

# La ricerca nello screening del cancro del colon-retto: focus 2014

## Lo studio CCANDY

**Cristiano Spada**

Digestive Endoscopy Unit  
Catholic University, Rome



# 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 (ESGE) Guideline

C. Spada<sup>1</sup>, C. Hassan<sup>1</sup>, J. P. Galmiche<sup>2</sup>, H. Neuhaus<sup>3</sup>, J. M. Dumonceau<sup>4</sup>, S. Adler<sup>5</sup>, O. Epstein<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. Delvaux<sup>7</sup>, J. Devière<sup>12</sup>, R. Eliakim<sup>13</sup>, 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>, M. Munoz-Navas<sup>19</sup>, T. Ponchon<sup>20</sup>, E. 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>, H. Tajiri<sup>25</sup>, E. Toth<sup>26</sup>, K. Triantafyllou<sup>27</sup>, A. Van Gossum<sup>12</sup>, G. Costamagna<sup>1</sup>

- ....specific studies based on **screening setting** are missing. CCE-screening may be cost-effective if it increases screening adherence compared to colonoscopy (EL 4, RG D).

# CCE

## *Results of comparative trials*

				Polyps $\geq$ 6 mm		Polyps $\geq$ 10 mm	
	# pts	Adeq cleansing	Excret rate	Sens	Spec	Sens	Spec
Eliakim Endoscopy 2009	98	78%	81%*	89%	76%	88%	89%
Spada GIE 2011	109	85%	81%*	84%	64%	88%	95%
Rex DDW 2013	884	80%	91%**	88%	82%	92%	95%
Hagel Can J Gastr 2014	24	90%	71% <sup>o</sup>	72%	91%	75%	100%

within 8(\*), (\*\*)<sup>o</sup>10 hours post ingestion and (° ) within battery life

# CCE and screening

## CCE in FIT+

- **62 FIT+ → 36 pts. with polyps/CRC**
  - **NPV** **90% (100% for  $\geq 10$  mm)**
  - **PPV** **89%**
  - **Post-CCE referral rate** **29%**



# The ORCA/CCANDY trials

new perspectives on screening

CCE ready for primetime in CRC screening?

# The ORCA trial

## new perspectives on screening uptake

### **P**Opulation colon cancer sc**R**eening by **C**Apsule endoscopy The **ORCA** trial

#### Objective

- To determine the **uptake** and **diagnostic yield** of primary **population screening** for CRC by means of CCE

#### • Study design

- Primary population screening trial
- Asymptomatic volunteers 50 – 75 years
- Active invitation, call – recall
- Invitation process until 1000 participants have been included
- Power calculation based on predetermined 95% CIs for uptake, and performance

# The ORCA trial

## new perspectives on screening uptake

- **Intervention**

- CCE by means of PillCam Colon2 (Given Imaging Israel)
- Colon cleansing by means of PEG (Moviprep) and sodium sulphate booster
- ***Prior to CCE, an optional complementary FIT (OC-Sensor) will be offered***
- Referral for colonoscopy in case of positive CCE (1 polyp  $\geq 6$  mm, or  $\geq 3$  polyps of any size, or a positive FIT ( $\geq 50$  ng/ml))
- Validated questionnaire on expected and perceived burden, prior to and 1 wk after CCE

# The ORCA trial

## new perspectives on screening uptake

### Primary endpoint

- CCE adherence/uptake

### Secondary endpoints

- Positivity rate
- Positive predictive value for detection of advanced adenoma, and cancer
- Correlation with FIT
- Burden
- Costs, cost-efficacy and long-term impact of CCE screening (life-years saved) determined by MISCAN modeling

# The CCANDY trial

## new perspectives on screening

**C**olon **C**apsule for **A**denoma and **N**eoplasia **D**iagnostic **Y**ield

- Italian Multicenter Trial (*n=400*)
  - *Roma*
  - *Torino*
  - *Milano*
  - *Reggio Emilia*
  - *Como*
- Comparative study (CCE2 vs OC)

# Regimen of preparation

Schedule		Intake
Day -2	Bedtime	Senna, 4 tb (48mg)
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)	<b>Capsule Ingestion*</b>
	<b>1<sup>st</sup> Boost</b> <i>after small bowel detection</i>	40 ml NaP + 1 L water with Gastrografin*** (50 ml)
	<b>2<sup>nd</sup> Boost **</b> <i>3 hrs after 1<sup>st</sup> Boost</i>	20 ml NaP + 0.5 L water with Gastrografin*** (25 ml)
	<b>Suppository **</b> <i>2 hrs after 2<sup>nd</sup> Boost</i>	10 mg Bisacodyl

\* 10 mg Metoclopramide tablet if capsule delayed in stomach >1 hr

\*\* Only if capsule not excreted yet

\*\*\* sodium-amidotrizoate and meglumine-amidotrizoate

# The CCANDY trial

## new perspectives on screening

**C**olon **C**apsule for **A**denoma and **N**eoplasia **D**iagnostic **Y**ield

Primary aim:

- **sensitivity and specificity**
  - **PPV and NPV**
- } for **CRC/advanced adenomas (AA)**

Population: **FIT+** patients, attending in an **organised screening programme**

# The CCANDY trial

## new perspectives on screening

**C**olon **C**apsule for **A**denoma and **N**eoplasia **D**iagnostic **Y**ield

Secondary aims:

- role of CCE as a primary **screening /triage test** to select subjects for OC+ polypectomy
- CCE **sens and spec by location** (distal vs prox) of AA/CRC
- **per-polyp analysis**
- the impact of the **QUICK view** reading.



# Enrollment status

*September 2014*

- Overall: 44 patients
  - Rome: 15
  - Turin: 11
  - Como: 11
  - Reggio Emilia: 7

# Results

*ITT*

- 44 patients signed IC
- Excretion rate 32/44 (73%)
- Adequate Cleansing level 39/44 (89%)
- 1 booster only 23/44 (52%)

# Results

## *Per Protocol*

- 44 patients signed IC
- 9 patients excluded
  - 4 early recording discontinuation
  - 2 patients withdrew IC
  - 1 technical failure (CCE entered colon in sleeping mode)
  - 2 only gastric images
- 35 patients included in the analysis

# Results

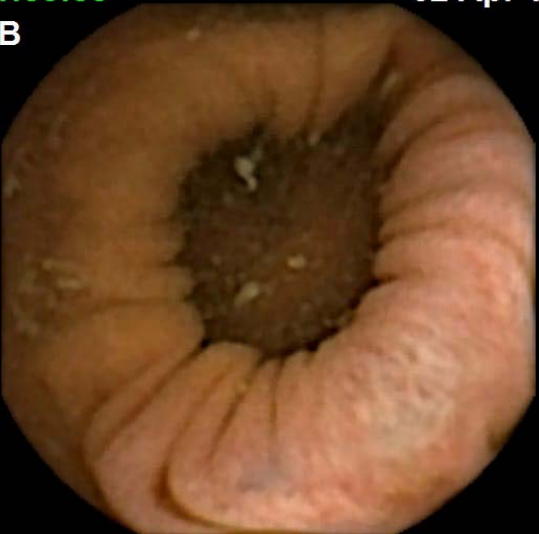
## *Per Protocol*

- Excretion rate 32/35 (91%)
  - Median colonic transit time 102 min (4-497)
  - Mean colonic transit time  $141 \pm 127$
- Adequate Cleansing level 34/35 (97%)
- 1 booster only 19/35 (54%)
- 3 boosters 5/35 (6%)

# Colon Capsule Endoscopy

01:53:33  
CB

02 Apr 14



PillCam® COLON 2

01:53:39  
CB

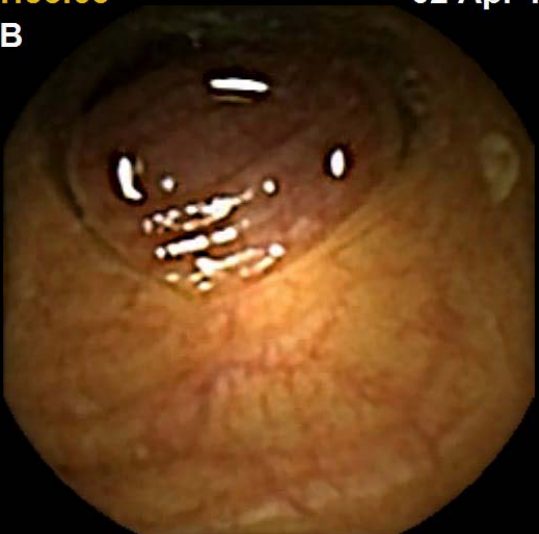
02 Apr 14



PillCam® COLON 2

01:56:03  
CB

02 Apr 14



PillCam® COLON 2

01:56:09  
CB

02 Apr 14



PillCam® COLON 2

03:30:57  
---



PillCam® COLON 2

03:31:16  
---



PillCam® COLON 2

# Pan-endoscopy in screening *FIT+*

