Endocuff-Assisted Colonoscopy Does Not increase the Sessile Serrated Lesion Detection Rate – A Randomized Controlled Trial

Alexandre Oliveira Ferreira (✉ alex.gastrohep@gmail.com)

Hospital Beatriz Angelo <https://orcid.org/0000-0001-9001-6329>

Maria Pia Costa-Santos

Hospital do Divino Espírito Santo: Hospital do Divino Espírito Santo de Ponta Delgada EPE

Carolina Palmela

Hospital Beatriz Ângelo: Hospital Beatriz Angelo

Luisa Glória

Hospital Beatriz Ângelo: Hospital Beatriz Angelo

Marília Cravo

Hospital da Luz: Hospital da Luz Lisboa

Jorge Canena

Hospital CUF Tejo

Mario Dinis-Ribeiro

Instituto Português de Oncologia do Porto: Instituto Portugues de Oncologia do Porto Francisco Gentil EPE

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Abstract

Background

Colorectal cancer (CRC) is a leading cause of cancer-related death. Colonoscopy has been shown to decrease the incidence of CRC by facilitating the detection and resection of adenomas and serrated lesions. Endocuff vision (EV) has been shown to increase the detection of adenomas. The aim of this study was to compare the detection of sessile serrated lesions during colonoscopy with and without EV.

Methods

A total of 257 patients who underwent elective colonoscopy were prospectively enrolled. The patients were randomly allocated to one of two groups according to the use of EV (standard colonoscopy vs. colonoscopy with EV). We compared the rates of detection of serrated lesions (including hyperplastic lesions ≥ 10 mm) and adenomas.

Results

The number of serrated lesions per colonoscopy was not significantly higher in the EV group (0.233 vs 0.156, mean difference 0.076, $p = 0.381$). None of the secondary endpoints regarding the detection rate of adenomas (65.9% vs 66.4%; OR 0.977, 95% CI 0.583–1.638; $p = 0.931$) or sessile serrated lesions (12.4% vs 7.8%; OR 1.671; 95% CI 0.728–3.836; $p = 0.226$) were superior in the EV group. The differences were not significantly altered after adjusting for either the Boston Bowel Preparation Score (BBPS) or withdrawal time.

Conclusion

EV did not increase the rate of detection of serrated lesions or adenomas.

Trial registration

ClinicalTrials.gov Identifier: NCT03856957. Registered 27 February 2019 - Retrospectively registered, <https://www.clinicaltrials.gov/ct2/show/NCT03856957>

Background

Colorectal cancer (CRC) is the most common cancer and the second leading cause of cancer-related death, with 242 000 deaths/year[1]. Colonoscopy has been shown to decrease both the incidence of CRC and the related mortality by facilitating the detection and allowing the removal of adenomas[2–7] and is endorsed as the preferred option for CRC screening and adenoma surveillance[8–11]. The adenoma detection rate (ADR) is currently the main quality indicator for colonoscopy[12, 13], as a higher ADR results in lower risks of CRC and mortality[14]. However, conventional colonoscopy has been shown to miss lesions in tandem studies, especially sessile serrated lesions (SSLs). [15–17]

Recently, a new endoscopic cap, Endocuff Vision™ (EV), was developed, and it is an improvement on a previous generation of Endocuff. This device is a soft plastic cap that is 2.5 cm in length with a cylindrical core and thin flexible projections fixed to the core that flatten colonic folds and stabilize the colonoscope tip, giving a better view of the entire colon.

Some studies have reported higher adenoma detection rates with Endocuff-assisted colonoscopy than with conventional colonoscopy[18–21]. The largest RCT involving EV (n = 1172) showed not only a significantly higher ADR but also a significantly higher SSL detection rate (+ 1.1%, p = 0.03)[21].

Nevertheless, the available data regarding the effectiveness of EV with regard to detecting SSLs are limited. There has been only one RCT involving patients with sessile serrated polyposis; evidence from RCTs is lacking. Few studies have specifically compared SSL detection rates between Endocuff-assisted colonoscopy and conventional colonoscopy, and those that have been performed have had conflicting results [22–24, 21].

Consequently, randomized studies are needed to accurately evaluate the effect of Endocuff-assisted colonoscopy on SSL detection and the detection of serrated lesions at least 10 mm in size; therefore, the present study was performed.

Methods

Study design

We performed a 2-arm superiority RCT to compare SSL detection rates between Endocuff-assisted colonoscopy and conventional colonoscopy at Hospital Beatriz Ângelo.

The study was approved by the institutional review board at Hospital Beatriz Ângelo and was registered at clinicaltrials.gov (NCT03856957). All patients gave a written informed consent.

The present study adheres to Consort Guidelines.

Study population

Subjects fulfilling the following inclusion criteria were assessed for inclusion in the study: aged 40-79 years; undergoing outpatient elective colonoscopies for screening, surveillance or diagnosis; and ability to give written informed consent prior to study participation.

Subjects fulfilling any of the following criteria were excluded from the study: severe diverticulosis, colonic stricture, primary sclerosing cholangitis, inflammatory bowel disease, known polyposis syndromes, personal colorectal cancer history or previous colorectal surgery, pregnancy or breastfeeding.

Outcomes

The primary endpoint was the average number of serrated lesions ≥ 10 mm in size detected per colonoscopy in the Endocuff-assisted and conventional colonoscopy groups. This endpoint included all sessile serrated lesions and hyperplastic lesions ≥ 10 mm.

The secondary endpoints were the SSL detection rate (number of patients with at least one SSL/total number of participants); adenoma detection rate (number of patients with at least one adenoma/total number of participants); number of adenomas detected per colonoscopy (number of adenomas/total number of participants); polyp detection rate (number of patients with at least one polyp/total number of participants); number of polyps detected per colonoscopy (number of polyps/total number of participants); adenocarcinoma detection rate (number of malignant adenocarcinomas/total number of participants); caecal intubation rate; caecal incubation time; withdrawal time; and incidence of procedure-related adverse events.

Study procedures and data collection

We used a block randomization table generated in STATA, and the investigators were blinded to the random allocation. Randomization was concealed until patient assignment. Consenting patients were randomly assigned to the Endocuff-assisted colonoscopy group or the conventional colonoscopy group before the procedure with a computer-generated randomization table in REDCap. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Sociedade Portuguesa de Gastreenterologia[25, 26]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails to track data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures to support data integration and interoperability with external sources.

The participating endoscopists were all experienced in optical colonoscopy (defined by having performed a minimum of 300 colonoscopies)[27]. The procedures were performed using a high-definition Olympus endoscope (CF-H190, CF-H180, PCF-H180AL/I or GIF-H180/H190). Colonoscopies were performed by one of ten endoscopists either without sedation, under conscious sedation or under deep sedation, as requested by the assistant physician. Antispasmodics (butylscopolamine) could be administered during the procedure if necessary.

The histologic evaluation of each lesion was performed by pathologists in our centre. The pathologists were blinded to the method used during the procedure.

Data collection

We recorded patient demographic and clinical data, including date of birth, sex, weight, height, body mass index, education level, smoking habits, personal history of polyps and polypectomy, date of previous colonoscopy and family history of CRC; colonoscopy data, such as the endoscopist performing the procedure, colonoscope type, indication for the procedure (screening, surveillance, or diagnosis), type of sedation (unsedated or conscious or deep sedation), the administration of antispasmodics (butylscopolamine), caecal intubation, intubation and withdrawal times, Boston Bowel Preparation Score (BBPS) in each colon segment (ascending, transverse and left colon) and adverse events; and for each lesion detected, the location, size, morphology (Paris Classification[28]) and histology (hyperplastic, adenoma, SSL or adenocarcinoma).

Sample Size

The prevalence of SSLs at the time of screening colonoscopy is close to 5% but ranges from 1 to 18%, with a mean of 1.62 lesions per patient[29, 30]. For serrated lesions ≥ 10 mm, we based our estimate on Rex's trial[31], which reported 0.05 proximal lesions per colonoscopy. Based on an observational study, Endocuff may increase the SSL detection rate 5-fold. We decided to be conservative in our estimate. Therefore, considering the number of lesions per patient as the primary endpoint and aiming to have 80% power at a 5% significance level to detect a difference from 0.05 to 0.15 lesions/colonoscopy, we needed a total sample size of 198 colonoscopies. We accounted for a 2% crossover rate and therefore adjusted the sample size to 216 colonoscopies. Furthermore, based on data from our institution, we anticipated that more than 80% of patients would have adequate bowel preparation according to the validated Boston Bowel Preparation Scale (BBPS)[32]. To compensate for poor mucosal visualization and lower lesion detection due to poor preparation, we further adjusted the sample size to 254 patients.

Statistical Analysis

The statistical analysis was conducted with the SPSS software package, version 21 (Statistical Package for the Social Sciences, IBM Corporation, Armonk, NY, USA). Categorical variables are expressed as frequencies and percentages, while continuous variables are described as the means and standard deviations or medians and ranges. The chi-squared test and Fisher's exact test were used to explore associations between categorical variables. Differences in means for continuous variables and dichotomous variables were analysed by t-tests or Mann-Whitney U tests, as appropriate.

An analysis to estimate the effect of the use of Endocuff on lesion detection outcomes was conducted using logistic regression. We performed multiple regression with adjustment for withdrawal time and bowel preparation.

Results

Patient and Procedural Characteristics

A total of 257 patients were recruited and randomly assigned to the Endocuff group (n=129) and the control group (n=128). The trial profile is depicted in figure 1, and baseline characteristics were balanced, as summarized in table 1. All randomized patients received the allocated intervention; however, in 9 patients, the EV was removed during the procedure, as the endoscopist found it difficult to progress to the caecum. These patients were included in the EV group as per the intention-to-treat principle. Ten endoscopists participated in the study, but 91% of the procedures were performed by six of these endoscopists; the proportions of procedures performed by these endoscopists were similar between the two groups.

The groups were also similar with regard to the procedural aspects that could impact the detection of lesions, such as bowel preparation quality and procedure durations. Procedural data are summarized in table 2. The proportions of patients undergoing caecal intubation were similar. In 3 patients in the EV group, it was not possible to reach the caecum even after removing the device from the colonoscope due to sigmoid fixation.

Outcomes

The outcomes are summarized in table 3. There was no significant difference in the primary endpoint, that is, the number of serrated lesions ≥ 10 mm in size per colonoscopy, or in any of the secondary endpoints with regard to the detection of lesions, adenomas or sessile serrated lesions.

The overall adenoma detection rate was 66.1%, the SSL detection rate was 10.1%, the rate of detection of serrated lesions ≥ 10 mm in size was 4.3%, and the detection rate of invasive neoplasia was 1.6%. The rate of detection of any polyp was 78.2%. The mean numbers of serrated lesions (including hyperplastic lesions ≥ 10 mm) were 0.233 and 0.156 ($p=0.381$) in the EV and control groups, respectively. The mean numbers of adenomas were 1.821 and 1.625 ($p=0.531$), respectively. The differences were not significantly changed after adjusting for either BBPS or withdrawal time.

Adverse Events

There were no major adverse events in any group; however, there were 3 mucosal lacerations in the Endocuff group, while there were no mucosal lacerations in the control group. These events did not require any specific intervention.

Discussion

Our study objective was to confirm the beneficial effect of EV on the results of optical colonoscopy, specifically the detection of SSL, as they are harder to identify. We also wanted to evaluate the effect of EV on the detection of adenomas. For the primary endpoint, which was the mean number of premalignant serrated lesions, including all histologically confirmed SSLs and hyperplastic lesions ≥ 10 mm in size, there was a nonsignificant trend towards a higher detection rate in the EV group (MD 0.0763; 95% CI

-0.095-0.248; $p=0.381$). There was no difference in the ADR, SSLDR, mean number of SSLs per colonoscopy or mean number of adenomas per colonoscopy.

Endocuff has been developed to improve the effectiveness of colonoscopy with regard to reducing the incidence of colorectal cancer. The first-generation Endocuff was shown to increase the adenoma detection rate[33] and decrease the adenoma miss rate[20], but not all studies showed such a clear beneficial impact, including a large RCT [22].

The largest trial of Endocuff Vision, the ADENOMA trial ($n=1772$), showed significant increases (4.7%, $p=0.02$) in the ADR and the SSL detection rate (1.1%, $p=0.03$), especially in the left colon, although the study was restricted to 797 patients who underwent colonoscopy for bowel cancer screening. In the non-screening colonoscopy subgroup ($n=975$), there was no difference between the groups.

Furthermore, SSLs are different from adenomas. They are preferentially located in the right colon, are usually flat with a mucus cap and are accompanied by subtle differences in the adjacent mucosa, which make them much harder to detect during conventional colonoscopy. Moreover, they are difficult to differentiate from hyperplastic polyps on histological examination [34], and large (≥ 10 mm) right colon hyperplastic polyps may in fact have invasive potential and could be managed as SSLs [35]. As a result of these characteristics, these lesions are associated with interval CRC [36, 37].

In a RCT conducted in the Netherlands, the primary endpoints were the mean number of adenomas per patient and the adenoma detection rates in the Endocuff-assisted colonoscopy and conventional colonoscopy groups. The authors also evaluated the serrated lesion rate and mean number of SSLs per patient and found no differences between the two groups (27% vs. 25%, $P=0.48$; 0.52 ± 1.15 vs. 0.48 ± 1.05 , $P=0.52$, respectively)[22]. However, hyperplastic polyps were also included in this analysis, and lesion size was not considered. Small purely hyperplastic lesions have a lower malignant potential; therefore, there is less interest in improving the rate of their detection than in improving that of larger serrated lesions[23]. A more recent study from the United States found a significantly higher SSL detection rate in the Endocuff-assisted colonoscopy group than in the conventional colonoscopy group (15% vs. 3%, $P \leq 0.0001$). However, that was an observational retrospective study conducted in a population of veterans, with a male predominance and multiple predisposing risks for adenomatous polyps; therefore, the results may not be generalizable to the general population[38]. In a very recent RCT on EV, which is currently the largest, higher rate of detection of both adenomas (40.9 vs 36.2%, $p=0.02$) and SSLs (2.3 vs 1.1%, $p=0.03$) were observed in the EV group[21].

Our study did not show any differences in the quality outcomes studied. While Endocuff Vision seems to be a useful add on for colonoscopy, as shown in the ADENOMA trial, its beneficial effect may be influenced by other factors, such as the skill of the endoscopist and prior detection rates.

The present study has several limitations: a relevant issue is the high overall lesion detection rate, as reflected by the ADRs of 65.9% in the EV group and 66.4% in the SC group and the SSLDRs of 12.4 and 7.8%. These are very high detection rates when compared to other trials, even if we take into account the

low volume of screening procedures included (15%). In the ADENOMA trial, they had an ADR of 56% in the Bowel Screening Programme and an ADR of 24% in the non-screening colonoscopies. Although the ADRs and SSLDRs were higher than anticipated, the sample size was calculated using an estimated mean number of serrated lesions ≥ 10 mm in size of 0.05, which was close to what we observed, so it is difficult to attribute the lack of difference to a lack of power in the study. Recently, a debate has started regarding whether the effectiveness of EV differs depending on the individual endoscopist. Some data suggested that “high detectors” obtained no additional benefit from using the Endocuff[39]; however, in a cluster randomized crossover trial performed in 2020, a subanalysis suggested that “high detectors” (defined as those with an ADR>25%) had a significantly higher ADR when using EV (mean difference 10.3%, $p=0.001$), while low detectors had a nonsignificant mean difference (6.7%, $p=0.11$)[40]. Our study did not allow us to explore this hypothesis due to the sample size and the fact that all endoscopists had ADRs above 40%, which may explain our results. Another limitation is that the blinding of the endoscopists was not possible to achieve, as they were always able to know whether the EV was on the scope. To overcome this limitation, we decided to perform the RCT with a single bowel exploration rather than in tandem, as this was probably the best trial design for the evaluation of a specific intervention.

Conclusion

In conclusion, our study did not show a significant difference in the detection of premalignant lesions when EV was or was not used during routine colonoscopy. There was a nonsignificant trend towards a higher rate of detection of serrated lesions in the EV group. A larger RCT in a bowel cancer screening population is needed to definitely determine the role of EV in improving the rate of detection of colonic serrated lesions.

Abbreviations

CRC - colorectal cancer

ADR – adenoma detection rate

SSL – sessile serrated lesions

EV – Endocuff vision

RCT – randomized controlled trial

BBPS – boston bowel preparations scale

MD – mean difference

Declarations

- Ethics approval and consent to participate

All participants gave a written informed consent.

The study was approved by *Comissão de Investigação Clínica* and *Comissão de Ética para a Saúde* at Hospital Beatriz Ângelo with the number 0304

- Consent to publish

The authors consent to publish

- Availability of data and materials

The Dataset is available upon request to the corresponding author

- Competing interests

The authors declare that they have no relevant conflict of interest.

- Funding

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- Authors' Contributions

AOF collaborated in the study design, data collection and analysis and manuscript writing

MPCS collaborated in the study design, ethics submission, data collection and analysis and manuscript critical review

CP collaborated in data collection and manuscript critical review

LG collaborated in the study design and manuscript critical review

MC collaborated in the study design and manuscript critical review

JC collaborated in the study design and manuscript critical review

MDR collaborated in the study design and manuscript critical review

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procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

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Tables

Table 1. Baseline characteristics of the study population

	SC Group (n=128)	EV Group (n=129)	P- Value
Age, y	64.01 (9.10)	62.10 (10.04)	0.112
Male sex, n (%)	69 (53.9)	68 (52.7)	0.848
Body mass index	27.60 (3.92)	27.41 (3.81)	0.695
Family history of CRC (1 st degree)	22 (17.2)	27 (20.9)	0.445
Previous colonoscopy, n (%)	59 (46.1)	59 (45.7)	0.954
Median time since last colonoscopy, months (minimum-maximum)	27 (3-144)	27 (3-230)	0.893
Personal history of polyps, n (%)	40 (31.3)	42 (32.8)	0.789
Indication			
· Screening	19 (14.8)	22 (17.1)	0.766
· FOBT	12 (9.4)	16 (12.4)	
· Surveillance	38 (29.7)	33 (25.6)	
· Diagnostic	59 (46.1)	58 (45.0)	

Table 2. Procedural characteristics

	SC Group (n=128)	EV Group (n=129)	P-Value
Deep sedation, n (%)	15 (11.7)	17 (13.2)	0.634
Conscious sedation, n (%)	103 (80.5)	98 (76.0)	
No sedation, n (%)	10 (7.8)	14 (10.9)	
Mean Boston Bowel Preparation Score			
· Left colon			
· Transverse colon	2.12 (0.48)	1.99 (0.56)	0.056
· Ascending colon	2.11 (0.51)	2.04 (0.53)	0.284
· Overall	2.05 (0.52)	2.02 (0.56)	0.644
	6.28 (1.41)	6.08 (1.51)	0.267
Butylscopolamine administration	11 (8.7)	12 (9.4)	0.842
Caecal intubation	124 (96.9)	123 (95.3)	0.527
Intubation time, min	7.64 (4.01)	7.03 (4.60)	0.285
Withdrawal time, min	12.82 (6.01)	11.94 (5.84)	0.259

Table 3. Lesions detected stratified by study group

	SC Group (n=128)	EV Group (n=129)	ITT OR/MD; 95% CI; p-value
PD(R), n (%)	98 (76.6)	103 (79.8)	1.213; 0.670-2.195; 0.524
ADR(R), n (%)	85 (66.4)	85 (65.9)	0.977; 0.583-1.638; 0.931
SSL detection (rate), n (%)	10 (7.8)	16 (12.4)	1.671; 0.728-3.836; 0.226
Serrated lesion $\geq$ 10 mm detection rate	3 (2.4)	8 (6.2)	2.733; 0.708-10.545; 0.145
Adenocarcinoma detection rate	2 (1.6)	2 (1.6)	0.992; 0.138-7.153; 0.994
Number of lesions, mean (SE)	2.46 (0.24)	2.91 (0.26)	0.454; -0.249-1.156; 0.204
Number of adenomas per colonoscopy	1.63 (0.22)	1.82 (0.22)	0.197; -0.421-0.814; 0.531
Number of SSLs per colonoscopy	0.156 (0.05)	0.233 (0.07)	0.0763; -0.095-0.248; 0.381
Number of serrated lesions ($\geq$ 10 mm) per colonoscopy	0.02 (0.01)	0.06 (0.02)	0.038; -0.012-0.088; 0.131

ITT – intention to treat; OR – odds ratio; MD – mean difference; CI – confidence interval; PDR – polyp detection rate; ADR – adenoma detection rate; SSL – sessile serrated lesion

Figures

Figure 1

Trial Profile SC, standard colonoscopy; EV, Endocuff Vision

Supplementary Files

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- [CONSORT2010Checklist.doc](#)