

## Study Summary

### Adenoma Detection by Endocuff-Assisted versus Standard Colonoscopy in Routine Practice: A Cluster-Randomized Crossover Trial

David Karsenti<sup>1</sup>, Gaëlle Tharsis<sup>1</sup>, Bastien Perrot<sup>2</sup>, Philippe Cattan<sup>1</sup>, Gilles Tordjman<sup>1</sup>, Franck Venezia<sup>1</sup>, Elie Zrihen<sup>1</sup>, Dominique Gillot<sup>1</sup>, Agnès Gillet<sup>1</sup>, Charles Hagege<sup>1</sup>, Joëlle Samama<sup>1</sup>, Isabelle Etienney<sup>1</sup>, Jean-Philippe Lab<sup>3</sup>, Bernard Guigui<sup>3</sup>, Jacqueline Zago<sup>4</sup>, Bouchra Benkessou<sup>1</sup>, Pascal Burtin<sup>5</sup>, Maryan Cavicchi<sup>1</sup>

#### Conclusion

The study confirmed that the second generation of ENDOCUFF VISION™ also leads to an improvement of the adenoma detection rate of 10%, mostly by enhancing the detection of small adenomas.

#### Objective

To evaluate the impact of ENDOCUFF VISION™ on the adenoma detection rate (ADR) in routine colonoscopy.

#### Design

Prospective cluster-randomized crossover trial comparing ENDOCUFF VISION™-assisted colonoscopy to standard colonoscopy (SC). Endoscopists were allocated to one of two research groups, balanced for baseline ADR, case volume, and gender. Each group consisted of 11 investigators. One group was randomly assigned to enroll patients with ENDOCUFF VISION™, the other with SC. Groups switched methods after half of the required sample size was enrolled.

#### Participants

The two groups of endoscopists encompassed 2,058 patients (SC: 1,032; ENDOCUFF VISION™: 1,026) assigned to routine colonoscopy over a period of 41 weeks. Patient groups were comparable in terms of age, gender, FIT+, BMI, bowel prep, and family history.

#### Results

- The overall ADR with ENDOCUFF VISION™ was significantly higher than without (29.4% vs. 39.4%;  $p < 0.001$ ).
- Especially small (5-9 mm) and diminutive (<5 mm) adenomas were identified more frequently with ENDOCUFF VISION™ (small: 9.3% vs. 13.7%;  $p 0.002$ ; diminutive: 20.4% vs. 27.9%;  $p < 0.001$ ).
- Among physicians with a baseline ADR higher than 30%, ADR with ENDOCUFF VISION™ was significantly increased (from 31% to 41%;  $p < 0.001$ ), whereas among physicians with a baseline ADR below 30%, no significant difference was identified (from 24% to 30%;  $p 0.11$ ).
- No complications or adverse events occurred during or after colonoscopy.

#### Key Findings

The large, prospective randomized study confirmed that ENDOCUFF VISION™ impacts the ADR during routine colonoscopy by mechanically reducing blind spots. The results suggest a systematic utilization of the technology in screening colonoscopies.

<sup>1</sup> Digestive Endoscopy Unit, Pôle Digestif Paris Bercy, Clinique Paris-Bercy, Charenton-le-Pont, France; <sup>2</sup> Methodology Unit, UMr inserM 1246 — sSphere, Université de Nantes, Université de Tours, Institut de Recherche en Santé (irs2), Université de Nantes, Nantes, Pays de la Loire, France; <sup>3</sup> Private Pathology Institute, Rue de Wattignies, Paris, France; <sup>4</sup> Private Pathology Institute, Rue du Colisée, Paris, France; <sup>5</sup> Digestive Oncology, Institut Gustave Roussy, Villejuif, Île-de-France, France