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MINIREVIEWS

New device to implement the adenoma detection rate

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Abstract

It is well-known that colonoscopy is considered the gold standard for colon cancer prevention. Although performed by experienced endoscopists, the matter remains of polyps missed during this examination. The reasons may include the size, shape and location of the lesions. Many colorectal cancer screening programs have been proposed to increase the adenoma detection rate. The substantial difference between these methods is whether the improvement in vision, particularly the detection of irregularities of the mucosa, is inside the endoscope electronic components (magnification, wide-angle vision, narrow band imaging, flexible spectral imaging colour enhancement, i-Scan) or outside the same, by the use of specific caps (EndoCuff, EndoVision, EndoRings). Endocuff is a plastic device mounted at the end of the scope with a constant vision field of the entire colon. The aim of this study is to explore the potential clinical and technical benefits of Endocuff.

Key words: Adenoma detection rate; Cap-assisted colonoscopy; Colorectal cancer; Endocuff-assisted colonoscopy; Standard colonoscopies

Core tip: One of the main goals of colonoscopy screening is to identify polypoid lesions, which are precursors of colorectal cancer. Once identified, the polypoid lesions need to be removed whenever possible. Throughout the years, many prototypes of colonoscopes, magnification techniques, and different devices such as caps have been developed for colonoscopy screening. Endocuff is a new device used to improve adenoma detection rates during colonoscopy. Based on the findings of many studies, Endocuff seems to be of great help in increasing the detection of colonic polyps, with no significant complications associated with its use.

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INTRODUCTION

Colorectal cancer (CRC) is one of the most frequently observed cancers, and screening programs, including the adenoma detection rate (ADR), play an important role in reducing its incidence. There are many screening methods such as withdrawal time and technique, second evaluation of the right colon, patient positional changes, gastrointestinal assistant participation during colonoscopy, water-aided technique, optimisation of bowel preparation, and antispasmodic administration[1].

Colonoscopy is globally recognised as the gold standard for CRC screening. A widely used indicator to emphasise "good colonoscopy" is the ADR, which refers to the number of patients out of every 100 undergoing first-time colonoscopy who have at least one adenoma removed[2]. Several studies showed that the prevalence of adenomas in asymptomatic adults vary from 25% to 40%[3-6]. Based on these findings, in 2014, a joint task force of the American College of Gastroenterology and the American Society of Gastrointestinal Endoscopy recommended an ADR benchmark of 25% for all patients (30% for men and 20% for women)[7]. ADR has been considered as the major quality measure predicting subsequent CRC incidence and mortality[8].

Over the years, several accessories have been developed in order to obtain a more accurate visualisation of the colon, facilitating and increasing the identification of polypoid lesions. Recently, one such new device called Endocuff has been developed.

The aim of this review is to identify the studies comparing Endocuff-assisted colonoscopy to standard colonoscopy considering the ADR as the end-point by searching through MEDLINE/PubMed and abstracts presented at international meetings, from January 2014 until January 2017. In particular, the following key-words were searched: "adenoma detection rate", "Endocuff" and "Endocuff-assisted colonoscopy".

TECHNICAL CHARACTERISTICS, METHODS OF USE AND INDICATIONS

The Endocuff™ Vision (ARC Medical Design and Norgine) is a new device created with the intent to improve the endoscopic view. It is a soft plastic cap of 2 cm in length, consisting of a cylindrical core in propylene endowed with small flexible finger-like projections made of a thermoplastic elastomer fixed to the core[9,10]. The first version of Endocuff™, dated in 2012 with the Food and Drug Administration approval, presented one proximal and one distal row of finger-like projections. On the contrary, the latest version, named Endocuff Vision™, has only one proximal row of more rounded finger-like projections in order to eliminate mucosal lacerations that were observed in the first model[11] (Figure 1). This device presents different colour-coded sizes (blue, green, purple, and orange) depending on the various colonoscopy compatible, both for paediatric than for adults instruments.

The device is for single use and is not recyclable. The usage is very simple, as it uses the distal end of the endoscope (Figure 2), which virtually coincides with the end of the tip of the colonoscope. Here, lubricants are not used due to their high risk of displacement from the scope during the procedure.

There are two principal indications for use: (1) keeping the suitable depth of endoscope's view field; and (2) helping the endoscope with being inserted into the gastrointestinal tract. During colon intubation, this accessory is practically invisible, and the projections do not interfere with the introduction. On the contrary, during the tool retraction, this device flattens folds, in particular of the sigmoid colon, and flexures of bowels (Figure 3).

Pioche *et al*[12] conducted a simulated pilot study which included an animal colorectal model used for learning and 32 endoscopists as follows, 16 Japanese and 16 visitors, in order to verify the Endocuoff's effectiveness in identifying the polypoid lesions. The model was specifically designed with the "packaging" of 13 polyps located in various locations, including those behind the folds. Endoscopists had a different degree of experience and worked randomly, either by performing standard colonoscopies (SC) or Endocuff-assisted colonoscopy (EAC). Their results showed that EAC detected more polyps compared to SC (mean lesions: 9.9 *vs* 7.5, $P = 0.03$) and that the use of this device was independent of the various endoscopic medical expertise levels[12].

CONTRAINDICATIONS

Reported contraindications in the usage of Endocuff Vision™ are: (1) known colonic strictures; and (2) active inflammatory disorders (acute infective colitis, colonic Crohn's disease, ulcerative colitis, and acute diverticulitis)[11]. Moreover, this device was not designed with the objective of deep ileal intubation, and it is strongly discouraged for complex sub-mucosal dissection (such as ESD, Endoscopic Submucosal resection).

ANALYSIS OF STUDIES AVAILABLE IN THE LITERATURE

The first report on the use of this accessory was

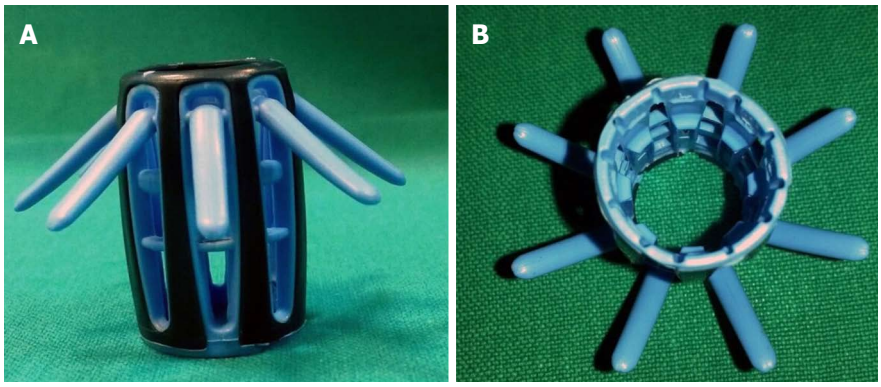

Figure 1 Endocuff's view: (A) lateral; (B) from above.

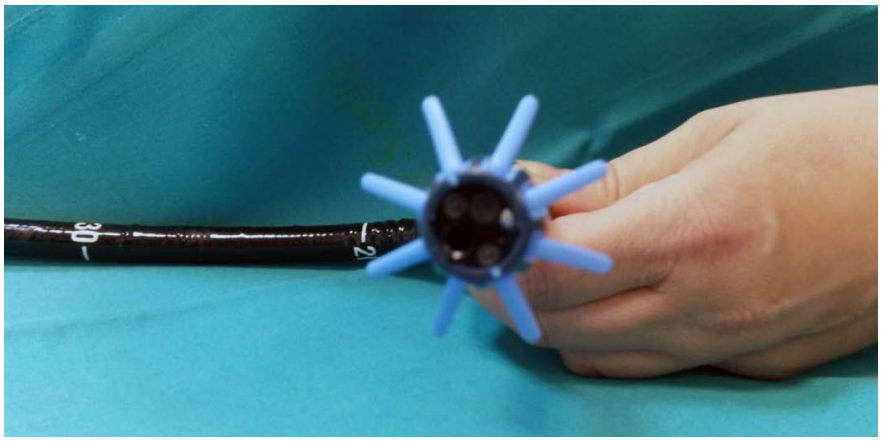

Figure 2 Endocuff Vision™ mounted at the tip of the colonoscope.

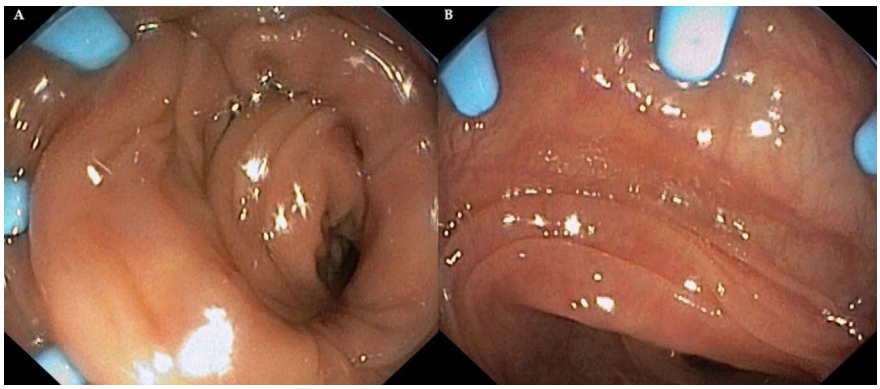

Figure 3 Endoscopic view of colonoscope retraction in which it's possible to note the flatting folds.

published in 2012 by Sanders and Tsiamoulos *et al*[9] of St Mark's Hospital in London. This was a single-centre, retrospective study with a small number of cases. The authors reported their experience with endoscopic cuff-assisted endoscopic mucosal resection (EMR) (5 patients) and control post scars-EMR (7 patients) for large flat/sessile sigmoid colon polyps. All the lesions were located in the sigmoid sigma, and no adverse events were seen.

Reviewed available studies focusing on EndoCuff-assisted colonoscopy are reported in Table 1. It was excluded from the analysis of the data, an ongoing study, promoted by Bevan *et al*[11]. It is a is a prospective, multicenter, randomised controlled trial comparing the ADR in patients undergoing EAC with SC. This study will be held at seven hospitals and will include the enrolment of 1772 patients[11].

REPORTED COMPLICATIONS

As observed in a recent meta-analysis[13], four studies[10,14,17,20] reported complication rates in the EC groups. The most frequent complication was superficial mucosal injury of negligible clinical significance that was found in 27 patients. Patient discomfort resulted in the removal of the cap in 23 cases, following which it was possible to complete the procedure. Another common complication was the loss of the device during the examination of 6 patients. In all these cases, the accessory was removed, and the study was complete. No perforations were reported[13]. Tsiamoulos *et al*[17] described elective removal in 4 cases due to sigmoid diverticulitis and 1 due to anal discomfort. Cattau *et al*[21] signalled one loss of the cap and one incomplete examination due to advanced diverticulosis. De Palma

Table 1 Studies focusing on EndoCuff-assisted colonoscopy

Ref.	Year	No. of patients (EAC)	No.of patients (SC)	Adenoma detection rate (%) (EAC)	Adenoma detection rate (%) (SC)	ADR significance
Floer *et al*[14]	2014	238	229	35.4	20.7	$P < 0.0001$
Lenze *et al*[15]	2014	50	//	34	//	//
Marsano *et al*[16]	2014	165	153	46.6	30	$P = 0.002$
Tsiamoulos *et al*[17]	2014	133	133 (pre-cuff period) 133 (post-cuff period)	68.98	55.13 61.74	//
Sawatzki *et al*[18]	2015	104	//	47	//	//
Chin *et al*[19]	2015	93	193	44.1	27.3	$P = 0.01$
Van Doorn *et al*[20]	2015	530	533	52	52	$P = 0.92$
Biecker *et al*[10]	2015	245	253	56	42	$P = 0.001$
Cattau *et al*[21]	2015	329	329	49.7	46.4	$P = 0.392$
Shah-Ghassemzadeh *et al*[22]	2015	219	230	62.1	49.13	$P = 0.0057$
Bhattacharyya *et al*[23]	2016	266	265	63	60.9	NS
Cavallaro *et al*[24]	2016	445	403	53	46	$P < 0.05$
De Palma *et al*[25]	2017	137	137	26.9	26.3	$P = 0.002$

EAC: Endocuff-assisted colonoscopy; SC: Standard colonoscopy; NS: Not significant; ADR: Adenoma detection rate.

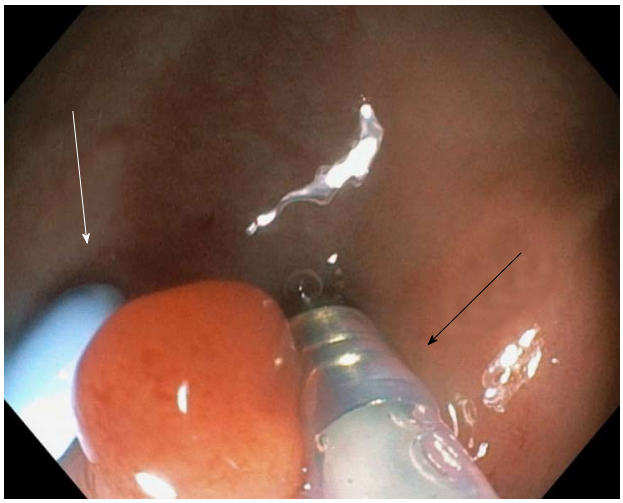

Figure 4 Endoscopic removal of a sessile polyp of the sigmoid colon, in which it's possible to see the Endocuff's flat (white arrow) and injection needle (22 G, Micro-Tech, Nanjing Co, Ltd) (black arrow).

et al[25] reported nine complications: 2 cases of device loss during the withdrawal and 7 cases of mucosal erosions, of which in 1 case was necessary sclerosis with adrenaline.

OUR INITIAL EXPERIENCE

The regional program for the CRC screening is operating at our Hospital. After the adhesion of the population to faecal occult blood test (FOBT), colonoscopy is mandatory. Colonoscopies, all conducted until the cecum, were performed using Endocuff Vision™ by expert operators with conventional colonoscopes (CF-Q165L, CF-H1285L, Olympus Optical, Hamburg, Germany). The bowel preparations used were the standard large-volume polyethylene glycol electrolyte solutions prepared the previous day or the split-dose regimens, depending on the time of the examination. Thirty patients (F 18, M 12) with a mean age of 67 years (range: 50-75 years), who underwent first-time screening colonoscopy, were studied. A total of 45 polyps were removed, 36 sessile (80%) and 9 pedunculated (20%). The sigma was involved in nearly half of the cases (45.7%). During our initial experience, we found polypoid lesions localised especially in the sigmoid colon that could be easily removed (Figure 4). No major adverse events were recorded, except for two cases of superficial "scratch-like" mucosal lesions of no clinical significance that occurred in the case of rigid colon due to inflammation (mild diverticulitis).

CONCLUSION

Prompt diagnosis of precancerous polyps during colonoscopy is extremely important in order to reduce CRC rate, especially in asymptomatic patients. During colonoscopy, the rate of colonic polyps missed varies from 6% to 27%[26]. It is known that the most effective way to estimate the adenoma miss rate, and consequently improve the ADR, is represented by the "back-to-back colonoscopy" technique performed in two consecutive same-day procedures in the same patient[27]. However, we cannot ignore this may double the potential complications, such as the risk of perforation.

The first study of this method using EndoCuff has been conducted by De Palma *et al*[25] in a single-centre randomised back-to-back-study. The participants underwent two colonoscopies, with and without the use of the device. The authors concluded that these kinds of examinations allow finding lesions missed by other procedures, but on the other hand, a limitation raised being the endoscopists not blinded for the presence of Endocuff[25]. From these studies emerge that the use of transparent plastic caps attached to the tip of the colonoscope can increase the ADR, with a mechanical mechanism of flattening the folds and the consequent increase of the visual field. This technique is known as cap-assisted colonoscopy (CAC). However,

several works show conflicting results with respect to improvement in adenoma detection by CAC. In particular, the ADR was not significantly improved in 6 studies analysed in a meta-analysis including 16 RCTs that compared CAC to standard colonoscopy[28].

As for the CAP, our results were not in agreement in defining the EAC superiority over SC. In fact, in three studies, there was no statistical significance between the two groups (EAC *vs* SC)[20,21,23]. As the Table 1 shows, this device can enhance the ADR.

The most frequently observed complication was the removal of Endocuff's due to the discomfort of the patient (24 times), followed by the loss of the device during the examination (9 times). No major complications were reported.

In Italy, CRC is one of the most frequently found cancers. At our local hospital, we started regional screening program for this kind of tumor from January 2012 onwards. In our country, the device has been registered in the database of medical devices of the Ministry of Health on January 29, 2016[29].

Our early experiences with EAC on a small population show that Endocuff can identify and facilitate polypectomy, especially in floppy folds of sigma, allowing better stabilization of endoscope in front of the polyp. Among 30 patients, we found 2 cases (6.6%) of insignificant superficial mucosal lacerations, probably related to the lack of experience with this accessory.

Some major limitations are represented by special circumstances such as sub-colonic strictures and acute inflammation of the mucosa (diverticulitis and inflammatory bowel diseases).

Unfortunately, when a person is subjected to colonoscopy for the first time, it is impossible to know any underlying diseases. Therefore, in some cases, it becomes necessary to remove the device in order to complete the procedure safely.

In conclusion, the results of EAC are still evolving. This accessory appears safe and useful in increasing the detection of the number of polyps and subsequently, the detection rate of adenomas. We recommend that Endocuff should be further investigated in other larger trials.

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