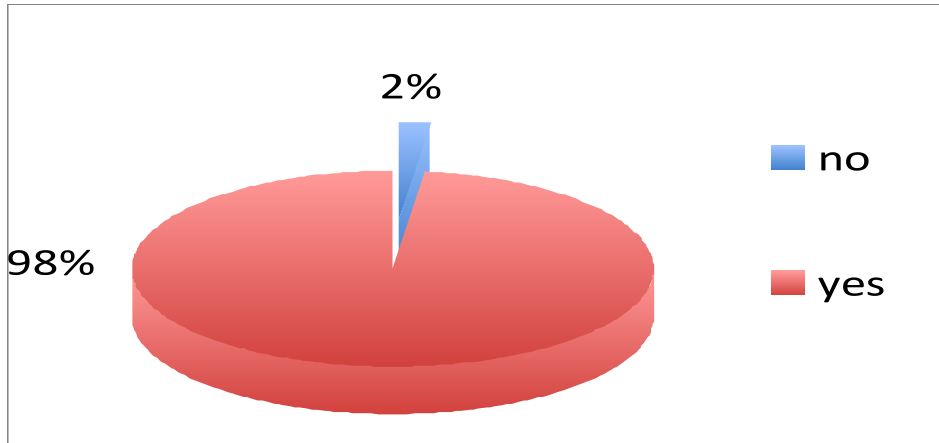


Significant findings (polyps/masses  $\geq 6$ mm) in segments not visualized by first CC

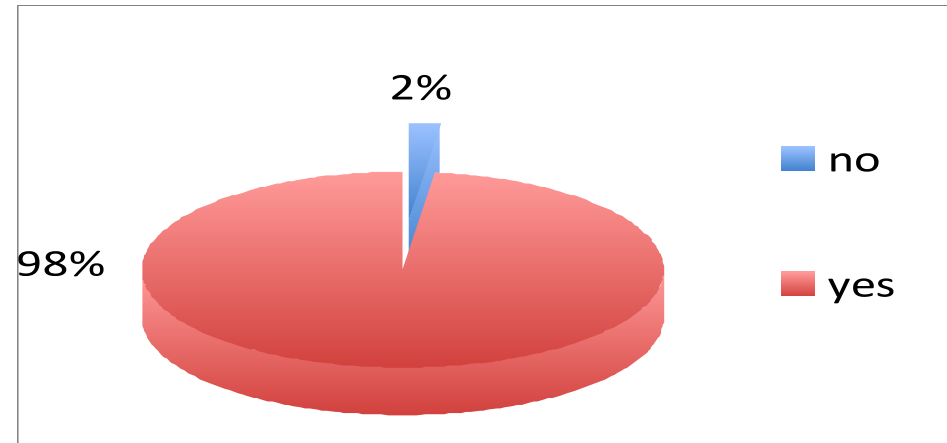
- In case of significant findings and/or discrepancies a second CC (gold standard) was performed within 2 weeks

# Completeness rate

## CCE



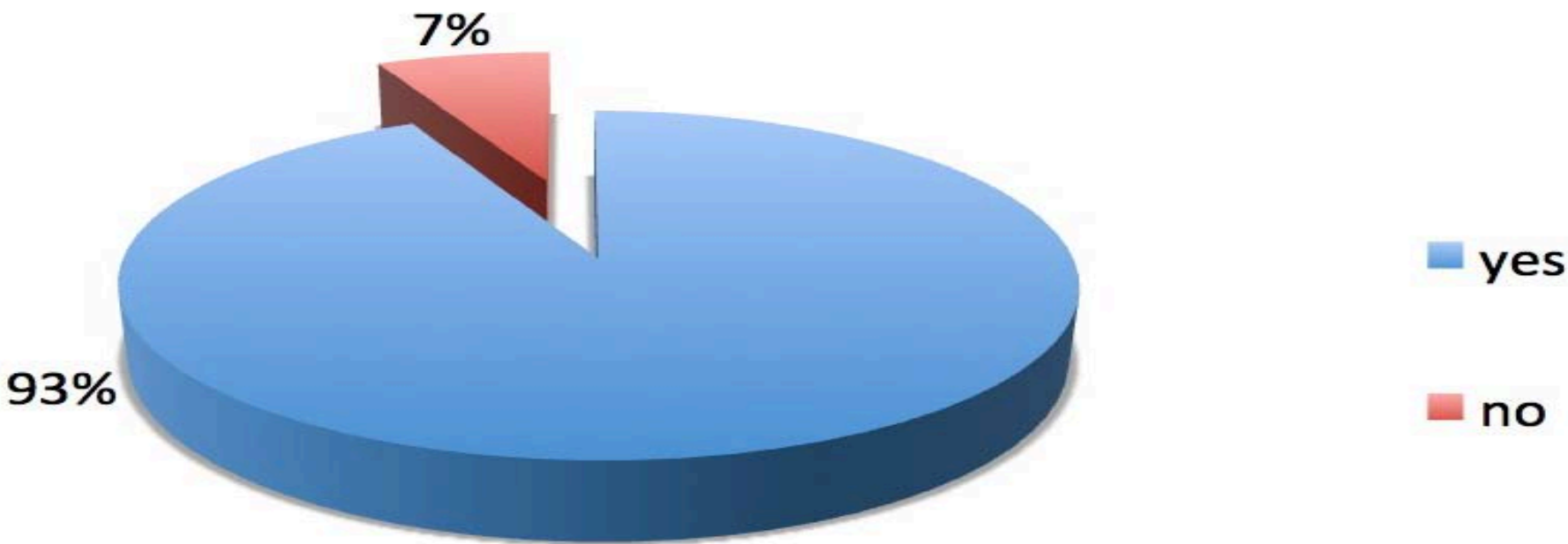
## CTC



- CCE delayed in GI tract
- Pt refused to continue CCE

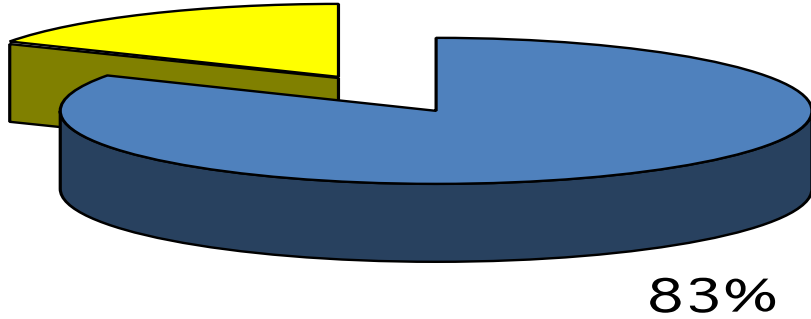
- CTC was not able to completely visualize the colon due to poor sigmoid distension

# Excretion rate

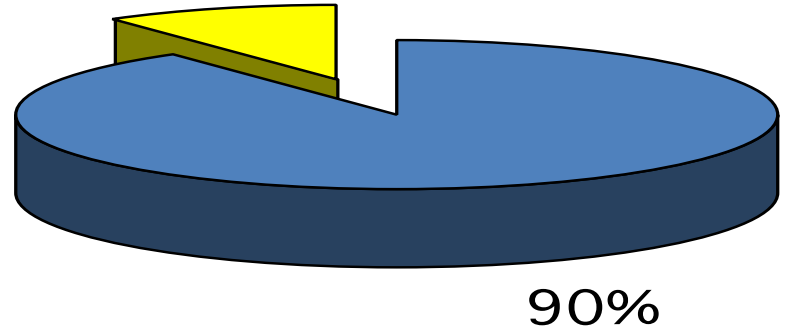


# Quality

**CCE**



**CTC\***



\*cleansing, distension, tagging

# Diagnostic Yield

98 patients enrolled

– CCE:

- Polyp  $\geq$  6mm      18/98 pts    18%\* (95% CI 12-27)
- Polyp  $\geq$  10mm    7/98 pts    7%\*\* (95% CI 4-14)

– CTC:

- Polyp  $\geq$  6mm      6/98 pts    6%\* (95% CI 4-13)
- Polyp  $\geq$  10mm    4/98 pts    4%\*\* (95% CI 2-10)

p<0.005

\*\* p=0.549

# Positive Predictive Value

## – CCE:

- Polyp  $\geq$  6mm      18/19 pts    **95%** (95% CI 74-100)
- Polyp  $\geq$  10mm    7/8 pts      **87%** (95% CI 47-100)

## – CTC:

- Polyp  $\geq$  6mm      6/7 pts      **86%** (95% CI 42-100)
- Polyp  $\geq$  10mm    4/4 pts      **100%** (95% CI 40-100)

p=NS

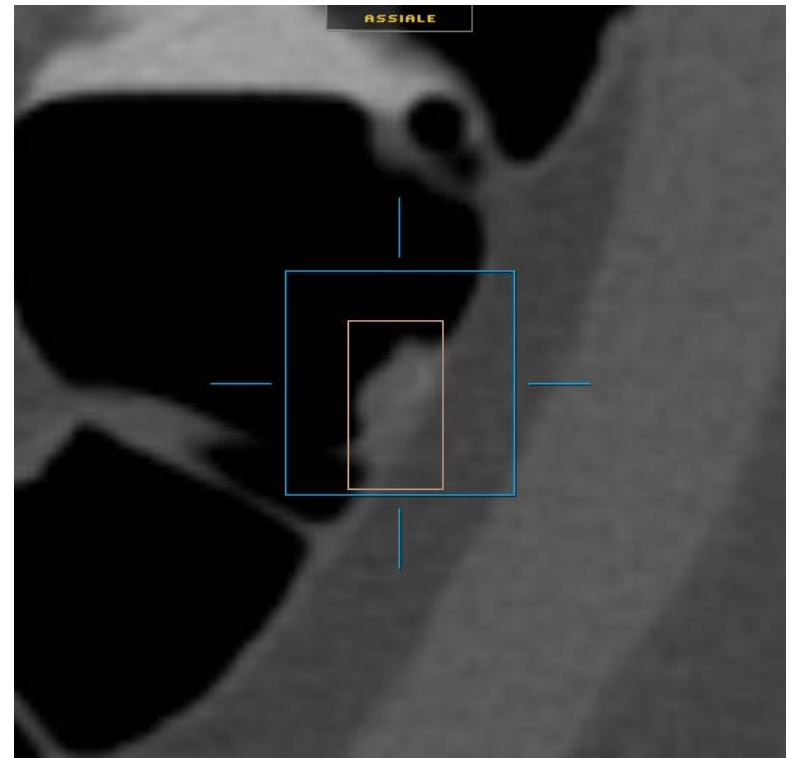


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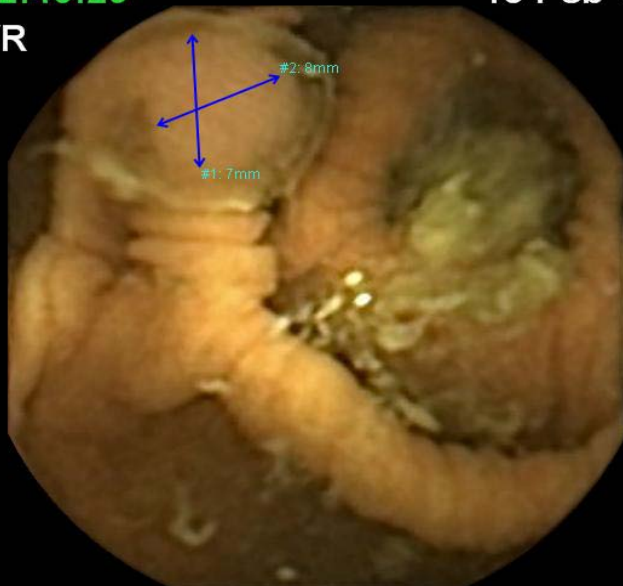
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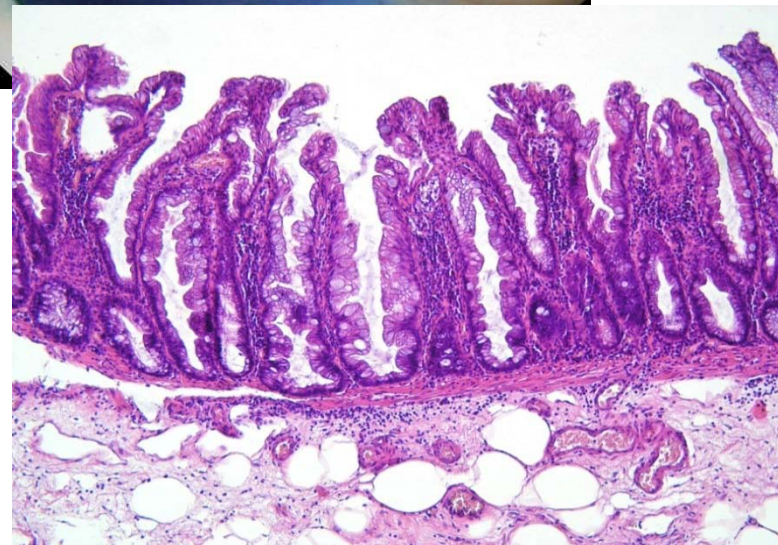
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15 Feb 12



PillCam® COL

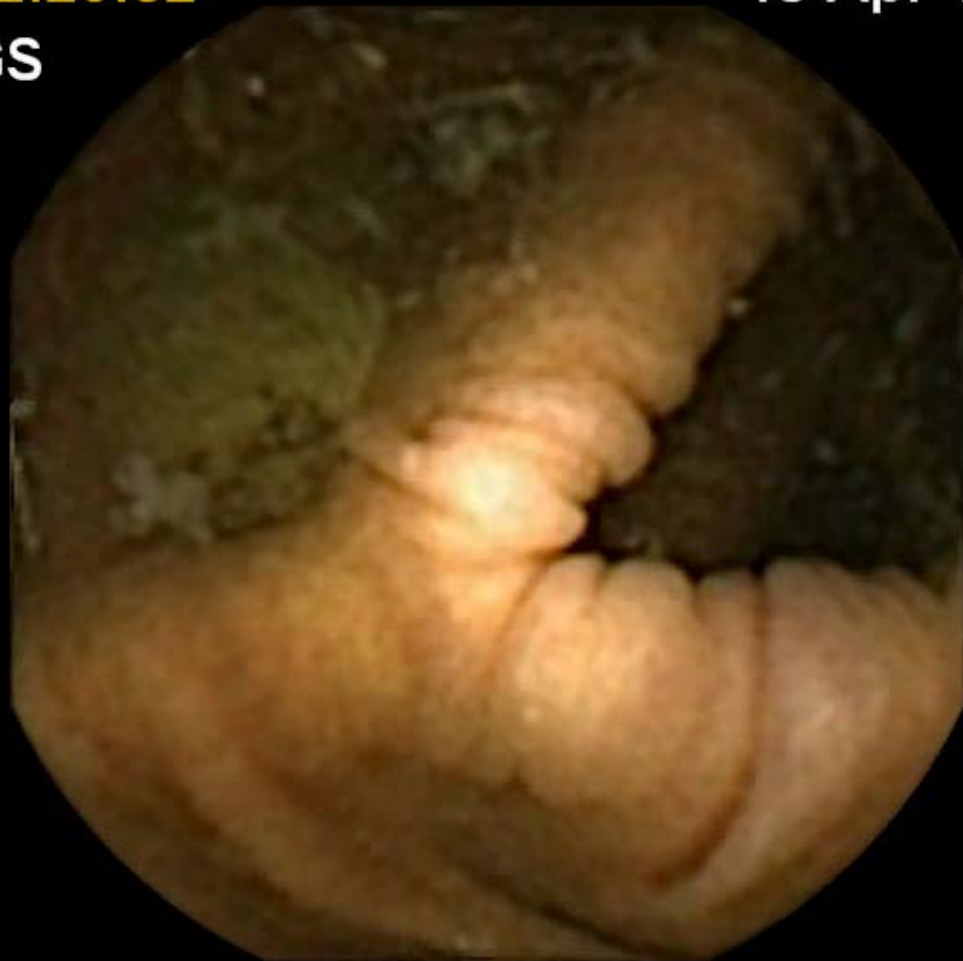
PillCam® COLON 2



02:20:52

18 Apr 12

GS



PillCam<sup>®</sup> COLON 2

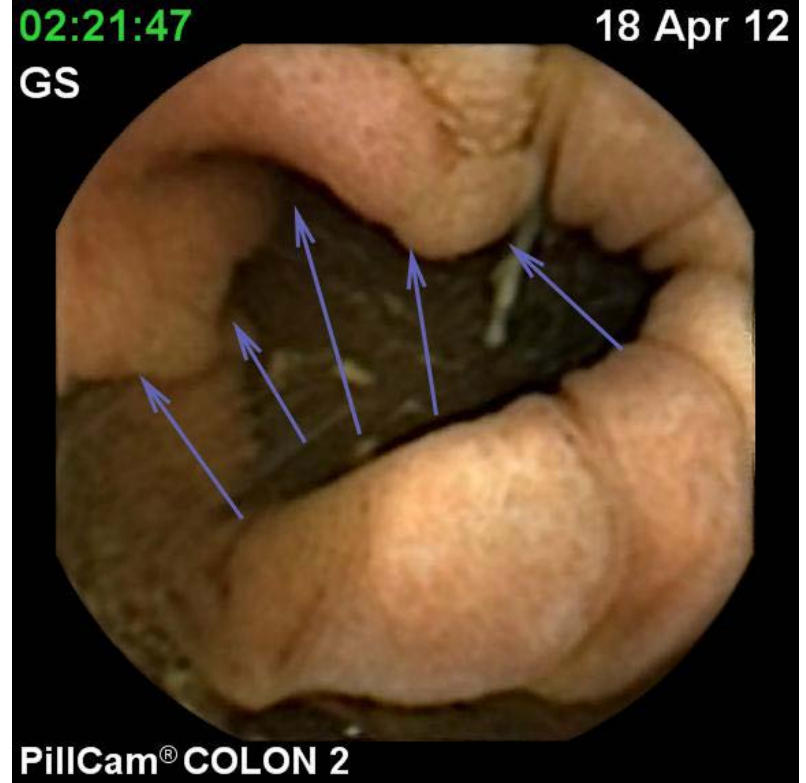
# CCE



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OC



VIII CONGRESSO NAZIONALE GISCOR  
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HGD-tubular villous adenoma



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# Colon Capsule for Adenoma and Neoplasia Diagnostic Yield

- Italian Multicenter Trial (*Roma, Torino, Reggio Emilia, Milano, Como*) (***n=400***)
- Organised population ***screening program***
- Comparative study (CCE2 vs OC)
- Aim: to assess Sens, Spec, PPV and NPV of CCE2 in detecting ***CRC*** and ***Advanced Adenomas*** in patients with a ***positive FIT***

# Second-generation colon capsule endoscopy is feasible in the out-of-clinic setting

Samuel Nathan Adler · Cesare Hassan ·  
Yoav Metzger · Yishai Sompolinsky ·  
Cristiano Spada

- 41 patients were enrolled
- Results:
  - **41/41 CCE performed out-of-clinic**
  - 16 (39%) called clinic (successful handled)
  - 35 (85%) had complete study (excreted capsule)
  - 10 (24%) subsequently underwent colonoscopy which confirmed the findings, including one colon carcinoma

***CCE at home!***



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## Conclusions

- 2nd generation colon capsule endoscopy (CCE2) is an **effective** method for visualizing the colon and detecting colonic polyps.
- The **increased** capsule **frame rate** of up to 35 images per second and **wider viewing angle** of 172° appear to have produced substantial improvement in polyp detection rate.
- PillCam COLON 2 has **high sensitivity** for identifying polyps and adenomas  $\geq 6$  mm and  $\geq 10$  mm



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## Conclusions

- To date, CCE is not alternative but **complementary** to conventional colonoscopy
- CCE is indicated in:
  - **Average risk** patients
  - Patients **not compliant** to colonoscopy
  - Patients for whom colonoscopy is **inappropriate/not possible**
  - Patients with **incomplete colonoscopy**





**Thank you!!**