

LONGER RIGHT COLON WITHDRAWAL TIME AND RETROFLEXION  
DURATION SIGNIFICANTLY INCREASES ADENOMA DETECTION  
RATE: A RANDOMIZED CONTROLLED TRIAL AT  
THREE ENDOSCOPY CENTERS

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By

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ABSTRACT

**Purpose**

Detection of adenomas is the foundation of colorectal cancer screening utilizing screening colonoscopies. Adenoma detection rate (ADR) is an increasingly utilized core quality measure for colonoscopies. Colonoscopy is an effective tool to prevent colon cancer but missed lesions can lead to development of interval colon cancer. These missed lesions are particularly in right-side of the colon. Careful examination of the right colon is recommended but the ideal withdrawal time for the right colon is unknown.

**Design /Method**

We conducted a prospective, randomized controlled trial in patients undergoing screening or surveillance colonoscopies for colorectal cancer at three hospitals. Adenoma detection rate was defined as the proportion of colonoscopies in which adenomas were detected, compared to all colonoscopies. ADR was compared in patients with < 3mins right colon (up to hepatic flexure) withdrawal time, to patients with  $\geq$  3mins right colon withdrawal time. Time spent from identifying the appendiceal orifice till the start of withdrawal, which included time spent intubating the terminal ileum and examining the ileum, was excluded as this time is usually not used to identify polyps. A secondary end point was to

observe if retroflexion for  $\geq 30$  seconds compared to  $< 30$  seconds improved ADR in the right colon.

## Results

A total of 250 patients after randomization were included in the analysis. This sample included 135 patients in the  $< 3$  minute right colon withdrawal group (RCWG) and 115 patients included in the  $\geq 3$  minute RCWG. Adenoma detection rate in the right colon was 33% if the right colon withdrawal time was  $\geq 3$ mins compared to 14% if it was  $< 3$  mins; the likelihood of finding right-sided adenomas was 3 times greater in the  $\geq 3$  min group compared to the  $< 3$  min group, (OR 3,  $p < 0.001$ , 95% CI 1.62-5.64). The adenoma detection rate in the right colon was also significantly higher when the modified right colon withdrawal time was used in  $\geq 3$ mins group vs.  $< 3$ mins group which also showed that the  $\geq 3$ mins group was 3 times more likely to find adenomas in the right colon compared to the  $< 3$  min group (OR 3,  $p < 0.001$ , 95% CI 1.62-5.64). Adenoma detection rate in the right colon was 45% when retroflexion was performed for  $\geq 30$  seconds compared to 23% in the group where it was performed for  $< 30$  seconds (OR 2.8,  $p = 0.01$ , 95% CI 1.26 – 6.0). Polyps that were seen only on retroflexion, which could not be seen on forward view, were significantly more likely to be found in the  $\geq 30$  second group (22%,  $n = 8$ ) compared to the  $< 30$  second group 3%,  $p < 0.001$ .

## Conclusion

Adenoma detection rate in the right colon was significantly higher when three minutes or more were spent examining the right colon during withdrawal. Significantly higher rates were seen even after taking polypectomy into account and in the average risk

screening population. Adenoma detection rate in the right colon was also significantly improved when retroflexion was performed for more than 30 seconds.

## APPROVAL PAGE

The faculty listed below, have examined a thesis titled, “Longer Right Colon Withdrawal Time and Retroflexion Duration Significantly Increases Adenoma Detection Rate: A Randomized Controlled Trial at Three Endoscopy Centers” presented by Mir Fahad Faisal, candidate for the Master of Science degree, and certify that in their opinion it is worthy of acceptance.

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## CHAPTER 1

### INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer related death in the United States.<sup>1</sup> Colonoscopy is considered the test of choice for screening for colon cancer<sup>2,3</sup> with the objective to reduce incidence and mortality from colorectal cancer.<sup>4</sup> The incidence of colorectal cancer has been shown to have progressively decreased in the United States since screening recommendations for colorectal cancer were first introduced in the 1970's. Adenomas are precursor lesions that can predict the risk of CRC, and removal of adenomatous polyps can reduce the occurrence of CRC by over 50%.<sup>2,5</sup> Therefore removal of precursor lesions can lead to prevention of colon cancer or detection at an early stage.<sup>4,6</sup> Adenoma detection rate (ADR) is an increasingly utilized core quality measure for colonoscopies.<sup>3</sup> United States has achieved the highest rates compared to other countries of adherence to screening recommendations of 60%.<sup>6</sup> However, missed rate of adenomas can be as high as 30%;<sup>2,5</sup> colonoscopies provide inadequate protection from right-sided colon cancer in particular.<sup>4,7,8</sup> In a large study at 13 centers in the United States, there were large variations (from 7.4% to 52.5%) found in adenoma detection rates among 136 gastroenterologists.<sup>1</sup> Each 1% increase in ADR was associated with 3% decreased risk of cancer; a 5% decrease in colorectal cancer death and adjusted hazard ratio was 0.52 (95% CI 0.39 to 0.69) was found when endoscopists from the highest quintile were compared to the endoscopists in the lowest quintile of ADR.<sup>1</sup>

The right side of the colon can be difficult to evaluate fully due to technical difficulty and maneuverability. A colonoscopy can provide a reduction in incidence and

mortality from colon cancer by 80% in the left colon but only 40-60% in the right colon.<sup>4,9,10</sup> Therefore, there is emphasis on improved examination of the right side of the colon but data are lacking on tools and techniques that can help improve the adenoma detection rate on the right side.

Withdrawal time is the time spent examining the colon during the screening process and is usually the time from identifying the appendiceal orifice until the withdrawal of the colonoscope to complete the exam. Some centers define withdrawal time as the time from examining the terminal ileum until the end of the exam, as occasionally intubating the terminal ileum can be challenging and this time is not spent examining the colon. A withdrawal time of at least six minutes has been shown to improve adenoma detection rate, but the ideal withdrawal time for the right side of the colon is unknown. Retroflexion in the ascending colon has been shown to improve adenoma detection rate,<sup>11</sup> but the optimal time for examining the right side of the colon during retroflexion is also unknown.

CHAPTER 2  
REVIEW OF LITERATURE

**Background**

Colon cancer is a leading cause of cancer death in males and females.<sup>1</sup> Colon cancer also creates a significant burden on the health care system. Colonoscopy has been shown to be an effective tool in decreasing the disease burden and improving mortality.<sup>4</sup> Adenomas are precursors to colon cancer in about 70% of colon cancer cases,<sup>12</sup> and the goal of screening is to remove adenomas and either prevent colon cancer or to detect lesions at an earlier stage. Colonic lesions on the right side of the colon have a significantly higher risk of being missed which is attributed at least in part to technical difficulty and colonic folds.<sup>4,9,13</sup>

**Epidemiology**

Risk of colon cancer increases with age and incidence varies in different parts of the world. According to the GLOBOCAN statistics, which estimate global cancer incidence and mortality, colorectal cancer accounts for about 1.31 million new cases per year worldwide and about 694,000 deaths per year. Colorectal cancer is more common in men compared to women and risk is also higher in African Americans compared to other race/ethnic groups. In the United States, it accounts for 134,000 cases per year and about 55,000 cancer deaths. The incidence and mortality from colon cancer worldwide is increasing whereas in the United States has decreased by 2.5-4% per year over the past 15 years.<sup>13</sup>

There has been a decrease in incidence in the United States with the incidence reduced from 87.3/100,000 cases in 1975-1979 to 53.2/100,000 cases in 2010-2013.<sup>14</sup> Colorectal cancer is higher after the ages of 40-50 years which explains why screening guidelines recommend global screening above the age of 50. The incidence in the population under the age of 50, however, has been increasing.<sup>14,15</sup> Left sided colon cancers are more common than right sided cancers, but there has been a trend towards increasing number of right sided colon cancers more recently.<sup>16</sup>

### **Pathogenesis**

Colorectal cancer most commonly arises from benign polyps in the colonic mucosa which develop into cancer over a period of many years. Adenomas precede colon cancer in 70% of cases.<sup>12</sup> Tubulovillous adenomas and sessile serrated polyps can also precede colon cancer development. Hyperplastic polyps are type of polyps that are largely not thought to progress to colon cancer. An adenoma takes more than 10 years to transform into a cancerous lesion<sup>4</sup> but can be earlier in familial cancer disorders. Therefore, a colonoscopy is recommended every 10 years in the average risk population; the screening interval is shortened if there is family history of colon cancer, personal history of colon polyps or the patient has a familial cancer disorder.

Various factors play a role in the adenoma to carcinoma sequence and include gene mutations, epigenetic alterations and local inflammatory changes.<sup>17</sup> Traditional tubular adenomas are initiated either after biallelic inactivation of the Adenomatous Polyposis Coli (APC) tumor-suppressor gene or by chromosome instability which in turn leads to gain and loss of genes, parts of a chromosome or whole chromosomes.<sup>17</sup> Sessile

serrated polyps are associated with CIMP (CpG Island Methylator Phenotype). Other genomic instabilities responsible for transformation of colonic epithelium to pre-cancerous or cancerous lesions are chromosomal instability, microsatellite instability, non-microsatellite instability, hypermutability, aberrant DNA methylation and global DNA hypomethylation.<sup>17,18</sup>

Chromosomal instability is the gain of one or more chromosomes or multiple structural abnormalities; it accounts for about 85% of all colorectal cancers.<sup>18</sup> Polyposis syndromes carry a high risk of colorectal cancer and these syndromes have specific gene involvement. Familial adenomatous polyposis syndrome (FAP) carries a nearly 100% risk of cancer in affected individuals, and average age of symptoms is at 16 years of age. APC gene, which is on chromosome 5, is also involved. Patients affected by this FAP require a total colectomy at a young age when the first polyp is found.

Attenuated FAP is a variant of FAP which also affects chromosome 5, but the site of mutation is different from the APC site. Lynch syndrome is more common than FAP, and the genes affected are the mismatch repair genes (i.e., hMLH1, or hPMS2, hMSH2 or hMSH6). Lynch syndrome is autosomal recessive compared to FAP which is autosomal dominant. Lynch syndrome causes adenomas in the right side of the colon more commonly, and risk of colorectal cancer is highest in middle age (30-39 years) and decreases thereafter.<sup>19</sup> MUTYH (mutY homolog) associated polyposis is an autosomal recessive disorder caused by mutation in the MUTYH gene which is a base excision repair gene that can damage the APC gene. Colorectal cancer risk is also higher in patients with long standing inflammatory bowel disease, previous abdominal radiation, transplant patients, obesity, red meat where a high fiber diet can be protective.

## **Clinical Presentation, Diagnosis and Staging**

A high index of suspicion is needed for early diagnosis of colon cancer as the clinical presentation can be variable and subtle. Early diagnosis can be made when patients get a screening colonoscopy.<sup>4,6</sup> Fecal-based screening tests, imaging studies for screening and other endoscopic approaches as discussed previously can also lead to early detection. Patients diagnosed during screening procedures are often asymptomatic at the time of diagnosis. However, the majority of patients (86%) under the age of 50 years who are diagnosed are likely to be symptomatic at the time of diagnosis and have worse outcomes due to the typical later stage of disease at diagnosis.<sup>20</sup> Patients can also present with iron deficiency anemia from chronic blood loss from the tumor. Presentation with intestinal obstruction or an acute GI bleeding is also encountered. Symptoms from unchecked growth of the cancer can lead to constipation and large bowel obstruction. Right sided lesions are more likely to present as iron deficiency anemia while left sided lesions are more likely to present with obstruction and malignant strictures. Patients presenting with obstruction can also present with abdominal pain, nausea and vomiting. Patients with more distal lesions, especially in the rectum, present with hematochezia.

If the disease is diagnosed late, patients can present with symptoms resulting from metastatic spread. This can include liver abnormalities, lung nodules, bony lesions or peritoneal lesions. These patients can also present with jaundice, shortness of air, bone pain or abdominal pain.

Diagnosis is usually made by colonoscopy or cross-sectional imaging. Even when imaging shows characteristic features of colon cancer, a colonoscopy is still usually pursued for tissue acquisition. A colonoscopy can also diagnose synchronous or meta-



synchronous lesions. If a patient is a candidate for resection, a colonoscopy can also localize the extent of the tumor, mark the sites of resection with tattoos and remove other polyps. Often times a malignant lesion will have a characteristic appearance but pathology is always obtained when possible. If a colonoscopy is unable to be completed, a double contrast barium enema, CT colonography or a colonic capsule can be used. Tumor markers including carcinoembryonic antigen (CEA) and carbohydrate antigen 19-9 (CA 19-9) can aid in diagnosis, but they have low sensitivity.<sup>21</sup> If advanced disease is suspected, a CT chest, abdomen and pelvis must be obtained for staging.

The TNM staging system is the most widely used and it classifies disease from Stage 0 to stage IV (see table on page 31 that is taken from [emedicinenet.com](http://emedicinenet.com)). T in the staging system indicates the primary tumor, N describes involvement of regional lymph nodes and M identifies presence or absence of distant metastasis.

### **Management**

Management is directed by stage of the cancer. Signs and symptoms along with the cancer stage are also taken into account when directing a management strategy.

Larger polyps are more likely to have malignant potential compared to smaller adenomas of <5mm.<sup>22</sup> When the disease is localized to the mucosa or at a focal point within a polyp (carcinoma in situ), endoscopic resection can be curative in some cases especially when the resection margins are cancer free. Endoscopic submucosal dissection (ESD) or endoscopic mucosal resection (EMR) can be used to remove large polyps and lesions amenable to endoscopic resection. Surgical resection is more commonly used for resection of the involved segment and regional lymph nodes. Surgery can result in a colo-colonic or ileo-colonic anastomosis, or it can lead to a temporary or permanent

colostomy depending on the location of the cancer, stage and local involvement. When there is wide spread metastasis, surgical management may be pursued if there are signs of bowel obstruction or bleeding from the cancer. When patients present with colonic obstruction from colon cancer, a colonic stent placed endoscopically is a reasonable approach in select patients, especially in patients who are not good surgical candidates. Risks and benefits should be discussed thoroughly with the patient and family before a treatment plan is made.

The role of adjuvant chemotherapy is most studied in stage III with lymph node positive disease where chemotherapy after surgical resection has been shown to reduce recurrence by targeting micrometastases and reducing mortality by 22-32%. Chemotherapy is not used in stage I disease and is controversial in stage II disease. The most commonly used chemotherapeutic options are 5 fluorouracil and oxaliplatin, and the most commonly used preparation is FOLFOX (oxaliplatin, 5FU and leucovorin). The role of radiation therapy in patients with colon cancer is usually limited to patients with rectal cancer especially at advanced stages.

According to data from the American Cancer Society, 5 year survival of patients with stage I colon cancer is 92% compared to only 11% at stage IV. Rectal cancers also have similar prognosis. This emphasizes the importance of early detection and management.

### **Adenoma Detection Rate in Colonoscopies**

Colonoscopy is an effective tool for reducing the burden of colorectal cancer and reducing mortality.<sup>4</sup>Polypectomy (complete removal of a polyp)during colonoscopy is the most effective intervention for preventing colorectal cancer.<sup>14</sup>The 10 year colon cancer

related death rate decreased by 53% when patients undergoing colonoscopy and polypectomy were compared to the general population in a large case control study.<sup>6</sup> Adenoma detection rate is the benchmark for measuring the quality of endoscopy. Adenoma detection rate is the proportion of adenomas or adenocarcinomas found by an endoscopist while performing screening colonoscopies for colorectal cancer. It is inversely related to risk of interval colorectal cancer and fatal interval cancer.<sup>1</sup> Missed lesions are more common in the right side of the colon.<sup>4,7</sup> Non-polypoid lesions are also a concern as they are more difficult to detect due to visual difficulties differentiating them from surrounding mucosa; these lesions can have a prevalence of 9.3% as studied in 1819 patients undergoing routine colonoscopy.<sup>23</sup>

An adenoma detection rate target was first proposed by the United States Multi-Society Task Force on Colorectal Cancer, in 2002, as a standard for quality endoscopy.<sup>24</sup> Adenoma detection rates of 25% for men and 15% for women were proposed. These standards have been adjusted to 30% for men and 25% for women in the 2015 ACG and ASGE quality indicator update.<sup>25</sup> Several interventions have been shown to be effective in improving adenoma detection rate. In one study, intervention in the form of two 1-hour sessions focusing on endoscopic technique and appearance of lesions significantly improved ADR.<sup>26</sup> Higher adenoma detection rates have been seen when an experienced nurse is present as a second observer in addition to the endoscopist.<sup>27</sup> Similarly higher adenoma detection rates have been shown with fellow (trainee) involvement during colonoscopy.<sup>28</sup>

## **Withdrawal Technique and Adenoma Detection Rate**

Withdrawal time has been shown to be closely associated with adenoma detection rate. This association is positively related as spending more time examining the mucosa during screening colonoscopy can increase adenoma detection rate.<sup>25,29,30</sup> Barclay et al first found a linear positive correlation between mean withdrawal time and adenoma detection rate.<sup>29</sup> Withdrawal time of 6 minutes has been postulated as a quality measure for screening colonoscopy.<sup>25</sup> In another study, a withdrawal time longer than 8 minutes was associated with an even higher rate of adenoma detection.<sup>30</sup> However, there are currently no guidelines available to specify time spent with respect to each part of colon. Klare et al. showed a significant association between observation time in the proximal colon and detection of adenomas<sup>31</sup> and concluded that the minimum time required for sufficient adenoma detection in the proximal colon is 4 min 7 sec. This population was undergoing colonoscopies for various indications and not only for screening for colorectal cancer. In one study with 850 patients undergoing a screening or surveillance colonoscopy, a second examination of the right side of the colon in either forward view or retroflexed view improved ADR as more lesions were found on a second exam. Second forward view compared to retroflexed second view was comparable.<sup>2</sup> Split dose bowel preparation has also been shown to improve adenoma detection rate compared to standard preparations.<sup>30</sup>

## **Retroflexion in the Right Colon**

Retroflexion in the right colon has been shown to improve visualization behind folds/flexure during the retroflexion maneuver.<sup>11</sup> The success of retroflexion in detecting adenomas can range between 79.5% to 95.9% and is operator dependent.<sup>32</sup> Various

reasons for failure of retroflexion have been proposed, including, but not limited to, anatomical restrictions/small right colon diameter, multiple co-morbidities, severe diverticulosis, abdominal pain, time constraints, failed retroflexion despite 2 trials, excessive instrumental looping, restricted mobility of the colon, equipment malfunctioning, poor bowel prep and experience of operator.<sup>2,5,33</sup> Retroflexion in the rectum is standard practice and has shown to improve adenoma detection rate; in one study, 50% of lesions in the anorectum were identified only on retroflexion.<sup>34</sup>

Earlier studies did not show significant differences in adenoma missed rate when retroflexion was compared with second examination of right colon with forward view.<sup>2,35,36</sup> However recent studies by Lee et al.<sup>5</sup> and Chandran et al.<sup>11</sup> have demonstrated increased adenoma detection, especially small sized (<5mm) polyps in the cecum and ascending colon with the help of retroflexion. One meta-analysis<sup>3</sup> revealed that retroflexed view detects approximately 17% of right sided adenomas that would have been missed with standard single forward view. Pishavan et al.<sup>37</sup> also showed the value of use of retroflexion for the resection of sessile polyps that were difficult to access by standard view alone. Yield of right colon adenomas is significantly increased when patient has a history of colon polyps, age equal to or greater than 55 years, poor quality impression during initial examination by endoscopist or finding adenomas on the initial examination of the proximal colon.<sup>2,32</sup> Generally, the technique of retroflexion is considered safe.<sup>3,5,11,33,35</sup> Complications associated with the technique appear to be rare and no additional analgesia or sedation is required.<sup>38</sup> There has been one case report demonstrating contained colonic perforation secondary to cecal retroflexion technique requiring conservative management. Incidence of major complications is similar in

comparison to those who are not exposed to cecal retroflexion.<sup>39</sup> Retroflexion attempt should be stopped if resistance is felt by the operator during bending or during advancement of scope to prevent complication.<sup>37</sup>

### **Devices / Technology and Adenoma Detection Rate**

Many reasons have been postulated for low adenoma detection rate of proximal colon including difficulty in examining behind haustrum, ileocecal valve, adenomas hidden behind proximal folds and inner aspect of hepatic flexures, and small flat polyps that are in the right side of colon.<sup>5,35,38</sup> Use of high definition imaging during colonoscopy significantly increases ADR and polyp detection rate compared to standard definition imaging.<sup>40</sup> Blue laser imaging has been shown to be superior to standard colonoscopy in detecting adenomas in a large multicenter study.<sup>41</sup> Full spectrum endoscopy provides a 330 degrees view instead of conventional 140-170 degrees.<sup>42</sup> This modality uses the forward tip as well as both sides of the tip which produces an image from each imager on a different screen. A multicenter study using this technique showed significantly lower adenoma miss rates when compared to standard colonoscopy (0% vs. 17% respectively p=0.02).<sup>43</sup>

Third Eye Retroscope, which is a retrograde viewing device, was shown to improve detection of adenomas when compared to standard colonoscopy. Adenoma miss rate was lower with Third Eye Colonoscopy (TEC) and the relative risk of missing polyps with standard colonoscopy was 2.56 compared to TEC.<sup>44</sup> Withdrawal time, however, was longer by TEC by an average of one minute, and total procedure time was also longer by 3 minutes. High definition chromoendoscopy has had mixed results compared to high definition white light endoscopy.<sup>45</sup> In addition, its use may not be justified in screening

colonoscopies as it takes significantly longer than standard colonoscopy. Narrow Band Imaging (NBI) was also similar to conventional colonoscopy when comparing adenoma detection rates in a meta-analysis.<sup>46</sup>

Two other devices that can be attached on the endoscope are caps and cuffs. These help flatten folds during withdrawal and examine behind folds. Cuffs can be of different type but most commonly have flexible branches which also serve the same purpose as caps. Cap-assisted colonoscopy was shown in a meta-analysis to have similar adenoma detection rates when compared to conventional colonoscopy.<sup>47</sup> Efficacy of cuff assisted colonoscopy was assessed in a randomized crossover trial of 274 patients who underwent cuff-assisted vs. standard colonoscopy. The cuff-assisted colonoscopy group had a higher ADR of 29.6% compared to 26.3% in the standard group,  $p < 0.01$ .<sup>48</sup>

Adenoma detection rate has been linked to mortality and interval development of colon cancers and thus we sought to determine interventions to help improve this outcome measure. At the time of study initiation there was no published data to suggest an optimal time for examination of the right colon in forward view or during retroflexion. Given the implications of missed lesions and the need for improving adenoma detection rate, we conducted a multicenter, randomized controlled trial to investigate the benefit of spending three minutes or longer in the right side of the colon during withdrawal.

Our research questions were:

1. Does spending three minutes or more in the right colon improve adenoma detection rate compared to spending less than three minutes?
2. Does spending thirty seconds or more in retroflexion improve adenoma detection rate compared to spending less than thirty seconds?

We hypothesized that spending three minutes or more in the right colon will improve adenoma detection rate compared to spending less than three minutes in the right colon. We also hypothesized that patients undergoing a longer period of retroflexion will have improved adenoma detection rate compared to patients undergoing retroflexion for a shorter duration.



## CHAPTER 3

### METHODS AND MATERIALS

#### **Study Design, Data and Data Source**

We performed a multicenter, prospective, case-control study at three hospitals in the Saint Luke's Health System Network. Data was collected from the electronic health record system at all hospitals as well as from patient encounters during their colonoscopy visit. Participating institutions were:

1. Saint Luke's Hospital of Kansas City Missouri
2. Saint Luke's North Hospital
3. Saint Luke's South Hospital

All data was filled in by nursing staff and by study investigators. Demographic information including age, sex, body mass index (BMI) and height were collected. Nursing forms included parameters that were filled out by nursing during the colonoscopy procedure. Please see attached nursing form in the appendix for more information. Patient stickers were placed on the patient chart to help identify the data so that charts could be accessed for adenoma and polyp detection rates. Data collected were transferred to a data collection sheet which was de-identified with linking information present in a key file. This file is planned to be destroyed along with patient forms once the publication plan is finalized. Institutional review board (IRB) was reviewed by the Saint Luke's IRB and was sent for further review by Schulman IRB which is an IRB based in Ohio which oversees studies at Saint Luke's which involve an intervention. IRB approval was obtained from Schulman. The quality committee and

Saint Luke's North and Saint Luke's South also conducted a separate review of the study and approved it before implementation.

### **Study Population**

Patients undergoing colonoscopy for various procedures were enrolled for the study.

#### **Inclusion Criteria:**

Adults aged 50 and older undergoing a colonoscopy procedure at St. Luke's Hospital of Kansas City Missouri Plaza location, Saint Luke's North Hospital and Saint Luke's South Hospital were included. Hemodynamically stable patients who were able to undergo informed consent for the procedure and for the study were included.

#### **Exclusion Criteria:**

Patients with surgical resection of all or part of the colon were excluded as these patients do not have a full length of the colon and may have had their right side of the colon resected. Withdrawal times, looping and other factors may also be affected in these patients. Patients who did not agree to take part in the study were also excluded. Patients under the age of 50, pregnant women, patients who are not able to speak English and who were not able to give informed consent were excluded. Patients with an emergent condition requiring urgent or emergent colonoscopy were excluded as to avoid delays in care. Patients who were found to have inadequate prep to allow screening for colorectal cancer were also excluded as adenoma detection rates have been shown to be less when bowel prep is inadequate.

### **Withdrawal and Termination Criteria:**

If patients withdrew consent to participate in the study at any time, they were allowed to withdraw from the study. If the patients met any of the exclusion criteria at the time of enrollment or were found to meet any criteria during the procedure, for example poor bowel prep or previous colonic surgery that was not part of the history, their participation was terminated and patients were excluded.

### **Measures**

#### **Primary Predictor/Intervention**

After informed consent was obtained, patients were randomized to either the group undergoing examination of the right colon for greater than or equal to 3 minutes or less than three minutes (withdrawal time). Withdrawal time was started after identifying the appendiceal orifice if terminal ileum intubation was not planned. If terminal ileum intubation was planned then withdrawal time was started after the intubation was completed or if the intubation failed. Withdrawal time of the ascending colon concluded after identifying the hepatic flexure. Right colon withdrawal time was the primary predictor. Modified withdrawal time was also calculated which took the time required for polypectomy into account. We only had polypectomy data for 25% of patients so we used this average to deduct the polypectomy time from all polypectomy. Average time required to remove the first ascending colon polyp was 45 seconds and time required to remove a second ascending colon polyp and subsequent polyps were 20 seconds each. Although this data is not 100% accurate, we used it as an estimate of right colon withdrawal time independent of time needed for polypectomy.

A secondary predictor was time spent during retroflexion, if retroflexion was performed. Groups comprised of patients undergoing retroflexion for  $\geq 30$  seconds and were compared to retroflexion for  $< 30$  seconds. This was at the discretion of the endoscopist. It was noted if the retroflexion was attempted and failed or if it was successful and the time spent during retroflexion was calculated. Retroflexion was not randomized as the practice of routine retroflexion varied among endoscopists. Randomization was also not ideal as, in some patients, retroflexion can be challenging and continued retroflexion if the lumen of the colon was not adequately seen can lead to no benefit and spending longer duration would have limited benefit. Barriers to retroflexion were also identified and were considered and assessed during data collection. Number of attempts made for retroflexion was also recorded.

Age was collected in years, sex was categorized as male or female. Body mass index was collected as a numerical value. American Society of Anesthesiologists (ASA) score was determined from 1-4 as per pre-procedure anesthesia evaluation. Race was defined as Caucasian, African American, Hispanic, Asian and other. History of colon polyps and family history of colon cancer were recorded. Smoking status was determined as current smoker or not a current smoker. Indication for the colonoscopy was collected. Bowel preparation scale was noted during the procedure according to the Boston Bowel Prep Scale and ranged from 1 (indicating inadequate bowel prep) to 3 (indicating excellent bowel prep).

### **Outcome Measures**

Adenoma detection rate was the primary outcome measure. It was defined as the proportion of colonoscopies in which adenomas were detected, compared to all

colonoscopies. Polyp detection rate was also calculated and was defined as the proportion of colonoscopies in which any type of polyp was removed during the exam compared to all colonoscopies. Adenoma detection rates were determined for each endoscopist and each fellow. Fellow involvement was also considered when analyzing adenoma detection rates.

### **Other Predictors/ Independent Variables**

Quality of bowel prep was also recorded in each segment of the colon. Type of colonoscope (adult, pediatric or hybrid Fujinon colonoscopes) used and looping during colonoscopy was also recorded. If retroflexion was attempted but failed, the endoscopist was asked to comment on the reason of failure with the choices being due to looping, narrow lumen of the colon, poor bowel prep, type of colonoscope used, technical difficulty or other and to specify. Utilization of pressure, total withdrawal time and time of day were also collected to check for an influence on the primary outcome measure.

### **Data Collection Procedures**

Patients who were scheduled to undergo a colonoscopy at Saint Luke's Hospital of Kansas City Missouri, Saint Luke's North Hospital and Saint Luke's South Hospital were identified by the study team by looking at the endoscopy schedule for the day. This information was available in paper form on the day of the procedures or electronically using the electronic health record. The sub investigators identified these patients, and patients meeting the inclusion criteria were approached by the study investigators to discuss the study and obtain informed consent prior to the procedure. If the patient agreed to participate in the study pertinent parameters were collected by the procedure nurse during the procedure. The nursing forms were provided to the nurses at each hospital

location. The forms, after being filled out, were picked up by the study investigators and kept at a secure location. Data from the study forms were entered into the data collection sheet. Other pertinent clinical and endoscopic parameters from the electronic health record were collected in an excel data sheet by investigators using their personal logins.

### **Data Management and Security**

The participants were assigned random study ID numbers and key that matched medical record number to study number was destroyed after all data collection. De-identified data were collected and no patient identifying information was collected in the final data sheet to prevent potential breach of confidentiality. The data and key (during data collection) were stored in a secure location. Only study investigators had access to this data. The excel sheet and key also had password protection. De-identified data will be stored for 2 years while link to data will be destroyed upon completion of the publication requirements.

### **Risks and Benefits to Patients**

There was thought to be no or minimal risk; physical, psychological, social or economical, to the patients except breach of confidentiality. Risks associated with retroflexion are extremely rare and only one reported case is available of perforation for this widely performed maneuver. The standard procedure time was not thought to be increased significantly due to the study procedures. The study participants were educated that the study procedures may or may not benefit them directly but may help future patients by investigating the research question of the study.

## Statistical Analysis

There were 250 patients included in the statistical analysis who met inclusion criteria. There were 135 patients randomized to the  $\geq 3$  minutes right colon withdrawal arm and 115 patients randomized to the  $<3$  minutes right colon withdrawal arm. Descriptive statistics were used to describe patient demographics and other parameters described in the measures section. We used logistic regression to assess the differences in ADR between the two withdrawal groups and also between the  $\geq 30$  second retroflexion group and  $< 30$  second retroflexion group. Logistic regression was also used to assess differences in polyp detection rates between the respective groups. Chi Square and t test were used to compare the two groups on categorical data and continuous data, respectively. All analyses were performed using SPSS, and p values of  $< 0.05$  were considered statistically significant.

## Sample Size Calculation

Sample size estimate was done *a priori*. Adenoma detection rate in the proximal colon have been reported as 15.5% based on a large study of 2167 screening colonoscopies.<sup>46</sup> Proximal colon in this study was defined as cecum up to the splenic flexure. In our study we considered the right colon to be from cecum to hepatic flexure and hence not including the transverse colon and splenic flexure. We estimated the baseline adenoma detection rate of 10% in the right colon to be on the conservative side based on above data. For our sample, we considered a two tailed alpha level of 0.05 (type I error rate) and considered the rate of type II error to be 0.2 as is standard. Sample size was based on 80% power. We estimated an effect size of 15 percentage points change and our required sample size was determined to be 226 patients with 113 patients in each arm.

## CHAPTER 4

### RESULTS

#### **Characteristics of the Study Population**

A total of 269 patients were enrolled and 250 patients were included in the analysis after patients meeting exclusion criteria were excluded. Mean age of the patients was 60.5 years (SD 8.5 years). 52% of patients were females and 47.6% were male. 75.8% of patients were white, 20% were African American, 1% Hispanic and 1% Asian. Mean BMI was 30.5 (SD 6.7) while median ASA score was 2 (SD 0.65). Fellows were involved in 83 colonoscopies (31%). Indication for 70% of the procedures was screening for colorectal cancer. There were no significant differences between the < 3 minute withdrawal groups and  $\geq 3$  minutes withdrawal group when considering age, sex, race, BMI, ASA score, family history of colon cancer or indications (Table 2 and Table 3, page 32 and 33 respectively).

#### **Results: Primary Outcome**

There were 135 patients included in the < 3 minute right colon withdrawal group (RCWG) while 115 patients were included in the  $\geq 3$  minute RCWG. Adenoma detection rate in the right colon was 33% if the right colon withdrawal time was  $\geq 3$  mins compared to 14% if it was < 3 mins. It was three times more likely to detect adenomas in the right colon in the  $\geq 3$  mins group compared to the < 3 min group (OR 3,  $p < 0.001$ , 95% CI 1.62-5.64). Polyp detection rate in the right colon was 49% in the  $\geq 3$  minute withdrawal group compared to 14% in the < 3 minute withdrawal group, and chance of finding a polyp on the right side was 5 times more in the  $\geq 3$  minute right colon group compared to the < 3 minute group (OR 5.1  $p < 0.001$ , 95% CI 2.84 – 9.32).



The adenoma detection rate in the right colon was also significantly higher when the modified right colon withdrawal time was used in  $\geq 3$ mins group (33%) vs.  $< 3$ mins group (14%) which also showed that the  $\geq 3$ mins group was 3 times more likely to find adenomas in the right colon compared to the  $< 3$  min group (OR 3,  $p<0.001$ , 95% CI 1.62-5.64). When considering the screening population, right colon ADR was significantly higher in the  $\geq 3$ mins group (33%) vs. 14% in the  $< 3$  mins group  $p=0.004$ ).

We also constructed a Receiver Operative Characteristic (ROC) Curve for time cut off for optimal adenoma detection rate. Area under the curve was 0.73,  $p<0.001$ , 95% CI 0.65-0.81. The cut-off point with optimal sensitivity and 1-specificity was found to be 3 minutes and one second for adenoma detection in the right colon.

Median time to reach cecum was 360seconds (6mins), median withdrawal time was 660seconds (11mins), and median right colon withdrawal time (RWT) was 165 seconds. There were no differences between the groups in indication  $p=0.4$ , family history of colon cancer  $p=0.7$  or retroflexion performed  $p=0.1$ . Overall adenoma detection rate in the whole colon was 50%. Average polypectomy time was 45seconds and 20 seconds for a second polyp in the ascending colon; this was excluded from RWT to generate a modified right colon withdrawal time (MRWT). A fellow was more likely to be involved when RWT was  $\geq 3$ mins (46%) vs.  $< 3$ mins (16%)  $p<0.001$ . There was no difference in the overall adenoma detection rate or that in the right colon based on fellow involvement ( $p=0.7$ ).

### **Secondary Outcome**

Retroflexion was performed in 101 patients (71%) for  $< 30$  seconds and 40 patients (29%) had retroflexion performed for  $\geq 30$  seconds. Adult colonoscope (12.8mm

diameter) was used in 82% of patients while a pediatric colonoscope (11.5mm diameter) was used in 18%.

Adenoma detection rate in the right colon was 45% when retroflexion was performed for  $\geq 30$  seconds compared to 23% in the group where it was performed for  $< 30$  seconds (OR 2.8,  $p=0.01$ , 95% CI 1.26 – 6.0). Polyps that were seen only on retroflexion, which could not be seen on forward view, were significantly more likely to be found in the  $\geq 30$  second group (22%,  $n=8$ ) compared to the  $< 30$  second group (3%,  $n=1$ ),  $p<0.001$ .

Successful retroflexion was defined as completing the retroflexion maneuver in the right colon. GI fellows were successful in retroflexion in 58% of cases while attending physicians were successful in 74% of cases  $p=0.027$ . Retroflexion success was 90% when there was no looping, vs. 89% with mild and only 25% with severe looping,  $p<0.001$ . Retroflexion was successful in 54% of the cases with Boston bowel prep score of 2 compared to 72% with score of 3 in the right colon  $p=0.005$ . Successful retroflexion was performed in 81% when no abdominal pressure was required vs. 58% with pressure  $p=0.001$ . Patients in whom retroflexion failed had a higher BMI (mean 31.6 vs. 29.8,  $p=0.04$ ). ASA score ( $p=0.6$ ), sex ( $p=0.7$ ), race (0.9) and type of colonoscope (0.6) were not significantly associated with retroflexion success. Chance of success was very low (3%) after the second attempt of retroflexion.

## CHAPTER 5

### DISCUSSION

Adenoma detection rate is the benchmark for measuring the quality of endoscopy. It is inversely related to risk of interval colorectal cancer and fatal interval cancer.<sup>1</sup> Several previous studies have shown that the risk of missing lesions is the highest in the right side of the colon<sup>4,7</sup> which could in turn lead to higher risk of interval colon cancer and mortality. In this study we aimed to assess the utility of a careful examination of the right side of the colon and its effect on adenoma detection rate. It has been shown previously that a longer withdrawal time can increase adenoma detection rate<sup>25,29,30</sup> and a withdrawal time of 6 minutes has been shown to significantly improve adenoma detection.<sup>25</sup> Currently there are no guidelines to recommend an adequate right colon withdrawal time, and endoscopists can spend a variable fraction of the 6 minute withdrawal time in the right colon. In our study we found a significant increase in adenoma detection in the right colon when more than 3 minutes were spent for right colon examination. This included forward view exam as well as retroflexed exam.

Our study showed that the < 3 minute group was 65% less likely to find adenomas in the right colon (OR 0.35,  $p < 0.001$ , 95% CI 0.177-0.616) compared to if the right colon was examined for  $\geq 3$  minutes. The rate of retroflexion did not differ significantly between the < 3 minute arm and  $\geq 3$  minute withdrawal arm. This suggests that retroflexion duration is independently associated with higher adenoma detection rate. We also analyzed a regression model to account for the interaction between a longer than three minute withdrawal and longer than thirty second retroflexion and adenoma detection rate. It showed no significant interaction  $p = 0.9$ .

Retroflexion for more than 30 seconds significantly increased adenoma detection rate. However, experienced endoscopist, no looping, better bowel prep and lower BMI of the patient were associated with successful retroflexion. Given that absence of these factors can be associated with a higher rate of failed retroflexion, they may also lead to a lower adenoma detection rate if retroflexion is limited.

Experience of the endoscopist and routine use of retroflexion by the endoscopist were associated with higher rates of success. This is consistent with previous studies.<sup>32</sup> Even when retroflexion was successful, endoscopists who routinely perform retroflexion were more likely to find polyps on retroflexion. This could suggest a learning curve with the retroflexion maneuver as well as visualization of polyps in retroflexion. It was also observed that the highest yield in retroflexion was when the colonoscope was retroflexed in the cecum and the colonoscope was withdrawn while in retroflexed position up to the hepatic flexure. This maneuver was most successful when torque was used to look behind fold just as one would in forward view. Locking the small dial on the colonoscope, during retroflexed withdrawal, was also helpful.

We saw that the withdrawal time in the right colon and during the colonoscopy procedure as a whole was longer when fellows were involved, but interestingly this did not affect adenoma detection rate. In previous studies it has been shown that having a second observer like an experienced endoscopy nurse who has more than two years of experience increased adenoma detection rate.<sup>27</sup> This could be a limitation of the withdrawal technique of a trainee or that our sample size of having fellow involvement was not large enough to achieve statistical significance.

ADR differs only slightly when the indication for a colonoscopy is considered. Diagnostic colonoscopies have a lower ADR while screening and surveillance colonoscopies have a higher ADR with a mean difference of 2.6% between screening ADR and overall ADR.<sup>49</sup> This difference has not been considered significant to alter ADR standards and may simplify ADR measurement.<sup>49</sup> Therefore, we considered all indications including patients undergoing colonoscopy for average risk screening for colorectal cancer, family history of colon polyps or personal history of colon polyps. Patients presenting with history of abdominal pain, melena and hematochezia were also considered but only if they were due for a screening or a surveillance colonoscopy.

Our study also showed that the < 3 minute group was 80% less likely to find polyps in the right colon (OR 0.19,  $p < 0.001$ , 95% CI 0.11-0.35) compared to the  $\geq 3$  minutes group. When considering adenoma detection rate of the whole colon, the  $\geq 3$  minute withdrawal group also had a higher overall adenoma detection rate of 50% compared to 32% in the < 3 minute group (OR 2.2  $p = 0.007$ , 95% CI 1.24- 3.81). This benefit is likely due to the higher adenoma detection rate of the right side of the colon as adenoma detection rates in the transverse colon (17.5% vs. 13.4%,  $p = 0.37$ ) and left colon (24% vs. 17%  $p = 0.18$ ) were comparable between  $\geq 3$  minute group and < 3 minute group respectively.

There were no adverse events related to the study interventions in our study. Only one patient had a splenic hematoma after colonoscopy. This is a patient in whom retroflexion was also performed. The case was discussed between the study team and the endoscopist. It was the opinion of the endoscopist and the conclusion of the study team that the complication was not related to retroflexion. The incident was reported to the

IRB. Spending  $\geq 3$  minutes in the right side of the colon was not associated with increased procedure-related or sedation-related adverse events.

It was observed that if a second attempt at retroflexion fails, subsequent attempts are very unlikely to be successful. We suggest that retroflexion in the ascending colon should not be attempted after two failed attempts as it may prolong procedure duration and may cause potential adverse events. The rate of retroflexion failure was not associated with the type of colonoscope used.

There were some limitations of the study. One limitation was that the polypectomy times were not consistently measured during the study resulting in our inability to calculate an accurate, modified right colon withdrawal time. This time was extrapolated based on the polypectomy times we had for 50 patients. Another limitation was that data was collected for various indications which have been shown to have a slightly different ADR than the screening population. However we aimed to show the efficacy of longer right colon withdrawal time and retroflexion in this study and both study arms had relatively equal number of high risk and low risk individuals. The endoscopists could also not be blinded and being in the longer withdrawal arm could have caused pressure of doing a more thorough exam.

The ROC curve suggested a withdrawal time in the right colon of 181 seconds which (three minutes and one second) which was close to the three minute time we planned to study *a priori*. We suggest that at least three minutes should be spent to examine the right side of the colon. Retroflexion should also be performed when possible and longer duration of retroflexion, with withdrawal while in retroflexion to examine the proximal and distal ascending colon, can help increase adenoma detection rate.

## CHAPTER 6

### CONCLUSIONS

Adenoma detection rate in the right colon is significantly improved when more than three minutes are spent examining the right side of the colon. Individuals in whom retroflexion was performed for longer than thirty seconds also had significantly improved adenoma detection rate.

# APPENDIX A

## TABLES

**Table 1. TNM Staging**

Primary tumor (T)		Regional lymph nodes (N)	
TX	Primary tumor cannot be assessed	NX	Regional lymph nodes cannot be assessed
T0	No evidence of primary tumor	N0	No regional lymph node metastasis
Tis	Carcinoma in situ; intraepithelial or intramucosal carcinoma (involvement of lamina propria with no extension through the muscularis mucosa)	N1	Metastasis in 1-3 regional lymph nodes (tumor in lymph nodes measuring $\geq 0.2$ mm) or any number of tumor deposits are present and all identifiable nodes are negative
T1	Tumor invades submucosa (through the muscularis mucosa but not into the muscularis propria)	N1a	Metastasis in 1 regional lymph node
T2	Tumor invades muscularis propria	N1b	Metastasis in 2-3 regional lymph nodes
T3	Tumor invades through the muscularis propria into the pericolorectal tissues	N1c	Tumor deposit(s) in the subserosa, mesentery, or nonperitonealized, pericolic, or perirectal/mesorectal tissues without regional nodal metastasis
T4	Tumor invades the visceral peritoneum or invades or adheres to adjacent organ or structure	N2	Metastasis in 4 or more lymph nodes
T4a	Tumor invades through the visceral peritoneum (including gross perforation of the bowel through tumor and continuous invasion of tumor through areas of inflammation to the surface of the visceral peritoneum)	N2a	Metastasis in 4-6 regional lymph nodes
T4b	Tumor directly invades or is adherent to other organs or structures	N2b	Metastasis in 7 or more regional lymph nodes

Distant metastasis (M)	
M0	No distant metastasis by imaging or other studies, no evidence of tumor in distant sites or organs. (This category is not assigned by pathologists.)
M1	Metastasis to one or more distant sites or organs or peritoneal metastasis
M1a	Metastasis confined to 1 organ or site (eg, liver, lung, ovary, nonregional node) without peritoneal metastasis
M1b	Metastasis to two or more sites or organs without peritoneal metastasis
M1c	Metastasis to the peritoneal surface alone or with other site or organ metastases

**Table 2. Anatomic stage/prognostic groups**

Stage	T	N	M	Dukes	MAC
0	Tis	N0	M0	--	--
I	T1	N0	M0	A	A
	T2	N0	M0	A	B1
IIA	T3	N0	M0	B	B2
IIB	T4a	N0	M0	B	B2
IIC	T4b	N0	M0	B	B3
IIIA	T1-T2	N1/N1c	M0	C	C1
	T1	N2a	M0	C	C1
IIIB	T3-T4a	N1/N1c	M0	C	C2
	T2-T3	N2a	M0	C	C1/C2
IIIC	T1-T2	N2b	M0	C	C1
	T4a	N2a	M0	C	C2
	T3-T4a	N2b	M0	C	C2
IVB	T4b	N1-N2	M0	C	C3
	Any T	Any N	M1a	--	--
IVB	Any T	Any N	M1b		
IVC	Any T	Any T	M1c	--	--

Taken from: [emedicine.medscape.com](http://emedicine.medscape.com)



Table 2. Patient Demographics

		< 3 Minute Group	>= 3 Minute Group	P value
Age		60.5 ± 9	60.3 ± 8	0.91
Sex	Male	47%	47.8%	0.95
	Female	52.6%	52.2%	
Race	White	76.3%	75.2%	0.07
	African American	19.3%	22.1%	
BMI		29.6	31.2	0.69
ASA Score	1	10.4%	10.6%	0.93
	2	61.5%	64.6%	
	3	26.7%	23%	
	4	1.5%	1.8%	
Colon Cancer in Family		14.2%	15.7%	0.745
History of Colon Polyps		20%	35%	0.048

Table 3. Procedure Characteristics

		< 3 Minute Group	>= 3 Minute Group	P value
Right Colon Boston Prep Scale	2	21.8%	9.5%	0.08
	3	73.6%	86.9%	
Type of Colonoscope	Standard	89.4%	73%	0.005
	Pediatric	9.8%	23.4%	
Looping	None	28.9%	23.9%	0.58
	Mild	31.6%	29.5%	
	Moderate	26.3%	35.2%	
	Severe	13.2%	11.4%	
Fellow Involvement		16.3%	46.1%	0.001
Abdominal Pressure Applied		53.4%	60%	0.33

APPENDIX B  
ILLUSTRATIONS

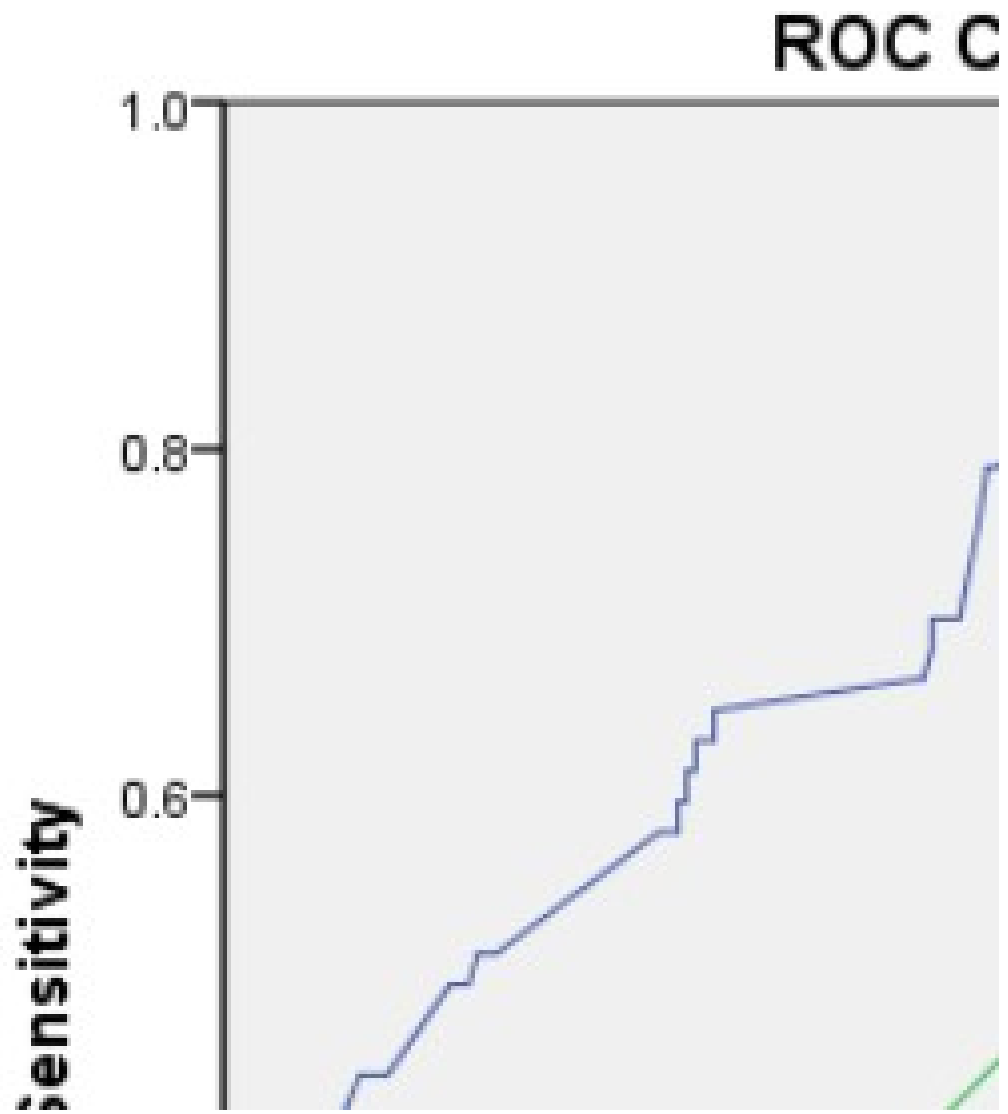
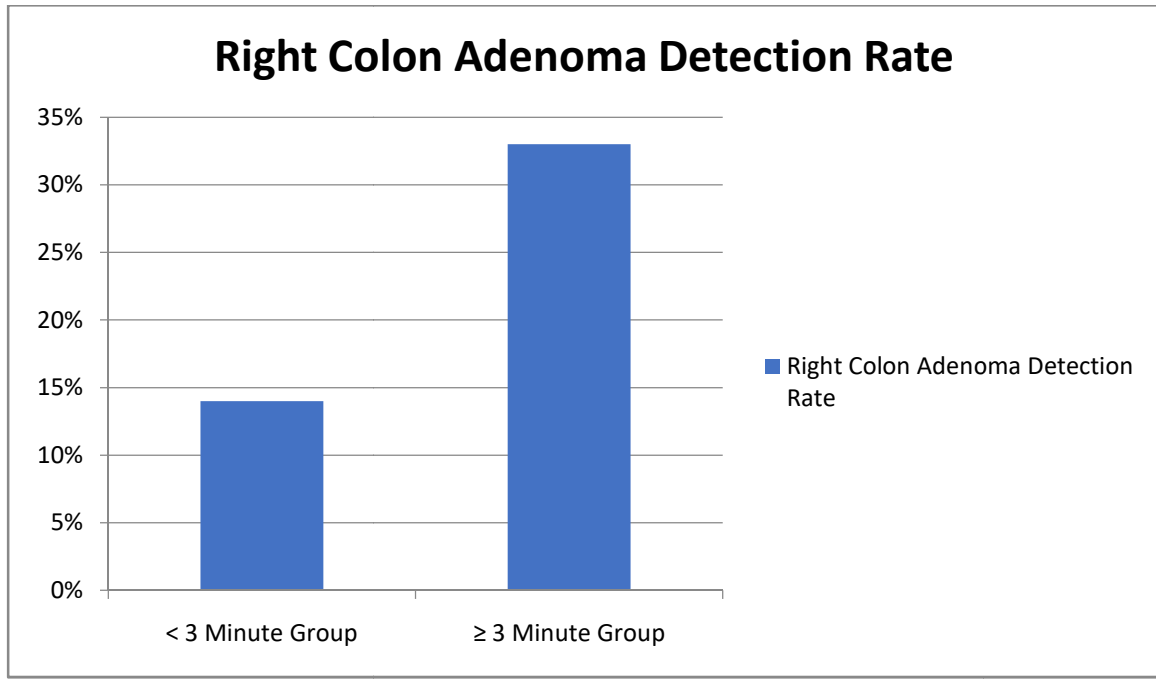
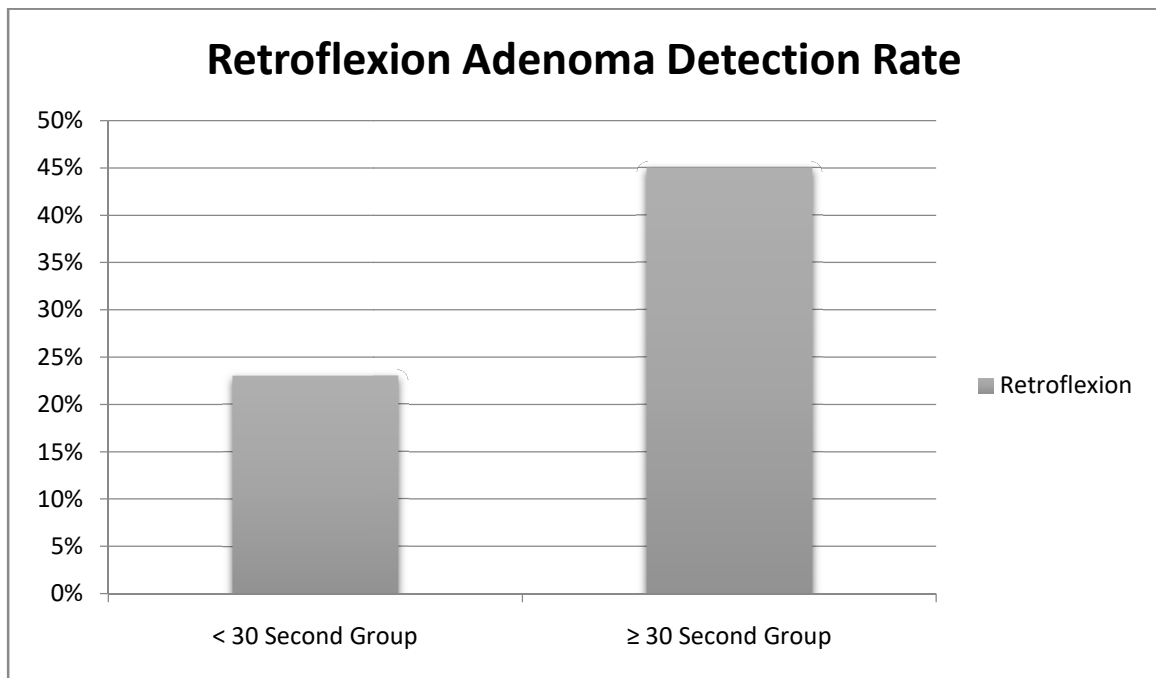


Figure 1. ROC



Graph 1, Adenoma Detection Rate in the Right Colon



Graph 2, Adenoma Detection Rate in the Right Colon with Retroflexion

## Retroflexion in the Right Colon



Image 1: The image shows the colonoscope retroflexed in the ascending colon so that the back sides of the folds are seen. The black object is the colonoscope looking back on itself while the white marks are the markings on the colonoscope. This image illustrates normal mucosa of the colon. No polyps are seen.

(Kushnir VM, Oh YS, Hollander T, et al. Corrigendum: Impact of Retroflexion Vs. Second Forward View Examination of the Right Colon on Adenoma Detection: A Comparison Study. *Am J Gastroenterol.* 2015;110(6):942. doi:10.1038/ajg.2015.144)

Figure 2. Reteroflexion Image

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APPENDIX C.

FORMS

Nursing Form for Data Collection

Retroflexion Study Form

Patient

**TO BE FILLED DURING**

If any of the following are present, Please exclude the patient

- a. Patients undergoing emergent endoscopy
- b. Patients who are not able to give consent
- c. Patients who do not agree to take part in the study
- d. Patients with surgical resection of all or part of the colon
- e. Age < 50

Age \_\_\_\_\_

\*\*BMI \_\_\_\_\_

ASA Score    I    II    III    IV

\*\*Family History of colon cancer (immediate relative)

\*\*History of colon polyps

\*\* Personal History of colon cancer

Smoker

Indication for Colonoscopy \_\_\_\_\_

\*\*Type of Colonoscopy            Adult            Hybrid

Name of Attending Doing the Colonoscopy \_\_\_\_\_

Fellow Involved?                    Yes

Name of Fellow \_\_\_\_\_

\*\*Looping during colonoscopy    None    Mild

\*\*Bowel Prep Quality (Boston Scale)    Right Colon

**Informed Consent Form For Study**

**Study**

**EFFICACY OF DURATION OF RETROGRADE  
EXAMINATION ON ADENOMA DETECTION  
RETROFLEXION IN**

You are being asked to take part in a research study of retrograde colonoscopy as a part of your care. You do not know the main purpose of research is to create new knowledge in general. Research studies may or may not benefit you.

Participation in this research is voluntary, and you will not be penalized if you decide not to participate. Either way, you can still get medical care.

This research study will take place at Saint Lukes Hospital. This consent form explains what you have agreed to.

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## **PROCEDURES**

Since you are scheduled for a colonoscopy examination study. If you consent to participate in the study, we will provide you with additional information about your procedure with the study. We do not anticipate for your procedure to be any more difficult than previous studies). There is no additional cost for your participation in the study. Examination and data will be analyzed.

You will be involved in this study for the length of time of the procedure from till the end of the procedure.

## **RISKS**

Risks are minimal and limited to the risk of bleeding. Risks associated with retroflexion are extremely rare and only occur in a small number of cases. This risk appears to be similar to that of a standard colonoscopy. A procedure that takes more than 3 minutes in the right colon will not put you at a higher risk of bleeding but has not been studied. Every precaution will be taken to minimize the risk of bleeding.

---



## **CONFIDENTIALITY**

The researchers will keep your records related to the study in a medical journal. Individual identifying information will not be used in any studies.

## **PAYMENT:**

There will be no payment for the study.

## **WITHDRAWAL FROM THE STUDY**

You can agree to participate in the study now and later decide to withdraw from the study at any time, you should contact your gastroenterologist involved in your care or the study investigator.

## **IN THE EVENT OF INJURY:**

If you have a serious side effect or other problem during the study, contact Dr. Mir Fahad Faisal or Dr. Sreenivasa Reddy at 5:00 p.m., a holiday or a weekend, you should contact your gastroenterologist on call or the GI fellow on call. We will discuss what type of treatment, if any, is best for you at that time.

---

any reason without your consent by the investigator

## **CONSENT**

Dr Sreenivasa S. Jonnalagadda or the research  
research study. They have explained what will  
explained any inconvenience, discomfort or risks

By signing this form, you are saying that you freely  
research study. You have read the information and

*You will be given a signed copy of the consent form*

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## VITA

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Dr. Faisal completed a residency in Internal Medicine at University of Missouri Kansas City in 2015, becoming board certified in Internal medicine later that year. In 2015, Dr. Faisal began a three-year fellowship in Gastroenterology at University of Missouri Kansas City. During his fellowship, Dr. Faisal began work toward a Master of Science in Bioinformatics degree. Upon completion of his fellowship and his degree requirements, Dr. Faisal plans to do a fellowship in Advanced Gastrointestinal Endoscopy at Beth Israel Deaconess Medical Center| Harvard Medical School, Boston, MA, starting 7/2018.