

Prospective Randomized controlled trial of High-Definition White-light colonoscopy versus High-Definition White-light colonoscopy with Endocuff Vision for endpoints of procedural times

NCT03361917

Prospective Randomized controlled trial of High-Definition White-light colonoscopy versus High-Definition White-light colonoscopy with Endocuff Vision for endpoints of procedural times

Primary Investigator:

Dr. Douglas Rex,
Indiana University Hospital
Indianapolis, IN 46202

Introduction:

Endocuff Vision (Olympus) is a disposable device that has 8 independently moving soft flexible arms arranged in a single row. The device comes in several sizes and can fit the tips of most commonly used colonoscopes. During intubation, the arms fall flat to the body of the scope as not to impede forward motion. Endocuff Vision is an FDA approved device that fits over the end of a colonoscope and has flexible soft fingers that project from the sides. These fingers can be used to pull back the folds in the colon and expose mucosa on the proximal sides. A number of studies indicate that Endocuff improves the adenoma detection rate (ADR) during colonoscopy. In a non-randomized retrospective evaluation, Endocuff resulted in better detection, faster insertion, and faster inspection (1).

Our aim in this study is to show in a prospective randomized trial Endocuff Vision could improve insertion because during loop withdrawal the cuff tends to stabilize the position of the tip, preventing its backward movement and speeding loop removal. Similarly, during inspection, the main goal is to evaluate the proximal sides of folds and flexures. The process is made easier and quicker by the device. Third, during polypectomy, Endocuff Vision helps to stabilize the position and the scope tip.

Methods:

This will be a prospective, randomized controlled study. Subjects referred for screening or surveillance colonoscopy will be prospectively enrolled. They will be randomized to one of two arms, i.e High Definition colonoscopy or High Definition colonoscopy with Endocuff Vision.

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. If this is of interest to the subject, the informed consent form is discussed and presented. The subject must sign the consent form prior to enrollment. This form 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

Objectives:

Primary objectives of the study are:

- To compare the insertion time, inspection time, the total time per polypectomy, and the total procedure time during High Definition colonoscopy with Endocuff Vision versus standard High Definition colonoscopy.

Secondary objectives:

- To compare the number of adenomas detected per subject with High Definition Endocuff Vision compared to Standard High Definition colonoscopy.
- To compare the detection rates for polyp subtypes (including advanced adenomas, serrated polyps, right sided adenomas, etc) for High Definition Endocuff Vision compared to Standard High Definition colonoscopy.

Primary End-point:

- The inspection time will be shorter because the proximal sides of the folds are more quickly exposed with Endocuff Vision compared to standard colonoscope alone because of the ability of the Endocuff Vision to stabilize the position of the colonoscope tip during loop withdrawal, thus preventing its backward movement and speeding loop removal.

Criteria:

All colonoscopies in the study will be performed by a qualified professional. Patients will be 40 and older and will be randomized to receive colonoscopy with or without the Endocuff. Data collected will include the type of scope used (adult versus pediatric), age, gender, indication, history of prior abdominal surgery and type, identification of diverticulosis classified as mild moderate or severe, insertion time, total procedural time, total withdrawal time, inspection time (withdrawal time minus anytime suctioning, cleaning, and diagnostic biopsy or therapeutic procedure), and polypectomy time for each polyp removed. For each polyp, we will record the location, size, shape, and pathology.

Inclusion criteria

- Referral for screening or surveillance colonoscopy
- Ability to provide informed consent
- 40 years and older

Exclusion criteria

- Prior history of colon cancer
- History of inflammatory bowel disease
- Prior surgical resection of any part of the colon
- Use of anti-platelet agents or anticoagulants that precludes the removal of polyps during the procedure
- History of polyposis syndrome or HNPCC
- Inability to give informed consent
- Family history of colon cancer in a first degree relative < 60 years or two first degree relatives with colorectal cancer

Statistical Analysis and Sample Size:

- Normally distributed continuous variables will be summarized using means and standard deviations while non-normally distributed continuous variables will be summarized using medians and ranges.
- The primary endpoints for the study will be the inspection time and insertion time, , the total time per polypectomy, and the total procedure time.
- The secondary endpoints will be total time per polypectomy, total procedure times, and adenomas detected.
- All colonoscopies in the study will be performed by a qualified professional. Patients will be 40 and older and will be randomized to receive colonoscopy with or without the Endocuff. Data collected will include the type of scope used (adult versus pediatric), age, gender, indication, history of prior abdominal surgery and type, identification of diverticulosis (classified as mild moderate or severe), insertion time, total procedural time, total withdrawal time, inspection time (withdrawal time minus anytime suctioning, cleaning, and diagnostic biopsy or therapeutic procedure), and polypectomy time for each polyp removed. For each polyp, we will record the location, size, shape, and pathology.

There will be a sample size of 200 subjects enrolled in this study. 100 randomized into two groups. With the sample size of 100 per group, the study will have 80% power to detect a 1 minute difference in the inspection time between the two groups. The inspection and insertion times will be compared using a two-sided two sample t-test, 5% significance level, and standard deviation of 2.5 minutes.

The data will be analyzed and the statistics performed by persons in the biostatistics department.

Safety Risks to the patient and Data integrity:

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. Data management will include double data entry and regular back-up of the data. Only approved personnel by the IRB will have access to the file storage. This file will also not have any identifiable 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). ZP Tsiamoulos et al. Gastrointest Endosc. 2017 Apr 13. Impact of a New Distal Attachment on Colonoscopy Performance in an Academic Screening Center