A comparison of 2 distal attachment mucosal exposure devices: a noninferiority randomized controlled trial

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Abstract

Background and Aims: Endocuff and Endocuff Vision are effective mucosal exposure devices for improving polyp detection during colonoscopy. AmplifEYE is a knock-off device that appears similar to the Endocuff devices but has received minimal clinical testing.

Methods: We performed a randomized controlled clinical trial using a noninferiority design to compare Endocuff Vision with AmplifEYE.

Results: The primary endpoint of adenomas per colonoscopy was similar in AmplifEYE at 1.63 (2.83) versus 1.51 (2.29) with Endocuff Vision; p=0.535. The 95% lower confidence limit was 0.88 for ratio of means, establishing noninferiority of AmplifEYE (p=0.008). There was no difference between the arms in mean insertion time, and mean inspection time (withdrawal time minus polypectomy time and time for washing and suctioning) was shorter with AmplifEYE (6.8 minutes vs 6.9 minutes, p=0.042).

Conclusions: AmplifEYE is noninferior to Endocuff Vision for adenoma detection. The decision of which device to use can be based on cost. Additional comparisons of AmplifEYE to Endocuff by other investigators are warranted.

Introduction

Effective detection of precancerous lesions during colonoscopy reduces the risk of interval colorectal cancer[1]. A variety of tools are available to improve detection during colonoscopy, including the mucosal exposure devices, Endocuff [2-8] and Endocuff Vision [9-11]. The original Endocuff device (Arc Medical Design, Leeds, UK) had 2 rows of fingers (Figure 1) and has been replaced by the Endocuff Vision, which has a single row of fingers that are 3 mm longer than those on the original Endocuff (Figure 1). Meta-analyses indicate that Endocuff produced an average 7% increase in the adenoma detection rate (ADR) [12]. A head-to-head comparison of Endocuff to EndoRings and including the FUSE wide angle colonoscope, found that Endocuff was associated with faster insertion times to the cecum and better detection, indicating that is was a dominant mucosal exposure device from the perspective of performance[13] . Recent studies measuring insertion and withdrawal times suggest that Endocuff Vision can provide better detection with less inspection time during withdrawal [10, 14].

AmplifEYE is a “knock-off” device with a single row of fingers and an overall appearance very similar to Endocuff Vision (Figure 1). By our measurement the AmplifEYE device is 1 mm longer than Endocuff Vision (25 versus 24 mm), and the Endocuff Vision arms are slightly shorter and more acutely angulated than the AmplifEYE arms. Endocuff Vision has slots in the body of the device to accommodate the arms when they fold down during insertion, whereas there are no such slots on AmplifEYE. Otherwise, the measurements and concept of the devices appear very similar (Figure 1). There are few data on the effect of AmplifEYE on detection compared with standard colonoscopy. In one randomized trial we identified on AmplifEYE in an abstract form, the device produced a 94% increase in polyps per colonoscopy compared with

standard colonoscopy (2.09 vs 1.07, p=0.005), but showed only a trend for an increase in adenomas per colonoscopy (1.14 vs 0.75, p=0.083)[15]. Because Endocuff Vision appears established as effective, and AmplifEYE appears to be an alternative that should function similarly, we performed a randomized controlled trial to test whether performance differences exist between Endocuff Vision and AmplifEYE.

Methods

We performed a randomized controlled clinical trial comparing the Endocuff Vision (Arc Medical Design, Leeds, UK) with AmplifEYE (Medivators Inc, Minneapolis, Minn). Permission to perform the study was granted by the Institutional Review Board at Indiana University on April 12, 2018. The trial was registered at Clinicaltrials.gov on June 6, 2018 as NCT03560128. Patients were recruited for the study between April 12, 2018 and December 18, 2018. Devices for both arms of the study were supplied by the manufacturers. No other support was received from either manufacturer. Neither manufacturer played any role in the design or conduct of the study or reviewed the results before publication.

The study was performed at 2 outpatient endoscopy units, one located at Indiana University Hospital and the second at a free-standing outpatient unit in Carmel, Indiana. Seven attending endoscopists participated in the study.

Eligible patients were those aged ≥40 years presenting for screening, surveillance, or diagnostic colonoscopy. Patients were excluded if they had previous resection of the colon or rectum,

inflammatory bowel disease, a polyposis syndrome, were referred for a procedure to remove a specific polyp, or referred for a previous incomplete colonoscopy (failed cecal intubation).

Patients were randomized to utilize the Endocuff Vision versus AmplifEYE using a computer generated randomization sequence. All patients provided informed consent to participate. Allocation was concealed using opaque envelopes until just before initiation of the procedure.

The primary endpoint for the study was the number of conventional adenomas per colonoscopy (APC). Secondary endpoints included the adenoma detection rate (ADR), the number of sessile serrated polyps per colonoscopy (SSPPC), number of patients with ≥1 sessile serrated polyp (sessile serrated polyp detection rate or SSPDR), number of patients with ≥1 polyp (polyp detection rate or PDR), number of polyps per colonoscopy (PPC), insertion time to the cecum, overall withdrawal time (including time for washing and polypectomy), and inspection time (overall withdrawal time minus the time for performance of polypectomy or biopsy and suction and washing). The time to insert to the cecum and the inspection time were measured by an assistant using a stopwatch. During insertion, the clock was stopped only when a polyp was detected and removed, but not for suctioning or washing. During withdrawal, the inspection time was measured by stopping the clock for all suctioning and washing as well as for removal of polyps or taking biopsies. Other secondary endpoints included the Boston Bowel Preparation Score (BBPS), the percentage of cases in which the device was removed to pass the sigmoid colon, and the cecal intubation rate. Proximal colon was defined as transverse colon and proximal, and distal colon was defined as splenic flexure and distal.

Seven attending gastroenterologists performed the colonoscopy withdrawals in the study. All have ADRs above the recommended threshold of 25% as measured in our quality program (data not shown). All are full-time lumenal clinical gastroenterologists. Median years as an attending in our units was 8 years. The majority (73%) of study procedures were performed by the senior author. Fellows assigned to assist specific physicians were allowed to perform insertion to the cecum, but did not perform withdrawal in patients participating in the study. The insertion time is presented for cases with and without fellow participation. Device removal was at the discretion of the attending endoscopist in all cases.

Statistical analysis: Based on previous data we estimated that the Endocuff Vision will result in an APC of 2.3. We considered a clinically acceptable APC for the Medivators device to be within 20% of this value or 1.84. To demonstrate noninferiority, using a one-sided 2-sample t-test, a coefficient of variation 1.5 for both groups a sample size of 588 patients (294 per group) needed to be randomized to have 80% power with a noninferiority margin of 20%.

The Endocuff Vision and AmplifEYE groups were compared for differences in categorical variables using chi-square tests, for differences in adenoma and polyp counts using negative binomial models, and for differences in other continuous variables using Wilcoxon Rank Sum tests. A 5% significance level was used for all tests. All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

Figure 2 shows a flow chart for patients screened, randomized, and who completed the study. There were 592 patients that were randomized and completed the study. Table 1 shows a comparison of demographic and some procedure features between the 2 study arms and demonstrates that there was no difference between groups in these factors.

The cecum was intubated in 591 of the 592 randomized patients. The AmplifEYE device was removed to pass the sigmoid colon in 17 cases (6%) versus 15 (5%) with Endocuff Vision; p=0.687. There were no adverse events, either perforation or significant mucosal tearing, in the study.

On an intent to treat basis, the primary endpoint of adenomas per colonoscopy (APC) was similar with AmplifEYE at 1.63 (2.83) versus 1.51 (2.29) with Endocuff Vision; p=0.535. The 95% lower confidence limit was 0.88 for ratio of means, establishing noninferiority; p=0.008. Table 2 shows all of the detection targets, none of which were significantly different between the study arms. There were also no differences between arms of the study in detection within the proximal or the distal colon (Supplementary Table 1).

Table 3 shows the results by individual study physician. Most of the study procedures were performed by a single physician. One physician with a small number of cases had a higher APC with Endocuff Vision.

The mean insertion time overall was 336 (221) seconds with AmplifEYE versus 331 (243) with Endocuff Vision; p=0.532. A gastroenterology fellow was involved in approximately one-quarter

of insertions in both arms. Considering only procedures when no fellow was involved, there was again no difference between study arms. Overall withdrawal times were similar and there was a small but statistically significant difference in inspection times among the arms. Similarly, there was no difference between the study arms in BBPS (Table 1).

Discussion

In a randomized controlled trial, we compared whether the AmplifEYE mucosal exposure device, which appears to be modeled on the Endocuff Vision, provides similar performance characteristics for detection during colonoscopy. Our results suggest that there are no major functional differences between the 2 devices. Thus, detection targets in the study were similar, as were insertion times and the percentage of cases in which the device was removed to accomplish sigmoid colon passage. The adjusted withdrawal time was actually slightly shorter with AmplifEYE than Endocuff Vision, though this was a secondary endpoint for the study. Considering all of the primary and secondary endpoints, it appears our study did not identify significant performance deficiencies in AmplifEYE.

Although seven attending clinical gastroenterologists performed the study colonoscopies, the majority were performed by the lead author. Our approach in recent detection studies in our unit is to report the results by individual author[13, 16], which is informative by demonstrating that device utility can be operator dependent[13]. The very high APC in both arms of this study by the lead author likely reflects that some surveillance patients have had previous large polyps resected, which are associated with a high prevalence of additional adenomas[17].

Our results could be interpreted to suggest that colonoscopists considering the use of a mucosal exposure device like Endocuff Vision or AmplifEYE could make the decision based largely on cost. The cost of add on devices used during colonoscopy is a major issue for many practicing colonoscopists. Although the cost per case is low and typically around $25 per device, the profit margin for colonoscopy in ambulatory surgery centers and office practices in the United States is narrow, and the device cost reduces the facility fee profit margin significantly. From a societal perspective, the use of mucosal exposure devices may be cost effective based on the increased ADR that they provide [18, 19] . Higher ADR is associated with higher polypectomy, pathology costs, and with more patients returning at shorter intervals for repeat colonoscopy. However, the high costs of cancer care offset the increased colonoscopy costs, so that higher ADRs are cost-effective. From the perspective of the endoscopy unit, the cost of add on mucosal exposure devices may be offset by improved reimbursement for polypectomy charges and increased total numbers of colonoscopies for surveillance over time when current postpolypectomy surveillance recommendations are followed [20]. In addition, the savings in time from shorter average colonoscope insertion and withdrawal times could improve endoscopy unit efficiency, and potentially allow for additional procedures per working day [21]. Despite these considerations, the obstacles created by cost indicate the need for similarly functioning devices with lower unit costs.

Endocuff Vision and AmplifEYE, when combined with high definition colonoscopes, may dominate other mucosal exposure devices for increasing detection[13]. However, a variety of approaches to improving ADR are now proven effective, including education on lesion

appearance and withdrawal technique[1, 22], double right colon segment examination[23, 24], and patient rotation to optimize colonic distention[25]. Highlighting tools such as chromoendoscopy[26, 27], narrow-band imaging (Olympus Corporation, Center Valley, Pa)[28], blue-light imaging (Fujifilm Co, Tokyo, Japan)[29, 30], linked color imaging (Fujifilm)[31, 32], and artificial intelligence highlighting[33] are also effective. Mucosal exposure devices and highlighting devices are potentially additive in their detection benefits.

Strengths of this study include its randomized design and large size. All of the study endoscopists had ADRs above recommended thresholds. Because some meta-analyses have suggested that the main benefits of detection devices occur in low-level detectors [12], there should be consideration of repeating the study in a group with lower baseline ADRs. However, a recent study showed that even very high-level detectors have improved detection with Endocuff [13]. Because the effects of mucosal exposure devices and other imaging features can be operator dependent, we recommend that other groups investigate the issue addressed by this study.

In conclusion, we found that AmplifEYE, a “knock-off” device that appears very similar in design to Endocuff Vision, has performance features similar to Endocuff Vision. These results suggest that cost can be considered by colonoscopists choosing between Endocuff Vision and AmplifEYE. We recommend that additional groups evaluate this issue.

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Table 1. Patient and procedure characteristics in both groups

	AmplifEYE, n=294	Endocuff Vision, n=298	*P* value
Age, years (SD)	62.1 (10)	63.2(9.7)	0.182
Male gender, n (%)	139 (47)	128 (43)	0.29
White, n (%)	264 (90)	268 (90)	0.767
Indication for procedure, n (%)			0.385
Screening	100 (35)	113 (38)	
Diagnostic	18 (6)	24 (8)	
Surveillance	171 (59)	160 (54)	
Fellow participation during insertion, n (%)	71 (24)	80 (27)	0.452
Prior abdominal surgery, n (%)	134 (46)	153 (51)	0.161
Total procedure time, min(SD)	21.1 (7.8)	21.5 (7.6)	0.215
Insertion time, min (SD)	5.6 (3.7)	5.7 (4.1)	0.532
With fellow participation	8.4 (5.2)	7.5 (4.6)	0.292
Without fellow participation	4.7 (2.5)	5.03 (3.6)	0.390
Overall Withdrawal time, min (SD)	14.6 (6.2)	14.9 (6.3)	0.28
Inspection time†, min (SD)	6.8 (2.3)	6.9 (1.6)	0.042
Boston Bowel Preparation Score	8.8 (0.7)	8.7 (0.9)	0.912
BBPS – Right colon segment	2.9 (0.3)	2.9 (0.3)	0.452
BBPS – Transverse colon	2.9 (0.3)	2.9 (0.3)	0.511
BBPS – Left colon segment	2.9 (0.3)	2.9 (0.3)	0.76

† Overall withdrawal time minus the time spent for washing and polypectomy (all patients)

Table 2. Detection targets

	AmplifEYE, n=294	Endocuff Vision, n=298	2-sided *P* value	*P* value for noninferiority†
APC (SD)	1.63 (2.8)	1.51 (2.3)	0.535	0.008*
ADR, n (%)	164 (56)	159 (53)	0.553	<0.001*
SSPPC (SD)	0.21 (0.7)	0.25 (0.7)	0.552	0.38
SSPDR, n (%)	40 (14)	46 (15)	0.527	0.314
PPC (SD)	2.71 (3.4)	2.55 (2.9)	0.498	0.001
PDR, n (%)	229 (78)	231 (78)	0.913	<0.001
AAPC (SD)	0.11 (0.4)	0.10 (0.4)	0.881	0.192
AADR, n (%)	25 (9)	23 (8)	0.726	0.124

† With a margin of 20%, 1-sided test;

* For APC, ratio of noninferiority (95% CI): 1.08 (0.88-1.33); For ADR, ratio of noninferiority (95% CI): 1.05 (0.92-1.18)

APC-Adenomas per colonoscopy, ADR-Adenoma detection rate, SSPPC-Sessile Serrated Adenoma/Polyps per colonoscopy, SSPDR-Sessile Serrated Adenoma/Polyp detection rate, PPC-Polyps per colonoscopy, PDR-Polyp detection rate, AAPC-Advanced adenomas per colonoscopy, AADR-Advanced adenoma detection rate

Table 3. APC by individual colonoscopists

Doctor	AmplifEye		Endocuff Vision		2-sided *P* value
	Number of procedures	Mean APC	Number of procedures	Mean APC	
1	6	0.17	9	1.44	0.039
2	5	0.2	3	-	0.993
3	7	0.29	4	1.25	0.240
4	18	1.06	24	1.42	0.570
5	204	1.94	226	1.61	0.193
6	19	1.32	10	1.3	0.982
7	35	1.0	22	0.91	0.818

† APC – Adenomas per colonoscopy

Supplementary Table 1. Detection targets by location

	AmplifEYE, n=294	Endocuff Vision, n=298	2-sided *P* value	*P* value for noninferiority†
Proximal APC (SD)	1.17 (2.3)	1.08 (1.7)	0.556	0.015
Distal APC (SD)	0.46 (1.01)	0.43 (0.95)	0.698	0.046
Proximal ADR, n (%)	132 (45)	134 (45)	0.987	0.007
Distal ADR, n (%)	80 (27)	81 (27)	0.994	0.048
Proximal SSPPC (SD)	0.15 (0.5)	0.17 (0.6)	0.571	0.406
Distal SSPPC (SD)	0.07 (0.5)	0.08 (0.4)	0.778	0.414
Proximal SSPDR, n (%)	32 (11)	33 (11)	0.941	0.19
Distal SSPDR, n (%)	11 (4)	17 (6)	0.261	0.7
Proximal PPC (SD)	1.62 (2.5)	1.59 (2.1)	0.886	0.014
Distal PPC (SD)	1.1 (1.7)	0.96 (1.4)	0.278	0.002
Proximal PDR, n (%)	177 (60)	188 (63)	0.471	0.003
Distal PDR, n (%)	145 (49)	145 (49)	0.872	0.002
Proximal AAPC (SD)	0.06 (0.3)	0.07 (0.3)	0.518	0.522
Distal AAPC (SD)	0.05 (0.3)	0.03 (0.2)	0.247	0.054
Proximal AADR, n (%)	15 (5)	17 (6)	0.746	0.373
Distal AADR, n (%)	11 (4)	8 (3)	0.466	0.112

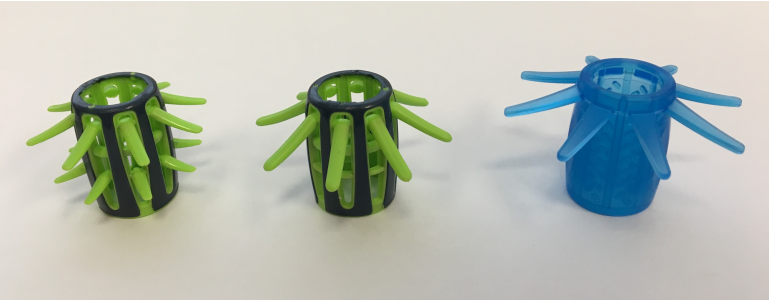
†margin of 20%

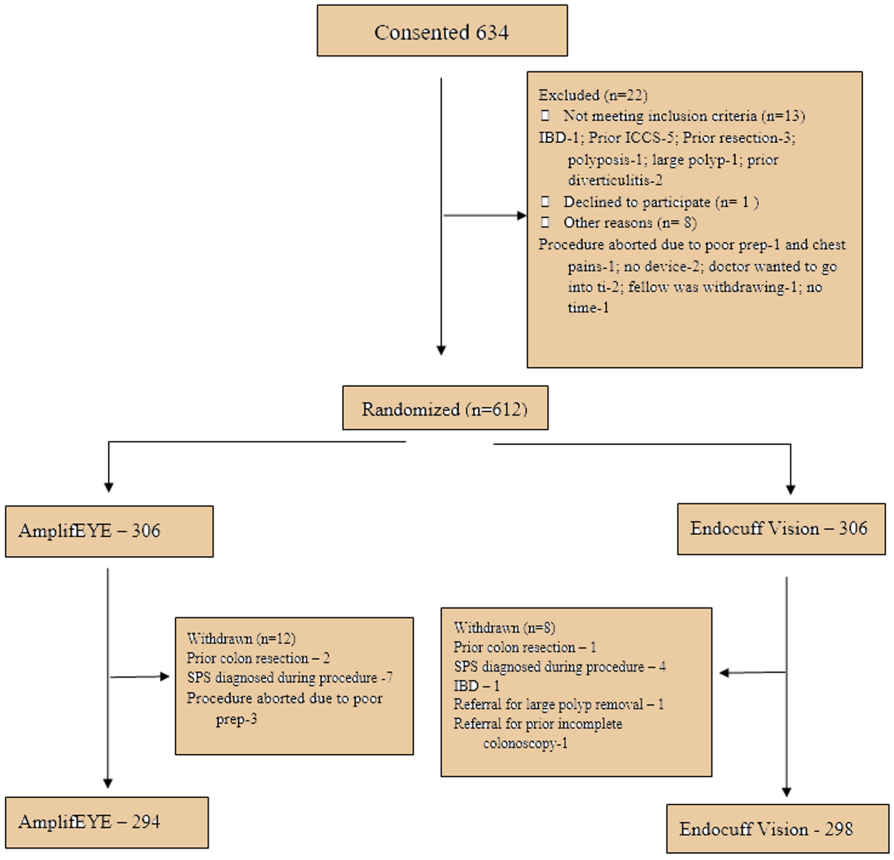
APC-Adenomas per colonoscopy, ADR-Adenoma detection rate, SSPPC-Sessile Serrated Adenoma/Polyps per colonoscopy, SSPDR-Sessile Serrated Adenoma/Polyp detection rate, PPC-Polyps per colonoscopy, PDR-Polyp detection rate, AAPC-Advanced adenomas per colonoscopy, AADR-Advanced adenoma detection rate

Figure legends

Figure 1. Photograph of the original Endocuff (left), Endocuff Vision (center), and AmplifEYE (right).

Figure 2. Flow diagram of patients through the study.





Acronyms list

ADR: adenoma detection rate

APC: adenomas per colonoscopy

BBPS: Boston Bowel Preparation Score

PDR: polyp detection rate

PPC: polyps per colonoscopy

SSPDR: sessile serrated polyp detection rate

SSPPC: sessile serrated polyps per colonoscopy