Efficacy of endocuff - assisted colonoscopy in the detection of colorectal polyps

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Abstract

Background: Colonoscopy is the gold standard for detecting colorectal adenomas and cancers. However, it fails to visualize the entire colon mucosa and consequently a significant number of polyps are still being missed. Endocuff is a new device that can be attached to the tip of the colonoscope to improve mucosal visualization, hence the quality in colonoscopy. This study aimed to describe the clinical characteristics and endoscopic images of colorectal polyps of patients who were endoscopically detected polyps and to assess the diagnostic yield of Endocuff – assisted colonoscopy (EAC) in comparison with standard colonoscopy (SC). **Subjects and methods:** An observational study was performed to compare EAC versus SC. A total of 308 adults ≥ 18 years referred for colonoscopy were randomly divided into two groups between 06/2022 and 07/2023, the EAC group included 154 adults and the standard colonoscopy included 154 adults. **Results:** Compared with standard colonoscopy, the PDR in patients increased by about 11% (70.1% vs. 59.1%, p<0.05) with the use of the Endocuff. The ADR was higher for EAC than for standard colonoscopy (20.8% vs. 16.2%). Polyp, adenoma ≤ 5mm and mean number of detected polyps per procedure increased significantly with the use of the Endocuff. No significant differences between EAC and standard colonoscopy groups in ileal intubation rate, cecal intubation time and withdrawal time. **Conclusions:** Endocuff-assisted colonoscopy seems to be safe and may bring benefits for improving the polyp/adenoma detection rates and the mean number of adenomas identified per patient, as compared with SC.

Keywords: *Endocuff; adenoma detection rate; colonoscopy; colorectal polyps.*

1. INTRODUCTION

Colorectal cancer (CRC) is considered the third most diagnosed cancer in males and the second in females worldwide [1, 2]. In the United States, the proportion of cases among those younger than 55 years increased from 11% in 1995 to 20% in 2019 [3] Most CRCs arise from precursor adenomatous or serrated polyps, presenting the opportunity for CRC prevention via the detection and removal of precancerous lesions before they progress to malignancy and metastasis [4] Colonoscopy is the gold standard tool for detecting and removing neoplastic polyps [5] Adenoma resection can lead to a 53-70% reduction in CRC mortality rate during the first ten years after colonoscopy [6]. However, the rate of adenoma missed during colonoscopy ranges from 6-27%, depending on the size of the adenoma [7]. According to research by Luz B.S.R. et al. (2021), the overall adenoma miss rate when using standard colonoscopy (SC) was 47.4% [6]; besides, Shunsuke Kamba et al. (2021 reported that the adenoma miss rate of SC was 36.7% and the polyp miss rate was 40.6% [8]. Many measures have been proposed to reduce the rate of missing colorectal polyps, including optimizing bowel preparation, slower withdrawal time, new endoscopic technologies… Among these measures, a simple but promising method is Endocuff - assisted colonoscopy (EAC). Endocuff is a recently developed device, it can be attached to the distal tip of the colonoscope to hold the colonic folds away from the field of view during withdrawal and has been designed to improve both the adenoma detection rate (ADR) and the user's control of the tip of the colonoscope [9]. In Vietnam, data about the efficacy of EAC in detecting colon polyps is still limited. Therefore, this study aims to assess the diagnostic yield of EAC in comparison with standard colonoscopy.

2. MATERIAL AND METHODS

Study design and participants

An observational study was conducted at the Gastroenterology and Endoscopy Center of the Hue University of Medicine and Pharmacy Hospital from June 2022 to July 2023.

All patients ≥ 18 years who were presented for colonoscopy at this hospital were considered for recruitment to the trial. We considered experienced

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endoscopists gastroenterologists with experience of over 5 years in flexible colonoscopy. The exclusion criteria were unsuccessful intubation of cecum, surgery history for colorectal cancer, inappropriate bowel preparation (Boston score < 5), withdrawal time < 6 minutes, and the contraindications to the use of Endocuff are as follows: (1) known colonic strictures, (2) inflammatory bowel disease such as Crohn's and ulcerative colitis, (3) acute infective colitis, and (4) acute diverticulitis [10].

A total of 308 patients referred for colonoscopy were randomly divided into two groups, the EAC group included 154 patients and the standard colonoscopy included 154 patients.

Data collection

The following data were collected: age, gender, digestive symptoms, preparation procedure and quality of preparation (assessed by the Boston Bowel Preparation Scale (BBPS)), caecal intubation time (seconds), ileal intubation (yes/no), withdrawal time (seconds), procedure time (seconds), location, number, and size of polyps (≤ 5mm, 6 to 9mm or ≥ 1cm) [11] and polyp morphology (sessile, subpedunculated, pedunculated) [12], and then compare these data between EAC and standard colonoscopy.

Statistical analysis

The data was entered and processed using EpiData 3.1 and SPSS 20.0 software. Categorical variables were presented as percentages and compared using the chi-square test or Fisher's exact test. Continuous variables were presented as mean (SD) or median (interquartile range); the differences in the mean values of continuous variables were compared using the T-test or Mann-Whitney U test. Statistical significance was set at $p<0.05$ with 95% confidence. Relative risk (RR) with a 95% confidence interval (CI) for each proportional outcome was calculated.

3. RESULTS

Patient characteristics and endoscopic images of colorectal polyps

We prospectively enrolled a total of 308 patients into the study who fulfilled the inclusion criteria. SC and EAC were performed in 154 patients and 154 patients, respectively. The median age of the study cohort was 54 years (IQR 43-64) and most participants were male, constituting 55.8% of the sample. The most common reason why patients go for colonoscopy is abdominal pain, accounting for 47.1% of cases. No significant differences between the two groups in terms of age, gender. The characteristics of the patients in this study are summarized in Table 1.

Table 1. Patient Characteristics and clinical characteristics.

Variable	EAC (n = 154)	SC (n = 154)	p-Value
Median age (IQR)	53 (43-62)	55 (44-67)	>0.05
	54 (43-64)		
Gender (male/female)	88/66	84/70	>0.05
Median BBPS (IQR)	8 (7-9)	8 (7-9)	>0.05
Clinical characteristics, n (%)			
No symptoms	51 (16.6)		
Abdominal pain	145 (47.1)		
Diarrhea	26 (8.4)		
Blood in stool	62 (20.1)		
Constipation	16 (5.2)		

Among the 308 patients, a total of 199 patients were found to have at least one polyp. The overall estimate of PDR was 64.6% (199/308) and the ADR in this study was 20.8% (64/308). We found that the commonest morphology of polyps in the patients was sessile (92%), and the majority (89.9%) was small size (6-9mm). Most of the polyps were located in the rectal region (41.2%), sigmoid (37.7%) followed by transverse colon (28.6%), ascending colon (27.1%), descending colon (25.1%), and caecum 13.6% (Table 3).

Efficacy of EAC in the detection of colorectal polyps in comparison with SC

Procedural Characteristics

Total colonoscopy was performed on all patients. In those patients with an EAC, the ileum could be intubated in 145 cases with no significantly different intubation rate compared with the SC with 149

patients (p> 0.05). Overall procedure time was approximately 1 minute longer in the EAC group (EAC: 15.66 min vs. SC: 14.57 min, p< 0.05). There were no significant differences in terms of mean withdrawal times, mean caecal intubation times and bowel preparation results (Table 2).

Table 2. Procedural Characteristics between EAC group and SC group.

Variable	EAC (n = 154)	SC (n = 154)	p-Value
Ileal intubation, n (%)	145 (94.2)	149 (96.8)	>0.05
Withdrawal time	9.10 ± 2.79	8.58 ± 2.45	>0.05
Caecal intubation time	6.55 ± 3.77	5.99 ± 3.11	>0.05
Procedure time	15.66 ± 4.86	14.57 ± 4.45	<0.05

Polyp, adenoma detection rate

A total of 477 polyps were detected during colonoscopy. In the EAC-group, 265 polyps were found while in the SC-group 212 polyps could be retrieved. The polyp detection rate (PDR) was significantly higher in the EAC-group compared to the SC-group (70.1% vs. 59.1%, p< 0.05) resulting in a PDR increase of about 11%. The ADR was 16.2% with standard colonoscopy versus 25.3% for EAC (p< 0.05) (Table 3). Moreover, the mean number of polyps per patient (MPP) seen in the EAC group was significantly higher than in the SC group [EAC: 1,72 ± 1,97 vs. SC: 1,38 ± 1,82, p <0.05] (Table 3).

Characteristics of endoscopic images

The number of polyps smaller than 5mm and sessile polyps detected in the EAC group was significantly higher than the one in SC group (n = 100 vs. 79, p< 0.05 and n = 100 vs. 83, p< 0.05 for sessile polyps). The detection rates for subpedunculated or pedunculated polyps were not different. In addition, there was no statistically significant difference in polyp site detection (Table 3).

Table 3. Characteristics of endoscopic images between EAC group and SC group

Variable	Total (n = 308)	EAC (n = 154)	SC (n = 154)	RR (95%CI)	p-Value
PDR, n (%)	199 (64.6)	108 (70.1)	91 (59.1)	1.29 (1.00-1.66)	<0.05
ADR, n (%)	64 (20.8)	39 (25.3)	25 (16.2)	1.29 (1.02-1.64)	<0.05
MPP, mean ± SD	1.55 ± 1.90	1.72 ± 1.97	1.38 ± 1.82		<0.05
Size of polyp, n (%) *					
≤ 5mm	179 (89.9)	100 (64.9)	79 (51.3)	1.34 (1.05-1.70)	<0.05
6-9mm	28 (14.1)	11 (7.1)	17 (11.0)	0.77 (0.48-1.24)	>0.05
≥ 10mm	23 (11.6)	13 (8.4)	10 (6.5)	1.14 (0.78-1.67)	>0.05
Distribution of polyp detection, n (%) *					
Cecum	27 (13.6)	15 (9.7)	12 (7.8)		>0.05
Ascending colon	54 (27.1)	32 (20.8)	22 (14.3)		>0.05
Transverse colon	57 (28.6)	32 (20.8)	25 (16.2)		>0.05
Descending colon	50 (25.1)	26 (16.9)	24 (15.6)		>0.05
Sigmoid colon	75 (37.7)	39 (25.3)	36 (23.4)		>0.05
Rectal	82 (41.2)	43 (27.9)	39 (25.3)		>0.05
Morphology of polyp, n (%) *					
Sessile	183 (92)	100 (64.9)	83 (53.9)	1.27 (1.00-1.61)	<0.05
Subpedunculated	11 (5.5)	7 (4.5)	4 (2.6)	1.29 (0.81-2.04)	>0.05
Pedunculated	26 (13.1)	15 (9.7)	11 (7.1)	1.17 (0.83-1.66)	>0.05
Complication	0	0	0		

*Total n = 199, MPP: the mean number of polyps per patient

4. DISCUSSION

Currently, colorectal cancer is common in the world. Polyp detection and removal is a critical issue in the prevention colon of cancer. Besides the fact that detection rates depend on the experience of the examiner [13] and the time of withdrawal during the colonoscopy [14] anatomic obstacles such as the hepatic flexure or the sigmoid also play an important role. Even under optimal cleansing conditions angulations in the sigmoid and the flexures as well as the presence of multiple folds of caecal lead to substantial miss rates of polyps that are located behind those folds [15] The EAC is an effective and inexpensive method for increasing the PDR, ADR without restricting the field of vision [16]

In this study, the majority of patients were male (55.8%) with a median age of 54 years (IQR 43-64), and the most common reason for colonoscopy is abdominal pain, accounting for 47.1% of cases. No significant difference in BBPS between the EAC and standard colonoscopy groups.

In 308 patients participating in our study, the proportion of patients diagnosed with colorectal polyps by EAC (70.1%) was statistically higher than by SC (59.1%) ($p < 0.05$). At the same time, endoscopy with EAC also helps increase the detection rate of adenomatous polyps (20.8%) compared to SC (16.2%), with statistical significance ($p<0.05$). In a meta-analysis of randomized controlled trials that pooled 13 studies, Jun Wang found that the rate of detection of polyps in the EAC group was 54.5%, which was statistically significantly higher than in the SC group with 46.5%, and the rate of adenoma in the EAC group (44.9%) was significantly higher than the SC group (39.1%), the pooled RR was 1.16 (95% CI 1.08-1.24, $p<0.00001$) [21]

The number of polyps per patient seen in the EAC group (1.72 ± 1.97 polyps) was significantly higher than in the SC group (1.38 ± 1.82 polyps) ($p < 0.05$). Yoshiki Wada et al. (2018) also showed that the group with EAC increased the average number of polyps per patient (1.33 ± 1.43 polyps) statistically significantly more than the SC group (0.83 ± 0.99 polyps) [9]. Besides, in our study, significantly more polyps smaller than 5mm in size as well as more sessile polyps were detected in the EAC group compared to the SC group ($n = 100$ vs. 79, $p<0.05$ and $n = 100$ vs. 83, $p<0.05$ for sessile polyps). Through our research, it has been found that Endocuff is beneficial in helping to increase the detection rate of small polyps ≤ 5mm and sessile polyps.

As left-sided colon cancers account for the majority of colon cancers, and the largest proportion of CRC occurs in the rectum and sigmoid colon [1, 22]. Our study showed that the rectum and sigmoid colon detected the most polyps in both endoscopy groups, but there was no difference in the polyp detection rate according to colon location between the two groups. Colin J. Rees et al. (2020) also found no statistically significant differences between the EAC groups and SC groups for polyp location ($\chi2(4) = 3.88$, $p=1$) [23]. However, Erwin Biecker et al. (2015) reported that the polyp detection rate was significantly improved for cecal polyps < 1cm in size when the EAC was used (37 vs. 14, $p=0.002$) [24] Martin Floer et al. (2014), when analyzing the polyp morphology, found that EAC detected more sessile polyps in the sigmoid (99 vs. 45, $p=0.002$) and caecal region (29 vs. 7, $p=0.003$) as well as more flat polyps in the transverse colon (10 vs. 0, $p=0.015$) compared to SC [25]. Endocuff is a device that can be attached onto the distal end of a colonoscope, which can help to flat the large mucosal folds in colon during withdrawing the colonoscope [26]. In the proximal colon there are often large folds. The mucosa behind these folds is often obscured when observed by standard endoscopy, but the use of the Endocuff would allow a better minimization of the blind spots. In the distal colon, especially in the sigmoid colon, which has overlapping mucosal folds, the use of Endocuff may allow the user to check for the presence of polyps in each fold during the withdrawal of the colonoscope. Our study showed an increased number of polyps detected in the entire colon, with no bias with regard to specific sites.

Another aspect is the importance of the withdrawal time for the ADR. Earlier studies have shown that insufficient withdrawal times correlate with a lower ADR and thus with a higher incidence of colorectal cancer [27, 28]. In our study, the median withdrawal time routinely at least 6 minutes in both groups, which is considered sufficient for standard colonoscopy according to current guidelines [27, 29]. Overall, our study shows that because the scope of mucosal observation becomes wider, the withdrawal time of the EAC group tends to be longer than the SC group, but this small difference has no statistical significance. Therefore, it can be said that the higher detection rate of polyps and adenomas in the EAC group is not due to the longer withdrawal time. Besides, there were no statistical differences in terms of mean caecal intubation times. The overall procedure time with EAC was significantly longer. However, we assume that the procedure time was

prolonged in the EAC group (15.66 vs. 14.57 min, p<0.05) due to increased colonoscopy and cecal insertion time and endoscope removal time in the group with EAC. No complication was found the the both groups.

There are some limitations in our study. The number of study subjects was limited and could not represent the rate of polyp detection in the community. In addition, we conducted a parallel study instead of studying both methods in the same group of subjects due to ethical concerns about exposing patients to the risk of having two procedures of colonoscopy.

In conclusion, Endocuff assisted colonoscopy is a simple, not expensive technique that seems to be safe and may improve PDR, ADR compared to standard colonoscopy. In addition, EAC can help to enhance the mean number of polyps per patient and small polyps ≤ 5mm as well as sessile polyps.

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author contributions

TTTT, VHT designed the study, wrote the manuscript. TTTT , THTN collected, analyzed and interpreted the data. VHT and TTTT critically reviewed, edited and approved the manuscript. All authors contributed to the article and approved the submitted version.

Conflict of interest

None

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