

**Comparison of Endocuff Vision to Medivators AmplifEYE for detection of precancerous colorectal polyps.**

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## **Comparison of Endocuff Vision to Medivators AmplifEYE for detection of precancerous colorectal polyps.**

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### **Background**

Endocuff Vision is a disposable device that fits over the end of a colonoscope. A row of flexible fingers extending from the device is used to flatten and deflect haustral folds during colonoscope withdrawal, which has been shown to improve adenoma detection, as well as detection of serrated polyps.

The Amplifeye device is a less expensive competitive device of similar design to the Endocuff Vision. Both Endocuff Vision and Amplify devices are FDA approved.

In this study, we propose to compare the Endocuff Vision and the Medivators AmplifEYE device in a randomized controlled trial using adenomas per colonoscopy as the primary endpoint. If the adenomas per colonoscopy with the Medivators device is shown to be non-inferior to Endocuff Vision, then the less expensive Medivators device could be used in place of the Endocuff Vision.

Both devices have been considered to be safe for use in clinical practice. Clinical trial evidence showing benefits of the Amplifeye device compared to no device have not been demonstrated.

### **Methods**

This will be a randomized controlled trial in patients age 40 and older undergoing colonoscopy for screening, surveillance, or diagnostic reasons. They will be randomized to one of two arms, i.e. High Definition colonoscopy with Endocuff Vision or High Definition colonoscopy with AmplifEYE.

A member of the research team will approach a potential subject to discuss participation in the study, including background of the proposed study, inclusion and exclusion criteria, benefits and risks of the procedures and follow-up. Prior to study enrollment, a subject must sign an informed consent document, which details the essential aspects of this study. The informed consent document will have prior approval of the study site's Institutional Review Board (IRB). Failure to obtain informed consent renders the subject ineligible for the study.

Data collected will include the type of scope used (adult versus pediatric); age; gender; indication; history of prior abdominal surgery and type; and identification of diverticulosis classified as mild, moderate, or severe. Additionally, exam time including insertion time, total procedure time, overall withdrawal time, and inspection time (withdrawal time minus anytime suctioning, cleaning, and diagnostic biopsy or therapeutic procedure) as well as retroflexion completion rates (ability to complete retroflexion) will be recorded. For each polyp, we will record the location, size, shape, and pathology. The bowel preparation will be evaluated and graded according to the Boston Bowel Preparation Scale. Complications including any mucosal trauma from the high definition colonoscope with Endocuff Vision or with AmplifEYE, perforation or gastrointestinal bleeding (requiring intervention) will be recorded.

## **Objectives**

The *primary endpoint* will be the number of conventional adenomas per colonoscopy of the Endocuff Vision Colonoscopy compared to that of the AmplifEYE colonoscopy. Adenomas per colonoscopy is calculated as the total number of adenomas detected divided by the total number of colonoscopies.

*Secondary endpoints* will include the following:

- Adenoma detection rate (calculated as the percentage of colonoscopies in which at least one adenoma was detected)
- Complications encountered during procedure (i.e., mucosal trauma, perforation, or gastrointestinal bleeding)
- Ability to pass device through the sigmoid colon (success rate of the device passing the sigmoid colon of the large intestine)
- Polyp detection rate
- Polyps per colonoscopy
- Exam times
  - *Total procedure time* – Total time of procedure from insertion to withdrawal
  - *Cecal insertion time* – Time of colonoscope insertion (from insertion into the rectum to the cecum)
  - *Overall withdrawal time* – Total time of colonoscope withdrawal (from cecum until the scope is withdrawn from the rectum)
  - *Inspection time* – Inspection time is defined the same as withdrawal time, but with the clock stopped for washing, suctioning, and polyp removal (or other non-inspection related activities)
- Cecal intubation rate (the success rate of reaching the cecum)
- Detection of serrated and flat lesions
- Retroflexion completion rate (ability to complete retroflexion)

## **Criteria**

All colonoscopies in the study will be done by Dr. Douglas Rex. Patients will be 40 and older and will be randomized to receive colonoscopy with the AmplifEYE device or with the Endocuff device.

### **Inclusion criteria**

- Undergoing colonoscopy for screening, surveillance, or diagnostic reasons
- Ability to provide informed consent
- 40 years and older

### **Exclusion criteria**

- Active inflammatory bowel disease
- Prior surgical resection of the colon
- Referred for resection of a polyp identified by another physician
- Referred for a previous incomplete colonoscopy
- History of polyposis syndrome or HNPCC

## **Randomization**

Once a patient has been screened to ensure the inclusion and exclusion criteria have been met and has provided consent for participation in the study, the subject will be randomized in a 1:1 ratio. Randomization outcomes include the Endocuff Vision Colonoscopy or the AmplifEYE Colonoscopy.

### **Statistical Analysis & Sample Size**

The primary endpoint will be the number of conventional adenomas per colonoscopy. Based on previous data (1) we estimate that the Endocuff Vision will result in an APC of 2.3. We consider that a clinically acceptable ADR for the Medivators device would be within 20% of this value or 1.84. To demonstrate non-inferiority, a sample size of 588 patients should be randomized.

With a sample size of 294 patients per group, the study will have 80% power to detect non-inferiority between the two groups, assuming tests using a one-sided two-sample t-test, a coefficient of variation 1.5 for both groups, and a noninferiority margin of 20%.

The number of conventional adenomas per colonoscopy will be compared between the Endocuff Vision and AmplifEYE groups using a two-sample t-test on the log-transformed adenoma count. Similar analyses will be performed for the number of polyps, serrated lesions, and flat lesions per colonoscopy. Two-sample t-tests (or Wilcoxon Rank Sum tests if non-normally distributed) will be used for comparisons of exam times. Chi-square tests will be used to compare the groups for differences in adenoma, polyp, serrated lesion, and flat lesion detection rates; complications; ability to pass the device through the sigmoid colon; and cecal intubation rate. A 5% significance level will be used for all tests.

In order to account for patient withdrawals, 20 additional patients will be enrolled in the study to ensure sufficient data will be included in the analysis.

### **Data Integrity and Safety**

Data will be collected onto paper Case Report Forms and then entered into an excel spread sheet. There will be a weekly copy of the data saved onto the shared drive. All paper charts pertaining to the patient will be kept under lock and key in coordinators office away from the endoscopy area. The data entry will be performed into an excel file which will be stored on an internal network drive with encryption and password security. Only approved personnel by the IRB will have access to the file storage. This file will also not have any identifiable patient information. A study log with the identifiable information will be kept in a separate folder to enable the investigators to assist in any research audit. No procedural data except the date of examination will be entered into this log.

Any subject who wishes to withdraw from this investigation on his/her own accord and for whatever reason is entitled to do so without obligation and prejudice to further treatment. In addition, the Investigator may decide for reasons of medical prudence, to withdraw a subject. In either event, the Investigator will clearly document the date and reason(s) for the subject's withdrawal from this investigation in the CRF and should indicate whether or not he considers it was related to the study interventions.

### **References:**

- (1.) Rex, D.K., et al. High-definition colonoscopy vs. Endocuff vs. EndoRings vs. Full-Spectrum Endoscopy (FUSE) for adenoma detection at colonoscopy: a multicenter randomized trial. *GIE* 2018 in press.