Original Paper

EndoCuff-Assisted Colonoscopy Versus Standard Colonoscopy in Colonic Polyp Detection-Experience from a Single Tertiary Centre

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ABSTRACT: Background. Standard colonoscopy fails to visualize the entire colon mucosa and consequently a significant amount of polyps are still being missed. New device, such as EndoCuff, have been developed to improve mucosal visualisation, hence the quality in colonoscopy. The aim of this study was to assess the diagnostic yield of EndoCuff-assisted colonoscopy in comparison with standard colonoscopy by taking into consideration several quality indicators. Methods. In this study, 965 adults ≥18 years referred for colonoscopy were randomly divided into two groups. The main statistical investigation compared the difference between EndoCuff-assisted colonoscopy (EC) vs. standard colonoscopy (SC) in the detection of colonic polyps and adenoma detection rate (ADR). The second inquiry sought to compare experienced vs. recently trained and female vs. male operators. Results. The ADR was higher for EC than for SC (37.50% vs. 26.64%). Regarding the mean number of detected polyps per procedure (MPP), the result was statistically significant when generally comparing the EC vs. SC (p=0.0009). There were no differences in MPP between EC and SC for recently trained endoscopists (p=0.7446), while a significant difference for experienced doctors (p=0,0020) was noted. A significant difference was observed between female doctors and male doctors only when using SC. EC was more helpful for female doctors when assessing MPP (p=0.0118). No serious adverse events related to EndoCuff-assisted colonoscopy was noted. Conclusions. EndoCuff-assisted colonoscopy seems to be safe and may bring benefits for improving the polyp/adenoma detection rates in regard to missed lesions, usually located in blind areas.

KEYWORDS: *EndoCuff, colonoscopy, adenoma detection rate, colorectal polyps, quality indicators.*

Introduction

Although conventional colonoscopy is currently the gold standard for colorectal cancer detection, a significant number of polyps are still being missed.

This method fails to visualize the entire colon mucosa in 10-15% cases, it has 98% specificity and approximately 97% sensibility for the detection of advanced malignant lesions, with a 85% sensibility for polyps larger than 5 mm, despite its poor sensitivity (78,5%) for smaller polyps [1,2].

Early detection is the cornerstone that leads to a significantly improvement of patients' outcome together with a decrease in costs and invasiveness associated with the curative techniques.

Prevention implies an early stage diagnosis of potentially curable colorectal neoplasia or the detection of precursor conditions carrying a significant risk of progression to cancer.

Hence, various endoscopic innovative imaging techniques have been developed in order to detect lesions that are still invisible under conventional methods.

As it is an operator depended technique, the imperfection of colonoscopy is caused by the endoscopist's variations in adenoma detection rates.

A low adenoma detection rate (ADR) is associated with the increase of interval colorectal cancer rates and with decreased rates of cancer survival.

The endoscopist's ADR, a reportable rate of the endoscopist's ability to find adenomas, attempt of endoscopic resection of pedunculated polyps and large sessile lesions(<2cm) preceding surgical referral, as well as complete colonoscopy with intubation of cecum have been established among good quality indicators [3].

The definition of ADR represents the percentage of patients undergoing complete screening colonoscopy in which at least one adenomatous lesion is detected. Improvement of ADR would lead to an increased number of colorectal cancer prevented cases.

However, it is a complex mechanism due to the interaction among various factors.

The ADR is actually variable as it depends not only on provider, but also on other factors

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such as patient's bowel preparation, withdrawal time and even physician characteristics [4].

Moreover, ADR is limited to average risk patients undergoing screening colonoscopy and only conventional adenomas are included [5], while sessile serrated are excluded.

The ADR is most commonly used along with PDR (polyp detection rate) and APC (adenoma per colonoscopy) as indicators that have proved their utility in studies.

Various technique strategies (optimizing of bowel preparation, water-assisted colonoscopy, improvement of training, slower withdrawal time, the use of antispasmodics, addition of a second observer, dynamic position chance) and new endoscopic technologies have been proposed to improve ADR.

Regarding the constantly emerging technologies, two main groups can be mentioned: 1) the devices developed for improving the identification of adenomas through enhanced color or contrast in comparison with normal colonic mucosa and 2) the devices aiming to boost the identification of adenomas through improving visualization of colonic mucosa behind folds [6].

EndoCuff is part of the latter category. It consists of a disposable rubber accessory attached to the tip of the endoscope, provided with a set of flexible circular arms that contribute to the gentle flattening and averting of colonic folds during colonoscopic withdrawal [7].

Some studies proposed that the EndoCuff device should be tested in ADR improvement training programs as a promising training tool [8,9].

The aim of this manuscript was to assess the diagnostic yield of EndoCuff-assisted colonoscopy (EC) in comparison with standard colonoscopy (SC) by taking into consideration quality indicators: number of detected polyps (NDP), MPP, PDR, ADR, hyperplastic polyps rate (HDR), endoscopist's experience, female vs. male operators' results.

Patients, Materials and Methods

This retrospective study included 965 adult patients (451 female, 514 males, age between 20 and 86 years) from a total of consecutive 1525 patients who underwent flexible colonoscopy in 2018.

The procedures (screening or diagnostic colonoscopies) were conducted at the Research Center of Gastroenterology and Hepatology Craiova, Romania.

Regarding bowel preparation, it was recommended the split-dose ingestion of a commonly prescribed oral electrolyte lavage solution (Fortrans®).

The quality of bowel preparation was graded according to the Boston Bowel Preparation Scale (BBPS).

All patients underwent deep sedation with intravenous propofol solution administered by a specialist anesthesiologist.

Written informed consent was obtained from all patients before the procedure, including the authorization to access their personal health information.

The Ethics Committee of the University of Medicine and Pharmacy of Craiova approved this study.

Colonoscopies were performed using a standard colonoscope and processor (Pentax scope EC-380FK2p coupled with the EPK-100p processor, Tokyo, Japan).

For one of the study subgroups, EndoCuff Vision (Arc Medical Design, Leeds, England) with only one row of projections was added to the colonoscope.

The patients were evaluated either by one of the three experienced endoscopists or by one of the two recently trained endoscopists.

We considered experienced endoscopists the gastroenterologists with an experience of over 10 years (more than 500 procedures yearly) in flexible colonoscopy.

Three endoscopists were women, while two endoscopists were men.

The patients included in the study did not had prior colonoscopies and were randomly selected to form the EC arm of the study.

The number of EndoCuff procedures was evenly distributed among the endoscopists, during the same period of time.

The polyps were endoscopically removed by either cold forceps, hot snare or cold snare (according to endoscopists' preference) and underwent histopathology diagnosis.

Those proven to be adenomas as well as hyperplastic polyps were considered for analysis.

The study was reviewed and approved by the University of Medicine and Pharmacy of Craiova Institutional Review Board.

All study participants provided informed written consent prior to study enrollment.

Technical appendix, statistical code and datasets are available from the corresponding author. Participants gave informed consent for data sharing.

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Exclusion criteria

Patients were excluded from this study in the following situations: an unsuccessful intubation of cecum, inflammatory bowel disease, surgery history for colorectal cancer, positive fecal occult blood test, adenomatous polyposis, colonic diverticulitis, patients' refusal of endoscopic polyp resection, inappropriate bowel preparation (Boston score <5).

Statistical analysis

The NDP, MPP, PDR, ADR and HDR were calculated for both EC and SC colonoscopies.

We considered the PDR, the ADR and the HDR as the percentage of patients who had at least one polyp removed per procedure, adenoma and hyperplastic polyp, respectively. NDP is the total number of detected polyps in 2018 by EC and by SC.

All variables were compiled in a database by using Microsoft Excel®.

We used unpaired two-tailed Student's t-test, set at p=0.05 as threshold of significance, to evaluate the EC and the SC results and categorical data test was also computed from an exact contingency table using two-tailed Fisher's test.

Thus, the MPP for EC vs. SC, the female endoscopists'vs. male endoscopists' MPP results for EC and SC, respectively, were compared.

Also, for both the EC and the SC, the results of the experienced operators vs. recently trained operators as well as the results of female vs. male operators were compared.

Results

In 2018, a total of consecutive 1525 patients, 780 women (51,14%) and 745 men (48,85%) underwent colonoscopy at the Research Center of Gastroenterology and Hepatology Craiova, Romania.

Ultimately, 965 patients, 451 women (46.73%) and 514 men (53,26%) qualified for this study and for the analysis, respectively (Figure 1).

The number EndoCuff procedures were evenly distributed among the endoscopists, regardless gender or experience.

A similar approach was chosen for the standard colonoscopies.

Patients' characteristics and the indications for colonoscopy were homogenous in both study arms (Table 1).

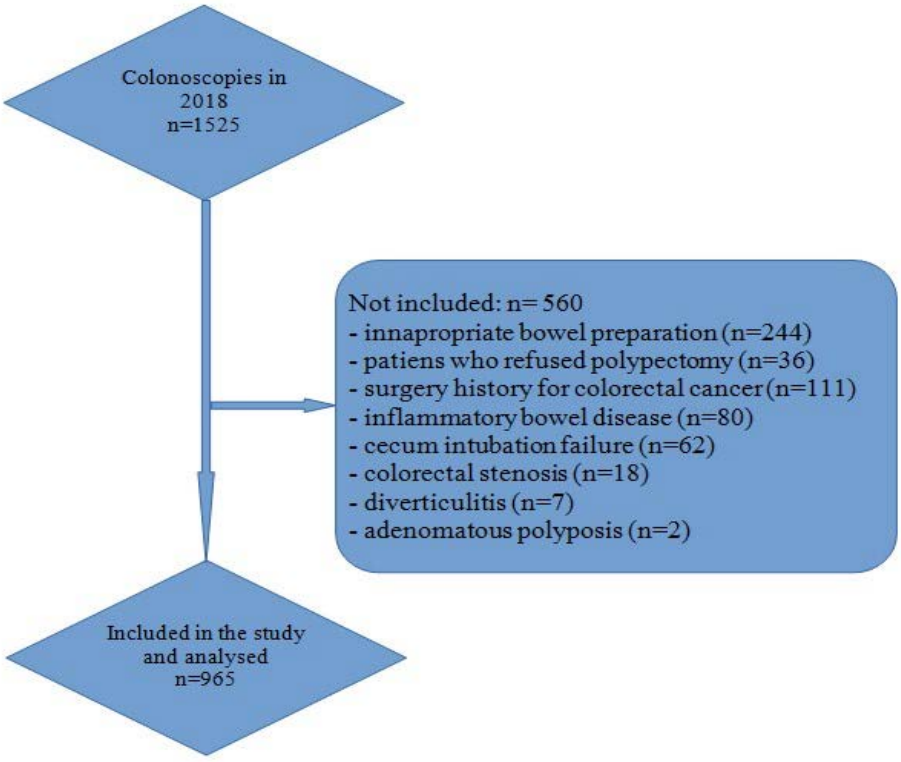

Figure 1. STROBE Flow Diagram.

Table 1. Patients and Procedures characteristics.

Patients (n=965)		SC	EC
Age (mean±SD)		55,4±7,2	60,2±6,3
Gender	Female (n=451)	230 (51%)	221 (49%)
	Male (n=514)	255 (49, 61%)	259 (50, 38%)
Place of residence	Urban	588 (70, 25%)	79 (61, 71%)
	Rural	249 (29, 75%)	49 (38, 29%)
Chronic disease		667 (79, 68%)	96 (75%)
Total number of colonoscopies (n=965)		837	128
Indication for colonoscopy	Screening (n=427)	355 (42, 41%)	72 (56, 25%)
	Diagnosis (n=538)	482 (57, 58%)	56 (43, 75%)
Boston Bowel Preparation Score (mean±SD)		8,3±0,6	8,5±0,3
Insertion time (minutes) (mean±SD)		6,5±3,7	7,2±3,3
Withdrawal time (minutes) (mean±SD)		12,5±3,7	13,8±4,1
Cecal intubation		100%	100%

SC-standard colonoscopy, EC-EndoCuff assisted colonoscopy, SD-standard deviation.

A total of 189 polyps (PDR=58.59%) were detected by EC and 841 polyps (PDR=45.40%) were detected by SC.

After resection, 48 polyps (37.50%) turned out to be adenomas and 19.53% (n=25) were hyperplastic polyps in the EC group.

In the SC group, 223 (26.64%) lesions were adenomas at histology and only 131 (15.65%) lesions were hyperplastic polyps.

MPP was 1.47 (SD 1.47) in the EC group, whereas we found the MPP being 1.00 (SD 1.49) in the SC group, results which prove to be statistically significant (p=0.0009).

Thus, EndoCuff is a very useful tool for increasing MPP (Table 2, Figure 2).

Table 2. Histology of resected polyps.

Resected polyps			
Histology	**SC**	**EC**	**p**
Total number of colonoscopies	837	128	N/A
Total number of detected polyps (NDP)	841	189	N/A
Patients with detected polyps (PDR)	38 (45.40%)	75 (58.59%)	*0.1225*
Patients with conventional Adenomas (ADR)	22 (26.64%)	48 (37.50%)	*0.0762*
Patients with hyperplastic polyps (HDR)	131 (15.65%)	25 (19.53%)	*0.3784*
Mean number of detected polyps per procedure (MPP)	1.00 (SD 1.49)	1.47 (SD 1.47)	***0.0009***

*SC-standard colonoscopy, EC-EndoCuff assisted colonoscopy, SD-standard deviation, N/A-not applicable.

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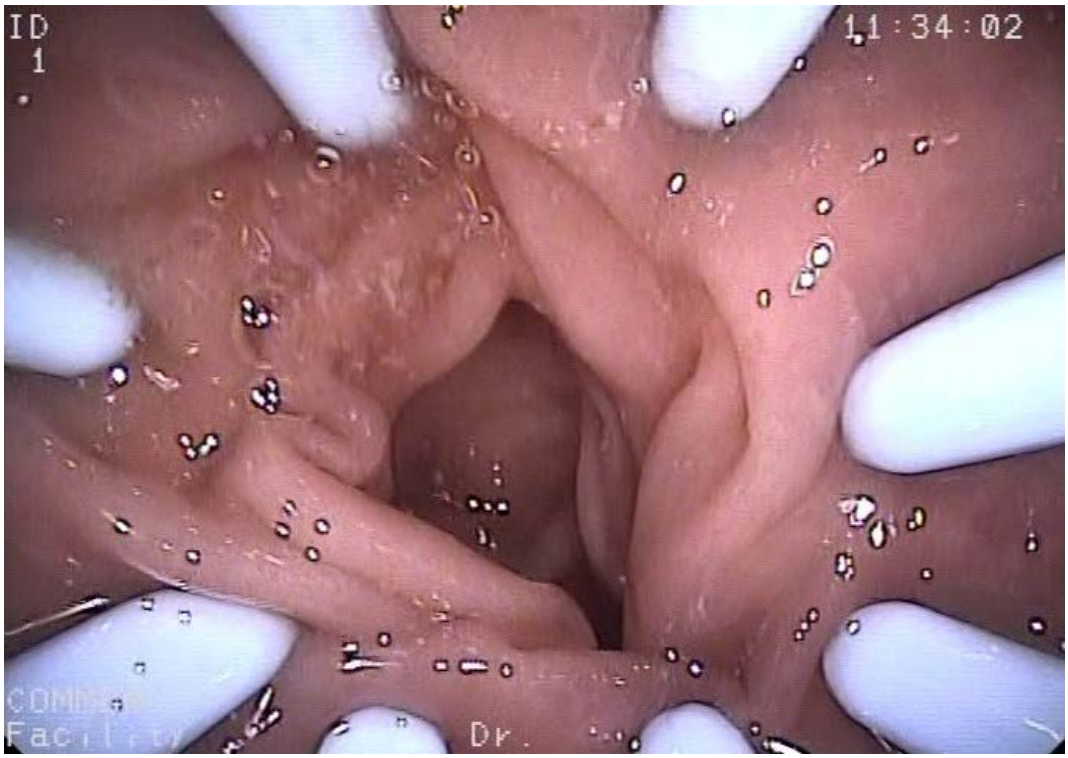


Figure 2. EndoCuff-assisted colonoscopy.

There was no important statistical difference between the female endoscopists and the male endoscopists when using EC for MPP (1.38 vs. 1.54).

Interestingly, a sex-related significant difference was found when using S (0.83 vs.1.10).

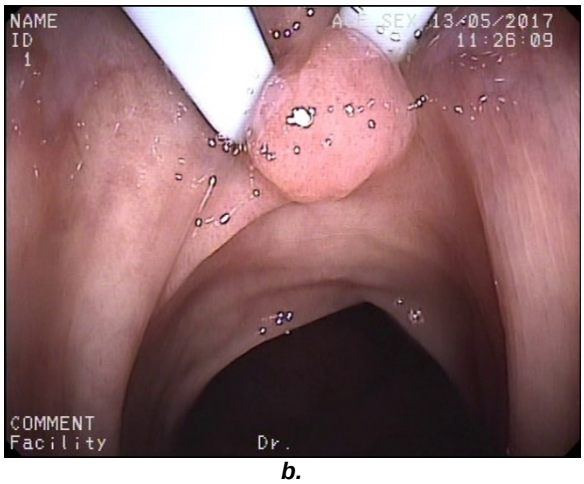
On the other hand, when comparing EC and SC, a difference was observed in both genders, but for female endoscopists was highly relevant for MPP (p=0.0118 vs. p=0.0503) (Table 3, Figure 3).

Table 3. Mean number of detected polyps per procedure (Female doctors vs. Male doctors).

MPP	F	M	*P*
EC	1.38	1.54	***0.6653***
SC	0.83	1.10	***0.0206***
p	***0.0118***	***0.0503***	

MPP-mean number of detected polyps per procedure, EC-EndoCuff-assisted colonoscopy, *SC-standard colonoscopy, F-female doctors, M-male doctors.

a.



b.

Figure 3 a,b. Adenoma detection using EndoCuff.

When taking into consideration the experience of operators, there was no difference between EC and SC regarding MPP in the group of recently trained endoscopists' MPP (p=0.7446).

On the other hand, we found a significant difference in experienced endoscopists for EC vs. SC (p=0.0020).

Thus, EndoCuff is a useful tool in the hands of experienced endoscopist for MPP.

Also, we observed a slight difference of MPP in the EC and SC groups for experienced and recently trained endoscopist, but without statistical significance (p=0.4747 vs. 0.2717) (Table 4, Figure 4).

Table 4. Mean number of detected polyps per procedure (Experienced doctors vs. recently trained doctors).

MPP	EXP	RT	*P*
EC	1.50 (SD1.95)	1 (SD 1)	***0.4747***
SC	0.99 (SD 1.63)	1.21 (SD 1.78)	***0.2719***
P	***0,0020***	***0,7446***	

MPP-Mean number of detected polyps per procedure, EC-EndoCuff- assisted colonoscopy,*SC-standard colonoscopy, EXP-experienced doctors, RT-recently trained doctors, SD-standard deviation.

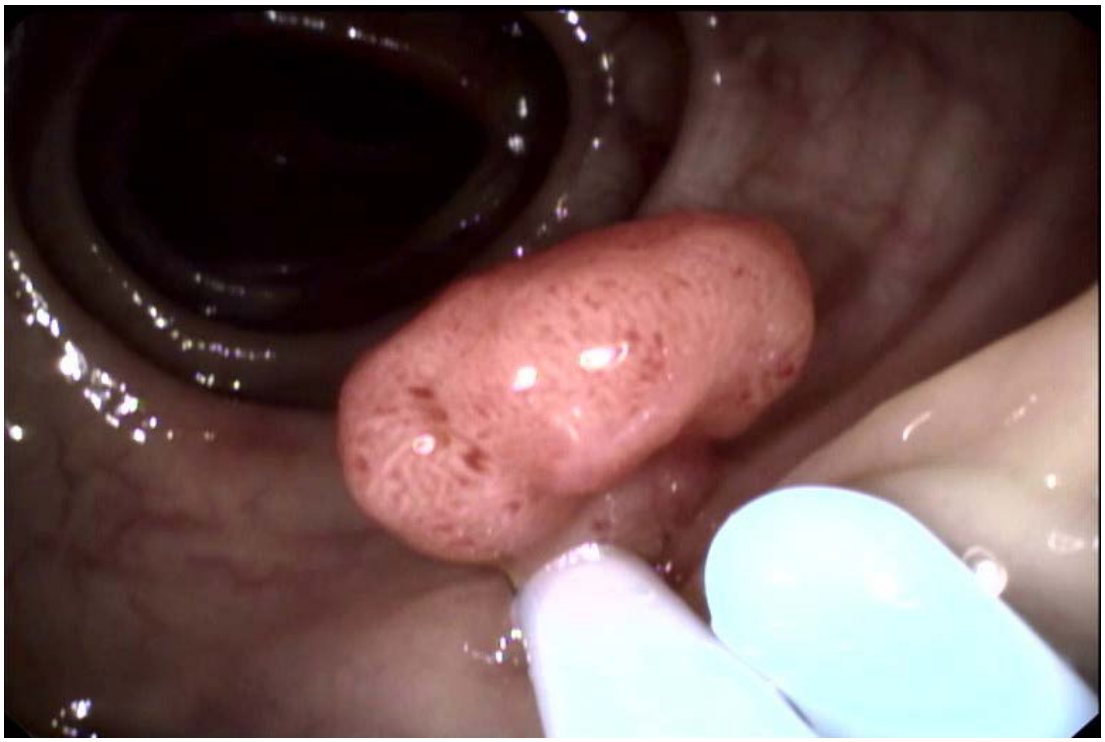


Figure 4. Snare polypectomy with EndoCuff device.

In SC groups, the RT group had a higher ADR than the experienced group (p=0.0104) while in EC group there was no differences between EXP and RT (p=0.7377).

However, there was no significant difference related to experience neither for EC group (p=0.7377), nor for SC group (p=0.0104) Table 5).

No statistical difference of the ADR between the female endoscopists and the male endoscopists was observed in both EC group (p=1.000) and SC group (p=0.3912) (Table 6).

Table 5. Adenoma detection rate (Young vs. experienced colonoscopists).

ADR	EXP	RT	*p*
EC	44 (36.67%)	4 (50%)	***0.7377***
SC	201 (26.34%)	22 (29.73%)	***0.0104***
p	***0.1007***	***0.4774***	

ADR-adenoma detection rate, EC-EndoCuff-assisted colonoscopy,*SC-standard colonoscopy, EXP-experienced doctors, RT-recently trained doctors.

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Table 6. Adenoma detection rate (Female doctors vs. male).

ADR	F	M	*p*
EC	19 (38%)	29 (37.18%)	***1.0000***
SC	77 (24.29%)	146 (28,07%)	***0.3912***
p	***0.1437***	***0.2624***	

ADR-adenoma detection rate, EC-EndoCuff-assisted colonoscopy, *SC-standard colonoscopy, F-female doctors, M-male doctors, EndoCuff caused no mucosal damage requiring a supplementary mucosal intervention.

Discussions

Although new minimally invasive imaging techniques are under continuous development in order to provide increasingly efficient, safer and personalized evaluation for colorectal cancer screening, distinguishing early colorectal lesions is still a challenge with current methods.

Studies concerning the role of high definition colonoscopy in colon polyps detection rate reported conflicting results, few randomized controlled trials suggesting an increase in detecting the small polyps, but with insignificant detection of advanced lesions [10,11].

Going further, a 2020 study revealed that i-SCAN and underwater colonoscopy determined higher PDR than the Endocuff-assisted and standard colonoscopy techniques, but without statistical significance [12].

ADR became one of the most important performance indicators for colonoscopy, endorsed by several professional societies [13,14].

Randomized parallel trials have shown that, compared to standard colonoscopies, EndoCuff improves the ADR [15,16] and significantly increases the PDR [16,17] especially when using the improved second-generation device [18].

Similarly, in our study, the overall PDR and ADR were higher in EC than in SC (58.59% vs. 45.40%; 37.50% vs. 26.64%, respectively).

Also, the EC detected a higher proportion of hyperplastic polyps as compared to SC (19.53% vs. 15.65%).

One limitation could be the fact that flat lesions might have been histologically misinterpreted as hyperplastic polyps instead of serrated adenoma, for instance.

Only conventional adenomas were included in this study, while other types such as serrated polyps were not assessed, an aspect which is consistent with existent literature where the ADR analysis is limited to conventional adenomas [18,19].

However, in a recent randomized controlled trial, the overall detection rate of sessile serrated polyps was low [20].

Regarding the mean number of detected polyps per procedure (MPP), the results are discordant in literature.

In our study, MPP was statistically significant when generally comparing the two groups (p=0.0009) which is consistent with other studies [19].

On the contrary, there are other more recent studies where there were no differences between the two devices in the mean number of adenomas and polyps per procedure [7].

EndoCuff brings clear advantages in the hands of experienced endoscopists and for recently trained endoscopists the device was a useful tool as well [21].

In some previous studies, the EndoCuff usage appears to improve ADR only for inexperienced endoscopists with a low ADR [16].

In our study, higher percentages were obtained when using EC vs. SC for both experienced doctors (36.67% vs. 26.34%) and recently trained endoscopists (50% vs. 29.73%).

Interestingly, on the contrary, there was no differences in MPP between EC and SC for recently trained endoscopists (p=0.7446), while there was a significant difference for experienced doctors (p=0.0020).

Thus, beyond the endoscopist's skill level, it is obvious that some polyps may be missed despite being within the visual field [22].

The differences could be explained by the fact that the quality indicators may depend on many other factors such as fatigue or emotional factors, "inattentional blindness" or "change blindness", "bad day" phenomenon, differences in endoscopist tracking patterns, failure to process an image on the screen due to distraction, interruptions in visual scanning or during eye movements or simply decay of performance with age [3,4,23].

A recent study [4] examined the endoscopists' characteristics associated with higher performance regarding the quality indicators in colonoscopy.

Interestingly, female gastroenterologists as well as recently trained physicians were more performant in polyp detection. Similarly, in this study the EC turned out to be more helpful for women doctors than the SC evaluations when comparing the MPP (p=0.0118).

Likewise, we have also obtained a significant difference between female doctors and male doctors only when using SC (p=0.0206).

Anyway, the performance of female endoscopists might have been the result of other characteristics or variables (e.g. meticulousity) [4], sex differences in color perception [24], rather than due to the advantages related to the device per se.

To our knowledge, this is the first study analyzing the associations between physician characteristics and performance when using EC.

Further randomized studies are necessary to appreciate the real impact of EC on endoscopists' characteristics.

Moreover, the second generation EndoCuff-vision causes less mucosal damage and it works equally well as the first-generation device interms of adenoma detection improvement [25].

Even more, a recent cluster-randomised crossover trial showed that EndoCuff had a positive impact in all colonic locations, excepting the rectum [26].

Although no mucosal lesions were reported in our study while using the second generation EndoCuff, one limitation could be the fact that possible increased discomfort during scope insertion was underestimated due to the fact that all patients were under deep sedation with propofol.

Another advantage of EndoCuff is the ability of the method to stabilize the colonic folds during polypectomy (cold or hot snare), especially for small or diminutive polyps, similar with the usage of transparent caps.

In this regard, the Evasta Study highlighted that Endocuff-assisted colonoscopy reduces the time span of polypectomy, which is believed to be a consequence of the extra stable scope position during resection [27].

Unfortunately, there are many potential sources of bias in this study.

Firstly, this is a retrospective study therefore collection bias is inevitable and might affect our analysis results.

Secondly, one major limitation could be the fact that we did not take into consideration the lesion size or location.

Another limitation is not looking upon the cases when the operators optionally used I-scan mode to improve polyp demarcation.

Other differences concerning inter-observer evaluation should not be underestimated. Bias in terms of technique regarding different operators performing the procedure should not be neglected.

Conclusions

Appreciating the adenoma detection rate is a complex process due to the interaction among various factors.

In this retrospective study, significant differences in polip detection rate, adenoma detection rate and hyperplastic polyp rate were found when comparing EndoCuff vision-assisted colonoscopy and standard colonoscopy.

The yield of EndoCuff dependant of endoscopist' experience and the influence of endoscopist's gender are interpretable.

Consequently, we concluded that EndoCuff assisted colonoscopy is a simple technique that seems to be safe and may bring benefits for improving the polyp/adenoma detection rates in regard to missed lesions usually located in blind areas.

Its current status still remains controversial, but future studies may possibly enable the role of EndoCuff assisted colonoscopies as an additional screening tool in colorectal cancer prevention.

Conflict of interests

None to declare.

Author contributions

Mihaela Calita and Petrica Popa had equal contributions to this paper thus share first authorship.

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