Colonoscopy in the prone position for patients with BMI >30 is superior to standard left lateral decubitus position

Protocol: IRB-HSR 20078

10/4/2017

PROTOCOL

Background

1. Provide the scientific background, rationale and relevance of this project.

In the United States, colonoscopy has become the most commonly used screening test for colorectal cancer (7). Colonoscopy is typically performed with the patient starting in the left lateral decubitus position, however there is little data to support this practice. Throughout the colonoscopy, patients are often re-positioned in a variety of ways (shifted into a prone or supine position) to facilitate passage of the endoscope. There are a number of patient characteristics that are known to make colonoscopy more technically challenging necessitating positional changes, including female gender, prior abdominal or pelvic surgery, and BMI > 30. Despite these differences, there is minimal data in the literature to guide endoscopists regarding which patient positioning strategies to employ based on individual patient characteristics. It is estimated that 35% of adult men and 40.4% of adult women were identified during recent a recent study to fall into the "obese" category with BMI ≥30 (8). Patient repositioning and application of pressure to the abdomen, another frequently used technique, can be particularly difficult for endoscopy staff to employ in a sedated, obese patient (9). The time from starting the colonoscopy until the colonoscope is advanced to the cecum, cecal intubaton time, is standardly recorded during colonoscopy. Longer cecal intubation times reflect more technically challenging procedures.

Several published studies investigating the Trendelenburg position (1) suggested decreased cecal intubation time, particularly in patients with significant sigmoid diverticulosis. However this technique revealed the increased occurrence of transient oxygen desaturation in obese patients which limited its use in this population. The right later decubitus position is frequently used to help advanced of the endoscope within the cecum or into the terminal ileum (2). In particular, women and patients who have previously undergone abdominal surgery seemed to benefit from right lateral decubitus position with improved cecal intubation times (4).
The prone position has been shown to successfully reduce ileal intubation times in a study involving 150 patients (3) regardless of BMI.
One study in particular (5) completed in 2012 at the North Texas VA Medical center showed patients with a BMI of >30 had shorter cecal intubation times and decreased need for re-positioning when colonoscopy was performed in the prone position. This study patient population was limited to all male veterans. The proposed mechanism is that of redistribution of abdominal pressure prevent loop formation, which should extrapolate to female patients as well.
This study reported no procedural sedation or airway related complications. It has been postulated that the prone position may actually be associated with a lower risk of obstructive apnea during sedation since the tongue is less likely to fall back (6).
Cecal intubation time is frequently used as a target metric for improvement in endoscopy as a shorter procedure in turn reduces length of time sedation is required.

Objectives/Hypothesis

Prone position of both male and female patients with BMI >30 will be less technically difficult in the prone position than in the more commonly used left lateral decubitus position. This will result in a more comfortable

patient experience as well as a reduced procedure times resulting in decreased need for sedation. There is no expected difference in complication rate for either position.

Study Design: Biomedical

1. Will controls be used?Yes

►IF YES, explain the kind of controls to be used.
Study participants will be randomized to either left lateral decubitus or prone position at the time of colonoscopy. Patients randomized to left lateral decubitus position will be consider the controls.

2. What is the study design?
Randomized control study

3. **Does the study involve a placebo?**No

Human Participants

Ages: 18-90
Sex: Any
Race: Any

Subjects- see below

INSTRUCTIONS: For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

1. Provide target # of subjects (at all sites) needed to complete protocol.150

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.
Expect 20% of screened patients will qualify and consent to participate in the study

3. How many subjects will be enrolled at all sites? 150

4. How many subjects will sign a consent form under this UVa protocol? **150**

Inclusion/Exclusion Criteria

1. List the criteria for inclusion

- Willingness and ability to comply with scheduled visits and study procedures.
- BMI >30
- Undergoing screening or diagnostic colonoscopy at UVA as part of clinical care

- Adults aged 18-90

2. List the criteria for exclusion

- Pregnant women (self reported).
- Cognitively impaired
- Hx colonic resection
- Cannot lay in prone position
- Hx of colon malignancy
- Procedure aborted due to bowel prep
- Severe pulmonary problems (baseline oxygen use)
- Inablility to consent

3. List any restrictions on use of other drugs or treatments.None

Statistical Considerations

1. Is stratification/randomization involved?

Yes – Randomization only

►**IF YES, describe the stratification/ randomization scheme.**

Study participants will be randomized to either left lateral decubitus or prone position at the time of colonoscopy. Randomization order will be computer generated with allocation concealment using sequentially numbered, sealed envelopes. Patients and co-investigators performing colonoscopy will not be blinded.

►**IF YES, who will generate the randomization scheme?**

____x_ Other*:* PI

2. What are the statistical considerations for the protocol?

-Prospective Randomized trial.
-Enrolled participants will be randomized to colonoscopy in the left lateral decubitus or prone position.
-The primary endpoint is cecal intubation time. Cecal intubation time is standardly recorded during all colonoscopies. Null hypotheses is that there will be no difference in cecal intubation times between the 2 groups. To detect an effect size of 60 seconds difference between the 2 groups (left later decubitus vs prone position) with a standard deviation of 120 seconds for the average colonoscopy = ~125 total study participants - 63 per group (alpha = 0.05 / type I error rate). Type II error rare: 0.2. Goal to enroll 150 to adjust for variability in cecal intubation time.

-Two secondary endpoints will be measured: complication rate in each group as well as sedation use.
-Complications during the procedure will be noted and charts will be reviewed for complications occurring within 30 days of the procedure. Complications will be recorded as either present vs absent.
-Sedation use is standardly recorded during all procedures. This is record as mg of fentanyl and mg of midazolam.

3. Provide a justification for the sample size used in this protocol.
To detect an effect size of 60 seconds difference between the 2 groups with a standard deviation of 120 seconds for the average colonoscopy = 125 total study participants - 63 per group (alpha = 0.05). Goal to enroll 150 to adjust for variability in cecal intubation time.

4. What is your plan for primary variable analysis?

T test for comparison of mean cecal intubation time in each group.

5. What is your plan for secondary variable analysis?

T test for comparison of mean amount of sedation used in each group as well as number of adverse events/ complications

6. Have you been working with a statistician in designing this protocol?No

7. Will data from multiple sites be combined during analysis? no

Study Procedures-Biomedical Research

1. What will be done in this protocol?
Patients that have been scheduled for colonoscopy will undergo chart review by the co-investigator (GI attening) scheduled to perform the colonoscopy or the GI fellow. Patients who meet inclusion criteria will be invited to participate at the time consent is obtained for the colonoscopy. Participants will then be randomized to one of two colonoscopy starting positions.
After randomization, patients will begin the colonoscopy in either the prone position or left lateral decubitus position.
Adjusting patient starting position to the prone rather than left lateral decubitus position is not expected to result in any additional risk to the patient beyond the standard risks related to colonoscopy. It is common practice to re-position the patient during endoscopy (including supine and prone positions) and some endoscopists commonly employ prone starting position for obese patients, although there is no estimate in the literature as to the prevalence of this practice.

No additional interventions will be performed for research purposes.
During the colonoscopy, the endoscopist will be allowed, as usual, to adjust patient position as needed to complete the procedure. Cecal intubation time, amount of sedation used, and any intra-procedural complications (hypoxia, hypotension, etc) will be recorded for data analysis. This information is standardly recorded in the procedure report in the patient's medical record. The study will not affect any interventions performed during the colonoscopy such as polyp removal or biopsies as, clinically indicated. Per endoscopy unit protocol, patients will be monitored in the recovery area and discharged home with supervision. The study requires no further direct patient interaction after the colonoscopy is completed. Charts will be reviewed at 30 days to assess for any delayed and unexpected complications.

2. **If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.** N/A

Subject Compliance with Study Procedures

1. **Explain how the study team will monitor the subject for compliance with the study procedures.** Patient compliance is only requiring at the time of the colonoscopy. The performing endoscopist will note of patient is not able to comply with starting position per randomization.

2. **Describe criteria for when a subject is considered to be non-compliant with study procedures.** N/A

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