# Endocuff assisted colonoscopy significantly increases sessile serrated adenoma detection in veterans

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**Background:** Colorectal cancer (CRC) is the second most common cause of cancer related deaths in the United States. Colonoscopy is the gold standard for the detection of CRC. There are many colonoscopy quality measures and among these the adenoma detection rate (ADR) has demonstrated a significant impact in reducing mortality from CRC. The primary aim of our study was to compare ADR and distribution of polyp type in patients undergoing Endocuff-assisted colonoscopy (EAC) versus standard colonoscopy (SC) in a VA system.

**Methods:** Retrospective data was collected from 496 patients who underwent routine screening, surveillance and diagnostic colonoscopies either via SC from January 6, 2014 through March 12, 2014 or EAC from September 24, 2014 through February 19, 2015. A total of 54 patients were excluded based on a personal history of CRC and prior resection, incomplete colonoscopy due to poor bowel preparation, and removal or loss of Endocuff (EC). Primary outcomes measured and compared were ADR and types of polyps found.

**Results:** The overall ADR in the EAC group was higher at 59.91% versus 50.66% for SC, accounting for a 9% increase (P=0.0508). EAC was able to detect a total of 59 sessile serrated adenoma/polyps (SSA/Ps) compared to SC only detecting 8 (P $\leq$ 0.0001). There was a significant increase in the SSA/P detection rate with EAC at 15% versus 3% in the SC group (P $\leq$ 0.0001).

**Conclusions:** EAC significantly increases the detection of SSA/P and has shown a trend in improving ADR in our veteran population.

**Keywords:** Colorectal cancer (CRC); Endocuff (EC); sessile serrated adenoma (SSA); adenoma detection rate (ADR); sessile serrated polyp; sessile serrated adenoma/polyps (SSA/Ps)

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#### Introduction

In the United States, colorectal cancer (CRC) is the third most common cancer diagnosis among both men and women and the second leading cause of cancer related deaths in the United States (1,2). Colonoscopy prevents CRC with studies showing that the removal of adenomatous polyps reduces CRC mortality (3). Among the many colonoscopy quality measures, adenoma detection rate (ADR) has a significant impact on reducing CRC, with studies showing that every 1 percent increase in ADR

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 Table 1 Study indications

| Indications       | EAC N [%] | SC N [%] | P value |
|-------------------|-----------|----------|---------|
| Screening         | 53 [24]   | 36 [16]  | 0.0273  |
| Surveillance      | 84 [39]   | 72 [32]  | 0.1400  |
| Abdominal pain    | 2 [1]     | 4 [2]    | 0.6857  |
| Diarrhea          | 3 [1]     | 12 [5]   | 0.0218  |
| FIT/FOBT positive | 36 [17]   | 51 [23]  | 0.1082  |
| Hematochezia      | 8 [4]     | 10 [4]   | 0.6870  |
| IDA               | 6 [3]     | 12 [5]   | 0.1720  |
| Other             | 25 [12]   | 28 [12]  | 0.7651  |

Other, changes in bowel habits, abnormal imaging findings, constipation, inflammatory bowel disease flare, rectal pain, weight loss. IDA, iron deficiency anemia; FIT/FOBT, fecal immunochemical test/fecal occult blood test; EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

decreases the risk for CRC by 3% (4,5).

Many accessories have been created to increase the detection of polyps and improve ADR. Among these the Endocuff overtube (MEDIVATORS) device has shown promise (6).

Our primary aim was to retrospectively compare ADRs and the distribution of polyp types with Endocuff assisted colonoscopy (EAC) and standard colonoscopy (SC) among a veteran population.

#### **Methods**

This study was designated as a Quality Improvement study by the Institutional Review Board (IRB) at the VA Loma Linda Health Care System (VALLHCS) and was approved by the IRB. We retrospectively reviewed patients who had received colonoscopies without Endocuff (EC) from January 6, 2014 through March 12, 2014 to compare to patients who underwent EAC from September 24, 2014 through February 19, 2015. Two staff endoscopists performed all procedures with experience using EC.

# **Patient** selection

A total of 442 patients undergoing routine screening, surveillance and diagnostic colonoscopy were included in the study (*Table 1*). We excluded patients with prior resection for CRC, poor preparations leading to incomplete colonoscopy, colonic strictures, or severe diverticulosis 637

leading to EC removal (Figure 1).

#### Endoscopic procedures

All patients in the Loma Linda VA system undergo split dose preparations with GOLYTELY (Braintree, New Jersey). Colonoscopies in both arms were performed with Olympus colonoscopes (190 series adult colonoscopes). Systems used for intraprocedural washing were the same for both endoscopists. The water exchange method was not used in either arm of the study. Patients were sedated either with moderate sedation using a combination of versed, fentanyl and Benadryl in a graded fashion to achieve adequate sedation, or with propofol in the presence of an anesthesiologist. A complete colonoscopy was defined as a colonoscopy that reached the cecum. The cecum was defined as identification of the ileocecal valve and the appendiceal orifice.

#### Measured outcomes

Statistical analysis was performed using SPSS (version 17), utilizing Chi-Squared and Fisher's exact test statistical analysis. Primary outcomes were to ascertain if EAC improves ADR, and to identify the distribution of polyp types found, i.e., tubular adenomas and sessile serrated adenoma/ polyps (SSA/P). We found a trend towards an increase in detection in the total number of SSA/Ps, and a SSA/P detection rate was calculated, defined as the percentage of colonoscopies that found at least one sessile SSA/P. Secondary outcomes were polyp detection rate (PDR), proximal colon ADR (cecum/ascending colon/hepatic flexure), distal colon ADR (transverse colon/splenic flexure/descending colon/ sigmoid colon/rectum), cecal intubation rates (CIR), and complications between both groups.

# Anatomy of the colon

The colon was divided into two segments, proximal and distal. The proximal colon was defined as the colon from the splenic flexure to the cecum. The distal colon was defined as the colon distal to the splenic flexure to the anal verge.

# Pathology

Pathologic slides were reviewed by four anatomic pathologists at the VALLHCS in both groups and were not



Figure 1 Study enrollment flow chart. EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

| Patient characteristics | EAC                 | SC                  | P value |
|-------------------------|---------------------|---------------------|---------|
| Median age (years)      | 65.00 (59.00–68.00) | 65.00 (60.00–69.00) | 0.0948  |
| Median BMI (kg/m²)      | 29.00 (26.60–32.26) | 30.01 (26.76–34.37) | 0.0761  |
| Gender, N [%]           |                     |                     | 0.0837  |
| Female                  | 11 [1]              | 21 [10]             |         |
| Male                    | 206 [95]            | 204 [91]            |         |

BMI, body mass index; EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

blinded. The same pathologists were involved during both time periods of the study. If discrepancies arose regarding pathologic diagnosis, especially SSA/P, a second opinion was obtained, and a consensus was put forth for diagnosis. If a hyperplastic polyp was diagnosed proximal to the splenic flexure, the endoscopist would ask to have the polyp reevaluated to determine if the polyp was a SSA/P.

# **Results**

#### Population/procedure characteristics

Out of the total population of 496 patients, 217 were

included in the EAC group and 225 were in SC group (*Figure 1*). There was a male preponderance in both groups with a lower number of females in the SC group that did not reach statistical significance (P=0.0837). The median age for both groups was 65 years (*Table 2*). Both EAC and SC groups had similar percentages of comorbidities (hyperlipidemia, diabetes, tobacco use and CKD). The EAC group was found to have a slightly larger number of patients with a positive family history of CRC but was not found significant (P=0.0531) (*Table 3*). A higher percentage of EAC underwent colonoscopy for screening than in the SC group (P=0.0273), whereas diarrhea as an indication

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| Patient characteristics | EAC N [%] | SC N [%] | P value |
|-------------------------|-----------|----------|---------|
| Diabetes                | 72 [33]   | 80 [36]  | 0.5991  |
| Chronic kidney disease  | 31 [14]   | 36 [16]  | 0.6154  |
| Family history CRC      | 38 [18]   | 25 [12]  | 0.0531  |
| Hyperlipidemia          | 138 [64]  | 143 [64] | 0.9420  |
| Opioid use              | 51 [24]   | 64 [28]  | 0.2364  |
| Tobacco use             | 59 [27]   | 47 [31]  | 0.1210  |

Table 3 Baseline clinical characteristics

CRC, colorectal cancer; EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

#### Table 4 Procedure characteristics

| Procedure characteristics | EAC, N [%] | SC, N [%] | P value |
|---------------------------|------------|-----------|---------|
| Procedure time (AM/PM)    | 135/82     | 157/68    | 0.0931  |
| Cecal intubation rate     | 214 [99]   | 221 [98]  | 1.000   |
| Quality of preparation    |            |           | 0.387   |
| Fair                      | 9 [4]      | 16 [7]    |         |
| Good                      | 206 [95]   | 208 [92]  |         |
| Poor                      | 2 [1]      | 1 [<1]    |         |

EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

Table 5 Types of polyps retrieved

| Polyp type                  | EAC | SC  | Chi squared | P value |
|-----------------------------|-----|-----|-------------|---------|
| ТА                          | 318 | 250 | 0.2537      | 0.6145  |
| TVA                         | 17  | 15  | 0.1728      | 0.6776  |
| Tubular adenoma<br>with HGD | 2   | 0   | -           | 0.5086  |
| Adenocarcinoma              | 2   | 0   | -           | 0.5086  |
| SSA/P                       | 59  | 8   | 28.5665     | <0.0001 |

TA, tubular adenomas; TVA, tubulovillous adenoma; SSA/ P, sessile serrated polyp & adenoma; EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

for colonoscopy was more predominant in the SC group (P=0.0218). All other indications were similar in both groups (*Table 1*). There was no statistical difference in the timing of the procedure (am/pm), and the preparation

Table 6 Procedure complications

| Complications | SC | EAC |
|---------------|----|-----|
| Bleeding      | 0  | 0   |
| Perforations  | 0  | 0   |

EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

quality (P=0.387). CIRs were similar in both groups, EAC at 99% *vs.* SC at 98% (P=1.000) (*Table 4*). Unfortunately, withdrawal times were unable to be retrieved.

# Polyp pathology

There were 59 SSA/P detected using EAC and only eight SSA/P using SC (Chi-square: 28.5665, 1; P value <0.0001). A similar number of tubular adenomas, tubulovillous adenomas, and adenocarcinomas were found in both groups (*Table 5*).

#### **Complications**

There were no reported complications related to EAC in our study period. The EC had to be removed in three cases due to severe diverticulosis (*Table 6*).

#### **Detection** rates

The SSA/P detection rate for EAC was 15% and for SC was 3%, accounting for an increase of 12% in the detection rates for SSA/P with EAC (P $\leq$ 0.0001). The PDRs between EAC (72.81%) and SC (72.44%) were not significantly different (P=0.9311). The ADR for EAC was 59.91% and for SC was 50.66%. Although this accounted for a 9% increase in ADR when using EAC, the difference was found not to be statistically significant (P=0.0508). The proximal colon ADR for EAC was higher by 7% compared with SC, it was not found to be significantly different (P=0.0927). Lastly, the distal colon ADR for EAC was higher only by 2% (P=0.5834) (*Table* 7).

#### **Pathologists**

There were a total of four anatomic pathologists during the review period in both groups. No difference was seen between SC and EAC in regard to pathologist distribution (P=0.2546) (*Table 8*).

| Table 7 Detect | tion rates |
|----------------|------------|
|----------------|------------|

| Table / Detection fates                       |            |           |                |             |         |
|---|------------|-----------|----------------|-------------|---------|
| Detection rates                               | EAC, N [%] | SC, N [%] | Difference (%) | Chi squared | P value |
| PDR   | 158 [73]   | 163 [72]  | 1              | 0.0075      | 0.9311  |
| ADR   | 130 [60]   | 114 [51]  | 9              | 3.8147      | 0.0508  |
| Proximal colon ADR                            | 81 [37]    | 67 [30]   | 7              | 2.8267      | 0.0927  |
| Distal colon ADR                              | 43 [20]    | 40 [18]   | 2              | 0.3008      | 0.5834  |
| Sessile serrated adenoma/polyp detection rate | 32 [15]    | 6 [3]     | 12             | 20.5128     | <0.0001 |

PDR, polyp detection rates; ADR, adenoma detection rates; EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

Table 8 Distribution of pathologists

| Pathologist | EAC, N [%] | SC, N [%] | P value |
|-------------|------------|-----------|---------|
| 1           | 36 [10]    | 28 [8]    | 0.2546  |
| 2           | 24 [7]     | 36 [10]   |         |
| 3           | 58 [16]    | 49 [14]   |         |
| 4           | 62 [18]    | 61 [17]   |         |

EAC, Endocuff-assisted colonoscopy; SC, standard colonoscopy.

# Discussion

This is the first study that demonstrates an increase in SSA/ P detection with the use of EC in a veteran population. EAC was able to detect a total of 59 SSA/Ps compared to SC detecting eight (P $\leq$ 0.0001), with a SSA/P detection rate of 15% with EAC and 3% with SC (P $\leq$ 0.0001). Even though we cannot entirely attribute the increase in detection solely on EAC given the inherent limitations of our study, we believe that EAC played a significant role in the increased detection of SSA/Ps. The suspected mechanisms that EAC improved polyp detection included but were not limited to, detection of polyps behind haustral folds by flattening the folds exposing polyps, and removal of mucus cap debris.

Improved detection of SSA/Ps has been observed in two studies involving cap-assisted colonoscopy, one when cap assisted colonoscopy was coupled with a water exchange technique, and a second from a post hoc analysis of a prior study (7,8).

Sessile serrated adenomas/polyps, which are characterized by their serrated and distorted saw tooth appearance in colonic crypts (9) are felt to be a distinct class of pre-malignant adenoma, accounting for one third of all sporadic colorectal neoplasms (10). SSA/Ps are difficult to detect given their innate characteristics using standard devices (11). They tend to be flat with minimal mucosal aberrations, found primarily in the proximal colon, and often have a mucus cap with adherent debris concealing the lesion (11). Prevalence rates for SSA/Ps are in the range of 1% to 22% (12-14) but currently there is no consensus on recommended SSA/ P detection rates. Interestingly the ADR does not include SSA/P detection, and may become a quality measure as we learn more about these lesions (13-15).

There are however recommended ADR targets. Increases in ADR are inversely correlated with CRC mortality and post colonoscopy CRC rates (4,14,16-19). These findings have led the American College of Gastroenterology Task Force on Quality in Endoscopy and the American Society for Gastrointestinal Endoscopy to update their ADR targets to >30% for men and >20% for women (20).

Since there has been a focus on ADR improvement, colonoscopic techniques, accessory technology and newer colonoscopes have been created to improve it. Some of these include: high-resolution endoscopic imaging, narrowband endoscopic imaging, wide-angle colonoscopes, high definition colonoscopes, third eye retroscopes, Full Spectrum Endoscopy, balloon assisted colonoscopy (G-Eye), second forward view of the right colon and cecal retroflexion (19,21-24). The latest accessory devices in this field are the transparent cap colonoscopy (Endocap) and EC. These newer devices are simple, disposable, and relatively inexpensive attachments to the standard colonoscope. Both devices report higher ADRs, minimal patient discomfort, low complication rates, high CIRs and no additional procedure time (6,25). Our study was able to reproduce an increase in ADR of 9%, although it did not reach statistical significance. Further prospective studies will need to be performed to determine which setting

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and patient characteristics would be best to use accessory technology, like EC during colonoscopy.

There are strengths to our study. We found a significant increase in the total detection of SSA/Ps, as well as the detection rate when compared to SC, which has not been described with the use of EAC. Furthermore, although our ADR and proximal colon ADR did not reach statistical significance there was a trend towards improvement with ADR at 9% as seen on previous studies (6) and proximal colon ADR at 7%. This may be secondary to our sample size and experience of the endoscopists. Even though withdrawal technique were not reported, we feel EAC may have a played an important role. This modest increase in ADR and proximal colon ADR has important implications as it may alter surveillance intervals in patients with adenomatous polyps and serrated lesions. Lastly, we demonstrated that EAC is a safe and inexpensive method to help detect these polyps and can be incorporated into standard practice immediately.

There are limitations to the assessment. The study was uncontrolled and retrospective in design; in order to validate our results further prospective studies need to be conducted to show a suspected increased SSA/P detection rate for use in standard CRC screening populations. This study was conducted in a veteran population, with a male predominance and multiple predisposing risks for adenomatous polyps, which may not translate into the general population.

Another limitation was the lack of inclusion of withdrawal time, as this has been shown to influence ADR. However, there is some controversy on withdrawal time itself influencing ADR, with evidence to show the techniques used during withdrawal and the quality of the examination to play a more significant role in increasing ADR (26). Even though we did not include withdrawal time or the techniques used during withdrawal we felt that the quality of the colonoscopies was high given a high CIR (98%) and a high ADR with SC (51%). Other limitations of the study are that the pathologists were not blinded to the results of the colonoscopy given the retrospective nature, and patients from EAC and SC groups were obtained from two different time periods, which could potentially bias the findings.

There was also a slightly larger population of patients in our EAC group with a positive family history of CRC, which may have influenced the prevalence of adenomas. Finally, our study included screening, surveillance and diagnostic exams. Further prospective studies in a screening population will be needed to appropriately evaluate the true effectiveness of EAC.

In conclusion, we observed an increase in detection of SSA/P with the use of EAC in a veteran population and a trend in improving ADR. Further prospective studies will be needed to study the SSA/P detection rates and ADR with EAC specifically in a screening population.

# **Acknowledgements**

None.

## Footnote

*Conflicts of Interest*: Jackson CS is a consultant for Endocuff by MEDIVATORS. The other authors have no conflicts of interest to declare.

*Ethical Statement:* This study was designated as a Quality Improvement study by the Institutional Review Board (IRB) at the VA Loma Linda Health Care System (VALLHCS) and was approved by the IRB (No. IORG0001204).

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