ORIGINAL RESEARCH

Adenoma detection by Endocuff-assisted versus standard colonoscopy in routine practice: a cluster-randomised crossover trial

David Karsenti ,[1] Gaelle Tharsis,[1] Bastien Perrot,[2] Philippe Cattan,[1] Gilles Tordjman,[1] Franck Venezia,[1] Elie Zrihen,[1] Dominique Gillot,[1] Agnes Gillet,[1] Charles Hagege,[1] Joelle Samama,[1] Isabelle Etienney,[1] Jean-Philippe Lab,[3] Bernard Guigui,[3] Jacqueline Zago,[4] Bouchra Benkessou,[1] Pascal Burtin,[5] Maryan Cavicchi[1]

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[1]Digestive Endoscopy Unit, Pôle Digestif Paris Bercy, Clinique Paris-Bercy, Charenton-le-Pont, France
[2]Methodology Unit, UMR INSERM 1246 SPHERE, Université de Nantes, Université de Tours, Institut de Recherche en Santé (IRS2), Universite de Nantes, Nantes, Pays de la Loire, France
[3]Private Pathology Institute, Rue de Wattignies, Paris, France
[4]Private Pathology Institute, Rue du Colisée, Paris, France
[5]Digestive Oncology, Insitut Gustave Roussy, Villejuif, Île-de-France, France

Correspondence to
Dr David Karsenti, Endoscopy Unit, Clinique Paris-Bercy, Charenton-le-Pont 75006, France;
karsenti@club-internet.fr

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ABSTRACT

Objective Endocuff Vision (ECV) is the second generation of a device designed to improve polyp detection. The aim of this study was to evaluate its impact on adenoma detection rate (ADR) in routine colonoscopy.

Design This cluster-randomised crossover trial compared Endocuff-assisted (ECV+) with standard (ECV-) colonoscopy. Two teams of 11 endoscopists each with prior ECV experience, balanced in terms of basal ADR, gender and case volume were compared. In randomised fashion, the teams started with ECV+ or ECV- and switched group after inclusion of half of the cases. The main outcome criterion was ADR difference between ECV+ and ECV-. Subgroup analysis was done for physicians with low and high ADR (< or ≥ 25%).

Results During two periods of 20 and 21 weeks, respectively, the 22 endoscopists included 2058 patients (1032 ECV- vs 1026 ECV+, both groups being comparable). Overall ADR for both groups taken together was higher with ECV (39.2%) than without (29.4%; p<0.001) irrespective of the sequence of use (ECV+ or ECV- first), but mostly in adenomas <1 cm. In the physician subgroup analysis, only high detectors showed a significant ADR increase (from 31% to 41%, p<0.001), while the increase in the low detectors was not significant (from 24% to 30%, p=0.11). ECV had a positive impact in all colonic locations, except for the rectum. No ECV- related complication was reported.

Conclusion We observed a significant ADR difference of approximately 10% by the use of ECV. By subgroup analysis, this increase was significant only in physicians classified as high detectors.

Trial registration number ClinicalTrials.gov (NCT03344055).

Significance of this study

What is already known about this subject?
- Adenoma detection rate (ADR) as main outcome quality parameter of colonoscopy has been shown to improve by the use of the Endocuff device; studies with the first generation were somewhat discordant as to the extent of the improvement.
- To which extent endoscopists with different ADR improve is not known.

What are the new findings?
- We confirmed that also the second-generation Endocuff Vision (ECV) leads to an overall ADR improvement of 10%, mostly in small adenomas.
- The improvement was only significant in endoscopists classified as 'high detectors'.

How might it impact on clinical practice in the foreseeable future?
- ECV should be systematically used in routine colonoscopy to improve ADR.

INTRODUCTION

Adenoma detection rate (ADR) has become the main quality benchmark in colonoscopy.[1–3]

Attaching devices such as Endocuff Vision (ECV) to the distal tip of the scope to flatten mucosal folds has been examined for possible ADR improvement, with somewhat discordant results in nine randomised controlled trials (RCTs).[4–12] All but two of the RCTs evaluated the first generation of the device. The second-generation ECV is somewhat different since it only features one (instead of two) row of eight longer and smoother barbs (figure 1) and has only been studied in a small RCT of patients with a positive faecal immunological test (FIT+)[8] and in a larger RCT including more varied indications, closer to common practice.[12] Most RCTs have included selected patients in academic centres, and partially focussed on screening colonoscopy; the effect on endoscopists with different basal ADR is not fully known either.[13] For all these reasons and because of its additional cost, the impact of ECV must be demonstrated, especially in non-selected patients admitted for routine colonoscopy. We therefore studied the impact of ECV on ADR and other polyp subgroups in routine colonoscopy, also in relation to the endoscopists basal ADR.

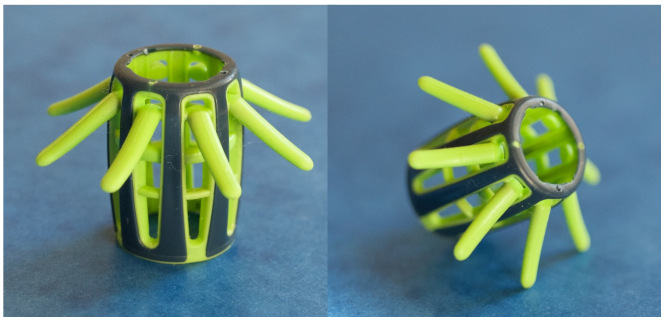


Figure 1 The second-generation Endocuff Vision.

PATIENTS AND METHODS

This prospective, monocentric, cluster-randomised crossover study comparing Endocuff-assisted colonoscopy (ECV+) to standard colonoscopy (ECV-), was conducted in our unit from November 2017 to September 2018.

All patients gave written informed consent to the endoscopic procedures and the study. The data were prospectively collected by extraction from our medical patient management software which includes all necessary data of the study case report form. The study was carried out according to the principles of the Declaration of Helsinki. The trial is registered at ClinicalTrials.gov and followed Consolidated Standards of Reporting Trials guidelines. All authors declare that they have access to the study data and have reviewed and approved the final manuscript.

The main outcome was overall ADR difference in the entire patient group with and without ECV. Secondary outcomes were differences in subgroups of polyps, namely overall polyp detection rate (PDR), mean number of adenomas per colonoscopy (MAP), advanced adenoma detection rate (AADR) and proximal serrated polyp detection rate (PSPDR) as defined below, as well as the impact of ECV on ADR. The latter as evaluated over a 2-year period preceding the study, and a cut-off of 25% was set.[2] Adverse events were also recorded as secondary outcome.

Patient recruitment

All consecutive patients aged ≥18 years who were scheduled for colonoscopy in our unit were screened by an endoscopist during colonoscopy planning. Inclusion was confirmed on the day of the colonoscopy, after having ruled out exclusion criteria and collected informed consent.

Exclusion criteria were: patients scheduled for partial colonoscopy or interventional colonoscopy (for known polyp resection, stent insertion, stenosis dilation or haemostasis), patients referred for polyp resection, previous colonic surgery, stenosis, recent acute diverticulitis, inflammatory bowel disease, polyposis syndrome, pregnancy, haemostasis disorders and inability to give informed consent.

Teams and randomisation

To limit the risk of bias, we formed two teams called 'Red' and 'Blue', of 11 endoscopists each. The teams were balanced in terms of gender, volume of activity and basal ADR as evaluated over a 2-year period preceding the study. The team that started with ECV+ was selected based on randomisation by an independent research assistant by use of a sealed envelope in the presence of numerous witnesses including a representative of each team and the Nurse in Chief of our unit. Once half of the inclusions had been treated, a switch was made and the other team performed ECV+. As detailed below, each group had to include 1000 patients (1000 ECV- vs 1000 ECV+) to observe a difference of 5%.

Data collection and post-colonoscopy management

The following data were collected using routine hospital software: age, gender, indication for colonoscopy, preparation procedure and quality of preparation (assessed by the Boston Bowel Preparation Scale (BBPS)[14 15]), caecal intubation time (seconds), ileal intubation (yes/no), withdrawal time (seconds) as defined below, localisation, number and size of polyps (<5 mm, 5 to 9 mm or ≥1 cm) and polyp histopathology. Personal history of adenoma/cancer was defined as: a patient in whom a previous colonoscopy had found at least one adenoma or advanced adenoma. Family history of adenoma/cancer was defined as: a patient with at least one first-degree relative diagnosed with colorectalcancer (CRC), a patient with at least two second-degree relatives diagnosed with CRC or a patient with at least one first-degree relative with adenoma irrespective of the age of the relative. Other indications for colonoscopy were: digestive symptoms, screening, FIT+, other indications (anaemia, bacteraemia…). Patients remained in the outpatient ward for at least 2 hours after the colonoscopy procedure and were examined to rule out any sign of perforation, bleeding, septic or other complications. Immediate complications defined by perforation, bleeding, sepsis or unexpected hospitalisation, were recorded. In case of suspected perforation, an abdominal CT-scan was performed. Bleeding was classified as severe if more than 2 units of transfused blood was needed, or mild if not.[16] Follow-up data (such as pain, vomiting, fever or other complications) were evaluated by clinical examination 2 hours after colonoscopy, and a CT scan and laboratory blood tests (blood count and C-reactive protein) were performed if necessary. A further clinical examination was performed in the days after discharge only if symptoms appeared after leaving our unit, according to current practice (no routine telephone call).

Definitions

Colonoscopy

Procedures were performed on patients under general propofol-induced anaesthesia on the back or in the left lateral decubitus position. The video colonoscopes used were EVIS EXERA III CF-H190 (Olympus Europe Inc, Hamburg, Germany) and less frequently EC-690 WM and EC-600WM (Fujifilm France (Medical Systems), Asnières, France). Good preparation was defined as a BBPS score≥6 with no subscore <2.[2 14] Withdrawal time was determined from the caecum to the anal verge, expressed in seconds and calculated on colonoscopies with no polyps.

Histopathology

An adenoma was defined as a tubular, villous or tubulovillous adenoma. Proximal serrated polyps (PSP) were defined as hyperplastic polyps located upstream the sigmoid colon, sessile serrated lesions and traditional serrated adenomas. Hyperplastic polyps of the rectum and sigmoid colon were excluded from PDR, as they are not considered at risk for CRC.[17] Advanced adenoma was defined as grade 4 or grade 5 of the Vienna classification (grade 4 corresponding to a non-invasive high-grade neoplasia, ie, high-grade adenoma/dysplasia, non-invasive carcinoma and suspicion of invasive carcinoma; grade 5 corresponding to an invasive neoplasia, ie, intramucosal carcinoma, submucosal carcinoma or deeper) or a polyp ≥1 cm.[18] Villous histology was

not included in our definition of advanced neoplasia, in line with the British consensus.[19]

Polyp rates

We determined ADR (percentage of colonoscopies with at least one adenoma), AADR (percentage of colonoscopies with at least one advanced adenoma lesion as defined below), PDR (percentage of colonoscopies with at least one polyp), PSPDR (percentage of colonoscopies with at least one proximal serrated lesion) and MAP (total number of adenomas divided by the total number of colonoscopies).

Sample-size calculation and statistical analysis

Assuming a 5% absolute difference in overall ADR in both examiner groups taken together (Red and Blue team, see above) with 30% in the ECV- group in routine practice[20] and 35% in the ECV+ group (based on previous positive series),[4 5] with a type I error of 0.05 (two-sided) and a power of 0.9, the study required a total 2000 patients. Quantitative variables were expressed as mean (SD) or as median (1st to 3rd quartile). Qualitative variables were expressed as numbers and percentages. Caecal intubation times and withdrawal times in the ECV- and ECV+ groups were compared using a Wilcoxon-Mann-Whitney test. Linear mixed models were not used for both time outcomes because they were not normally distributed; thus, the comparisons of caecal intubation time and withdrawal time between the two groups were unadjusted.

Primary and secondary outcomes were compared using absolute differences (in percentage points). In order to take into account the cluster crossover design of the study, we performed mixed effects logistic regressions (except for MAP, for which a mixed effects Poisson regression was used), including fixed effects on the type of colonoscopy (with or without ECV), the period and the interaction between the type of colonoscopy and the period. We also added a random effect on the clusters (endoscopists) and on the interaction between the clusters and the period. Intraclass correlation coefficients (ICC) were estimated using Stata's estat icc command. Analysis was conducted with Stata software V.15.1.

RESULTS

From 13 November 2017 to 10 September 2018, during two periods of 20 and 21 weeks (2 weeks of summer closing of the unit), respectively, a total of 2400 patients were considered for the trial. Among the 2400 patients, 342 were subsequently excluded for the following reasons: secondarily decline of study participation (25%), inflammatory bowel disease (35%), known tumour or polyp referred for biopsy or resection (11%), recent acute sigmoiditis (6%), inability to give consent (3%), previous colonic surgery (4%), known stenosis (2%), coagulation disorders (2%), already included in another study (2%) or other reason (10%).

A total of 2058 patients (991 men/1067 women) were finally included, as illustrated in the trial flow chart (figure 2). Indications for colonoscopy were: familial history of polyp/cancer in 21% (n=424), personal history of polyp/cancer in 29% (n=604), screening in 6% (n=126), FIT+ in 6.5% (n=130), digestive symptoms in 32% (n=661) and others indications in 5.5% (n=113). The mean age of the patients was 58±13 years. Patient characteristics were comparable in both groups (1032 ECV- vs 1026 ECV+) (table 1). Preparation was good or very good (no subscore <2) in 96% (n=1936/2022). Mean withdrawal time was 512±248 s, and median withdrawal time was 452 s (367 to 600). Caecal intubation time was significantly lower with ECV (320 s (232 to 494) in ECV- vs 294 s (219 to 454) in ECV+, p<0.001), and withdrawal time was also significantly lower with ECV (466 s (385 to 630) in ECV- vs 430 s (360 to 556) in ECV+, p<0.001). Ileal intubation rate was significantly lower with ECV (266/956, ie, 28% in ECV+ vs 387/969, that is, 40% in ECV-, p<0.001). No patients were lost during follow-up.

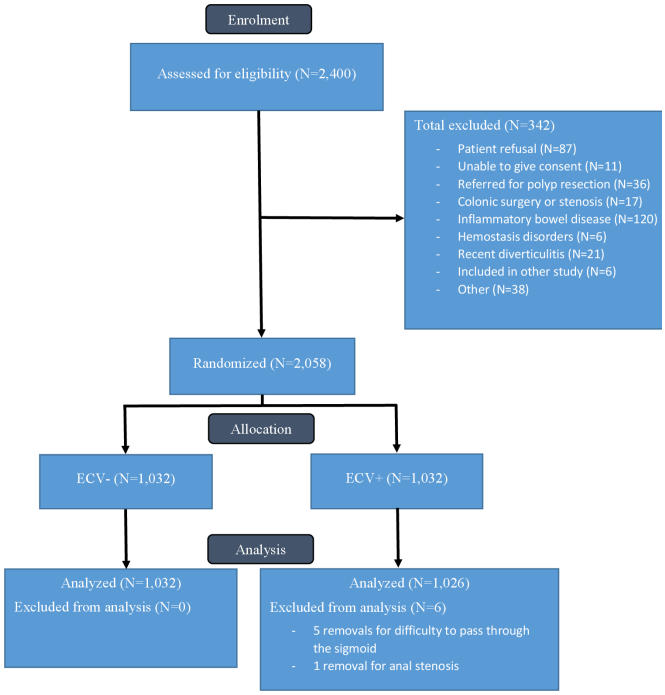


Figure 2 Study flow chart. ECV, EndocuffVision.

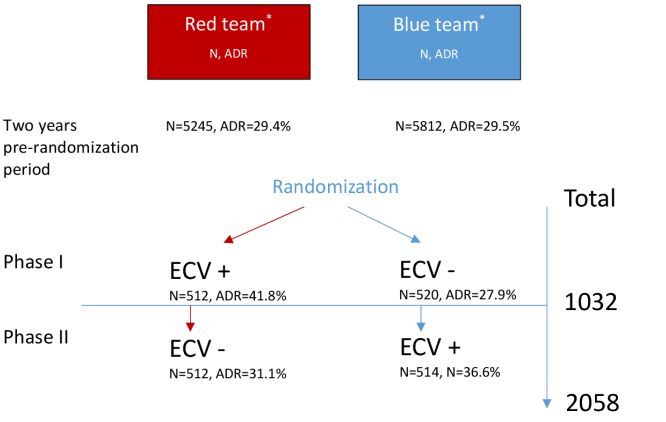
Twenty-two endoscopists participated in the trial with almost equal patient numbers in both study groups (ECV- 1034 vs ECV+ 1024). Based on randomisation, the Red team began with ECV+ during the first phase of the study and then switched to ECV- for the second, while the Blue team inversely began with ECV- and switched to ECV+ (figure 3). We had 6 'low detectors' (mean basal ADR <25%), and 16 'high detectors' (mean basal ADR ≥25).

Table 2 shows percentages and estimated absolute differences taking into account the cluster crossover design, for the primary outcome (overall ADR in both groups) and the secondary

Table 1 Comparison of ECV- and ECV+ groups

	ECV- n=1032	ECV+ n=1026	Total n=2058
Mean age, y (SD)	57.4 (13.1)	59.25 (12.2)	58.3 (12.7)
Gender			
Female, n (%)	527 (51%)	540 (52.6%)	1067 (52%)
Male, n (%)	505 (49%)	486 (47.4%)	991 (48%)
Perso/Fam history	514 (50%)	514 (50%)	
FIT+	56 (5.4%)	74 (7.2%)	130 (6.3%)
Body mass index, (SD)	25.5 (4.6)	25.6 (4.4)	25.5 (4.5)
Smoker, n (%)	170 (16.8%)	162 (16.1%)	332 (16.3%)
Good prep*, n (%)	972 (95.6%)	963 (96%)	1936 (95.75%)
Incomplete colonoscopy, n (%)	8 (0.8%)	8 (0.8%)	16 (0.8%)

*Boston score ≥6 with no subscore<2.
ECV+, Endocuff-assisted colonoscopy; ECV, Second-generation Endocuff Vision; ECV-, standard colonoscopy; FIT+, faecal immunological test.



* Two teams of 11 endoscopists, each balanced in terms of gender, volume of activity and basal ADR as evaluated over a two-year period preceding the study

Figure 3 Study design - cluster-randomised crossover trial, workforce and mean ADRs. ADR,adenoma detection rate; ECV+, Endocuff-assisted colonoscopy; ECV-, standard colonoscopy.

outcomes (PDR, AADR, PSPDR and MAP). ICCs are given in the online supplementary appendix 1.

ADR improved in this study for the whole population from 29.4% (ECV-) to 39.2% (ECV+); p<0.001. The ADR difference was significant for both teams who used ECV in different sequence, increasing from 27.9% to 36.6% for the Blue team (p<0.001) between period 1 and 2, and decreasing from 41.8% to 31.1% for the Red team (p<0.001), which started with ECV in period 1 and changed to no ECV in period 2. The comparison to the pre-study ADR taken from unobserved colonoscopies during the preceding 2 years as compared with ADR during the two study periods in both teams is shown in table 3. ADR in relation to colonic location is shown in figure 4 (significant effect overall except for the rectum), and in relation to high and low detectors is shown in table 4: ECV significantly improved ADR only in the 'high detector' group.

Complications: None had bleeding, sepsis or even unexpected hospitalisation after colonoscopy procedures. A pneumoperitoneum occurred, 24 hours after a diagnostic colonoscopy without resection of polyps in a patient in the ECV+ group. The pneumoperitoneum spontaneously resolved and had no lasting consequences following a few days' medical management. In this case, the causality of ECV was not clearly confirmed because of the delayed perforation and the absence of visible mucosal lesions during endoscopy on a well-prepared colon. It has also been suggested that the pneumoperitoneum may have been caused by the spontaneous microperforation of a sigmoid diverticulum triggered by the colonoscopy procedure.

ECV had to be removed in six patients (0.6%) because of the inability to pass through the sigmoid in five cases, and because of anal stenosis in one case. No spontaneous dislocation was observed.

Table 2 Percentages and estimated absolute differences taking into account the cluster crossover design, for primary outcome (ADR) and secondary outcomes (PDR, AADR, PSPDR and MNP)

	ECV- n=1032	ECV+ n=1026	Estimated absolute difference in percentage points *(95% CI)	P value
ADR				
All, n (%)	304 (**29.4%**)	402 (**39.2%**)	9.6 (5.5 to 13.6)	<0.001
>1 cm, n (%)	75 (7.3%)	90 (8.8%)	1.1 (-1.4 to 3.6)	0.39
5–9 mm, n (%)	96 (9.3%)	141 (13.7%)	4.3 (1.6 to 7.1)	0.002
<5 mm, n (%)	210 (20.4%)	286 (27.9%)	7.7 (4.0 to 11.3)	<0.001
PDR, n (%)	389 (37.7%)	474 (46.2%)	8.4 (3.5 to 13.2)	0.001
AADR, n (%)	95 (9.2%)	114 (11.1%)	1.5 (-1.4 to 4.4)	0.32
PSPDR, n (%)	123 (11.9%)	128 (12.5%)	0.74 (-2.4 to 3.9)	0.64
MAP, mean (SD)	0.54 (1.10)	0.78 (1.32)	0.19† (0.08 to 0.30)	<0.001

*Taking into account the cluster crossover design.
†Difference between Poisson rates.
AADR, advanced adenoma detection rate; ADR, adenoma detection rate; ECV+, Endocuff-assisted colonoscopy; ECV, Second-generation Endocuff Vision; ECV-, standard colonoscopy; MAP, mean number of adenomas per colonoscopy ; PDR, polyp detection rate; PSPDR, proximal serrated polyp detection rate.

Table 3 ADR comparing pre-study ADR with ADR during the two study periods in the two teams of physicians

	Pre-study	Study Period 1	Study Period 2	P value*
Red team ADR, %	29.4	41.8	31.1	<0.001
Blue team ADR, %	29.5	27.9	36.6	<0.001

*Comparison between the two study periods.
ADR, adenoma detection rate.

DISCUSSION

This randomised study confirms that ECV-assisted colonoscopy using the second generation device has a higher adenoma detection rate than standard colonoscopy; we found that such an effect can be detected also in routine indications and was especially effective in the subgroup of physicians with high pre-study ADR (≥25%). Studies with mostly the first-generation device have shown some ADR increase as summarised in two meta-analyses, with ORs of 1.49 (95% CI 1.23 to 1.80) and 1.20 (95% CI 1.06 to 1.36), respectively.[13 21] Notably, in the second meta-analysis, a significant improvement was observed in physicians with an ADR of less than 35%, but not in those with 45% or more.[13]

It is not fully known whether the second-generation device which is different from the first generation in some aspects (one instead of two rows of smoother and longer barbs) reaches similar results and whether results of both devices can be pooled

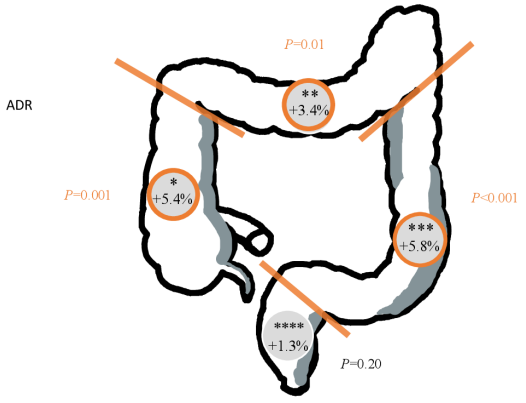


Figure 4 Increase in ADR in ECV+ versus ECV- patients according to colonic location. ADR,adenoma detection rate; ECV+, Endocuff-assistedcolonoscopy; ECV-, standard colonoscopy.

Table 4 ADR in both groups according to low and high detectors among physicians

	ECV- n=1032	ECV+ n=1026	Estimated absolute difference in percentage points *(95% CI)	P value
Low detectors† (6), n (ADR)	59 (23.7%)	59 (30.0%)	6.7(-1.6 to 15.1)	0.11
High detectors‡ (16), n (ADR)	245 (31.3%)	343 (41.4%)	10.3(5.7 to 15.0)	<0.001

*Taking into account the cluster crossover design.
†Low detectors: endoscopists with a mean basal ADR <25%.
‡High detectors: endoscopists with a mean basal ADR ≥ 25%.
ADR, adenoma detection rate; ECV-, standard colonoscopy; ECV+, Endocuff-assisted colonoscopy.

in meta-analyses. There are two RCTs on the second-generation ECV available to date.[8 12] The first study, which involved 534 exclusively FIT+ screening patients, found no impact of ECV on ADR, possibly because of a very high ADR (63%=in the control group).[8] The second study on 1600 patients (45% screening) found that ECV significantly improved ADR with a 4.7% improvement.[12] In our study, ECV did not significantly increase AADR (9.2% vs 11.1% with ECV, p=0.32), probably because ECV is most useful for adenomas <1 cm (7.3% vs 8.8% with ECV for adenomas >1 cm, p=0.39).

Our large study on ECV in routine practice also confirms the safety of ECV with no side effects, as reported in the two other RCTs,[8 12] in contrast with the 4% to 7% of mucosal bleeding in patients with diverticulosis with the more traumatic first-generation EC device.[4 13] Removal of ECV due to inability to pass through the sigmoid colon was reported in 4.1% to 6.4% of patients in the previous trials on ECV,[8 12] but was negligible (0.6%) in our study. In addition, antispasmodics which were more frequently used in the ECV group in a previous study (64.3% vs 70.6% with ECV, p=0.002) to aid insertion of the scope through the sigmoid, were never used in our study.[12] These two differences may have been due to the fact that all colonoscopies were performed under deep sedation (propofol) in our study, as in routine practice in France. Lastly, as already suggested,[12] ECV significantly shortened caecal intubation time, probably thanks to the ability of ECV to flatten folds, thus aiding the endoscopist in navigating the colon more easily. It is worth noting that, despite its positive impact on ADR, ECV significantly shortened withdrawal time as suggested in smaller studies.[7 22] In contrast, ECV makes ileal intubation more difficult (28% in ECV+ vs 40%, p<0.0001).

Our study has several strengths. Together with the British study,[12] it is the largest RCT on ECV in routine practice. Thus we can conclude that ECV increases ADR in routine colonoscopy also performed outside of academic centres. Due to the variability of basal ADR in our endoscopist population, two different 'detector groups' were formed to determine in which group ECV is the most useful. In contrast to previous data (mostly evaluating the first-generation ECD), ECV had a significant positive impact on ADR in our study in the 'high detectors'.[13] The ADR increase in the 'low detectors' was statistically not significant; so it can only be speculated that an even higher subgroup number would have reached statistical significance also in this group. In general, based on our study results we recommend the systematic use of ECV for routine colonoscopy.

The positive impact of ECV on ADR and the absence of impact on PSPDR suggest that ECV (i) enables exploration of a greater colonic surface area—especially behind colonic folds—and thereby reduces blind spots but (ii) does not increase the quality of visualisation. We could therefore conclude that ECV does not compete with technologies such as contrast image enhancement or artificial intelligence but may be complementary.

The benefit of ECV was exclusively in finding more small adenomas; the rate of advanced histology is generally low, but ranges from 0.6% to 6.8%.[23] Furthermore, almost all ADR increases by endoscopic imaging technology (if any) or by the use of mechanical devices were due to increases in small adenomas. ADR in general was shown to correlate with interval colorectal cancer, independent of the size of adenomas.[1]

Our study also has some limitations. First, it is a monocentric study. The colonoscopy quality criteria obtained in a single team such as ours with a long-standing awareness policy for quality in endoscopy (suboptimal preparation in only 4.3%, mean withdrawal time >8 mn) undoubtedly had a positive impact on detection rates. This may perhaps limit the reproducibility of the results. On the other hand, colonoscopy quality criteria applied to both groups and endoscopists had a wide range of ADR as in usual clinical routine. We performed a parallel instead of a tandem study which has been recommended as preferable by some[4 9 12] due to ethical concerns about exposing patients to the risk of a double colonoscopy. In addition, applicability of a back-to-back study to routine practice is debatable and would also have resulted in a smaller cohort of participants. Our study method was a cluster-randomised crossover trial, in which randomisation was not performed patient by patient. We chose this method to facilitate the inclusion procedures and to ensure that as few as possible inclusions were lost. No carryover effect after the switch could be evocated for the use or not of ECV, and no potential confounders between the two groups were noted (table 1). We also observed that ADR in the ECV- group was equal to the ADR recorded in the previous 2 years (29.4% vs 29.4%, respectively), suggesting the absence of a study effect (Hawthorne effect). Results for secondary outcomes and subgroup analysis were not adjusted for multiple testing, thus they should not be interpreted as confirmatory results. Lastly, the two groups of low and high detectors were determined according to a cut-off of 25% ADR as recommended for screening colonoscopy over the age of 50.[2] Our study had different age groups and case mix. Thus, in an unselected population of any age and any indication as in our study, the ADR cut-off is probably rather close to 20%.

In conclusion, our large prospective randomised study confirmed impact of ECV on ADR in routine colonoscopy also for the second generation, especially for adenomas <1 cm in diameter, and with physicians with already high ADR, thus suggesting the systematic use of ECV in routine colonoscopy. The positive impact was observed in all colonic locations, except for the rectum. Thus, ECV reduces blind spots but does not increase the quality of visualisation. We could therefore conclude that ECV does not compete with technologies such as contrast image enhancement or artificial intelligence but may be regarded complementary.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The protocol was approved by the Ouest-VI ethics committee of University Hospital – Brest, France, (#CPP Ouest 6 – CPP 995 DM2) and the French national drug safety agency (ANSM; #2017-A00549-44).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

ORCID iD
David Karsenti http://orcid.org/0000-0003-1487-2814

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