EVALUATION OF AN EDUCATIONAL INTERVENTION TO IMPROVE COLONOSCOPY QUALITY IN ST. JOHN'S, NL

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ABSTRACT

The Canadian Association of Gastroenterology (CAG) implemented the Colonoscopy Skills Improvement (CSI) program across Canada with the goal of improving colonoscopy quality. The objective of this study was to assess the impact of the CSI program on colonoscopy quality in St. John's, NL.

Nineteen endoscopists practicing in a tertiary referral centre who have participated in CSI training since October 2014 were evaluated. For each endoscopist fifty consecutive procedures immediately before, immediately after, and eight months following CSI training were included. The primary outcome was change in adenoma detection rate (ADR). Secondary outcomes included number of adenomas detected per colonoscopy (APC), cecal intubation rate, and sedative usage and dosing.

Patient characteristics were similar between time points. ADR did not significantly improve immediately after CSI training (31.8% v. 33.6%, p=0.484) or at the eight-month assessment (31.8% v. 35.3% p=0.107). There was no significant change in APC or completion rate at any time point. There was a statistically significant decrease in the average dose of Fentanyl (72.8mcg v. 64.8mcg v. 63.5mcg, p<0.001) and Midazolam (2.49mg v. 2.17mg v. 2.11, p<0.001) immediately after CSI training that persisted at eight months.

Participation in the CSI program is not associated with change in ADR. CSI training is associated with decreased sedation dosing during colonoscopy.

Key words: Colonoscopy, Quality improvement, Sedation, Adenoma detection rate

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LIST OF ABBREVIATIONS AND SYMBOLS

ADR	Adenoma Detection Rate
ANOVA	Analysis of Variance
APC	Adenomas Per Colonoscopy
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
CAG	Canadian Association of Gastroenterology
CSI	Colonoscopy Skills Improvement
EMR	Electronic Medical Record
EPIC	Endoscopic Polypectomy Improvement Course
EQUIP	Endoscopic Quality Improvement Program
FAP	Familial Adenomatous Polyposis
FIT	Fecal Immunochemical Test
gFOBT	guiac-based Fecal Occult Blood Test
GRS	Global Rating Scale
HNPCC	Hereditary Nonpolyposis Colorectal Cancer
MEI	Magnetic Endoscopic Imaging
PDR	Polyp Detection Rate
RCT	Randomized Controlled Trial
SEE	Skills Enhancement for Endoscopy
SPS	Serrated Polyposis Syndrome
SSP	Sessile Serrated Polyp
TET	Train-the-Endoscopy Trainer
TSA	Traditional Serrated Adenoma
UK	United Kingdom

CHAPTER 1 INTRODUCTION

1.1 Colorectal Cancer (CRC)

Colorectal cancer is a common and lethal disease. Globally, it is the third most commonly diagnosed cancer in males and the second in females. [1] In Canada, it is the second leading cause of cancer death in men and the third leading cause of cancer death in women. There will be an estimated 26 800 new CRC diagnoses in Canada during 2018 and approximately 9400 of those will die from it. [2] The risk of developing CRC increases with age, with more than 90% of diagnoses being made in patients older than 50 years.[3]

Colorectal cancers arise from colorectal polyps, which are abnormal collections of cells originating from the lining of the colon or rectum. Colonic polyps may be neoplastic or non-neoplastic and are classified based on histologic type. Adenomas are the most common type of neoplastic polyps and have potential to develop into CRC. The most common non-neoplastic polyps are hyperplastic and hamartomatous polyps.

Transformation of a polyp to a cancer happens through the well-described adenoma-carcinoma sequence. [4] Simply put, this sequence is a stepwise pattern of mutational activation of oncogenes and inactivation of tumor suppressor genes that results in cancer formation. The adenoma-carcinoma sequence is thought to progress over eight to ten years in most cases. Removal of adenomatous polyps early in this sequence can prevent cancer development.

Colorectal cancer occurs in hereditary, sporadic, and familial forms. Hereditary CRC is characterized by a history of CRC in other family members, a young age at onset, and genetic defects that lead to a propensity for cancer in multiple organ systems. Two

extensively studied hereditary colorectal cancer syndromes include familial adenomatous polyposis (FAP) and hereditary nonpolyposis colorectal cancer (HNPCC). These account for 5-10% of all colon cancers.

FAP is an autosomal dominant genetic condition in which affected individuals develop hundreds to thousands of adenomatous polyps in the colon. Polyps begin developing as early as the teenage years and will almost invariably become malignant over time. The average age at which an individual with FAP develops colon cancer is 39 years. [3] The lifetime colorectal cancer risk approaches 100% in individuals with FAP. These patients are also at risk for developing duodenal adenomas and gastric polyps. Genetic testing for FAP is available and once diagnosed, surgical removal of the entire colon and rectum (proctocolectomy) is recommended.

HNPCC, also known as Lynch syndrome, is an autosomal dominant disorder that carries a 70-80% lifetime risk of developing colon cancer and a 30-60% risk for developing endometrial cancer in women, as well as increased risk for multiple other cancers. [3] Clinically these patients have only a small number of colorectal polyps found on colonoscopy. The increased cancer risk is due to inherited mutations that impair DNA mismatch repair. Clinical scoring systems, such as the Amsterdam criteria, are used to identify high-risk individuals for genetic testing, which can establish a diagnosis of Lynch syndrome. [5] Once diagnosed, these individuals can be entered into an appropriate screening program.

Familial colon cancers account for 15-30% of all CRC cases. For familial colorectal cancer, lifetime risk increases for members of families in which the index case is young (<50 years) and the relative is closely related (first-degree). [3] Risk for these

cancers increases as the number of family members with colorectal cancer rises. Individuals who have a first-degree relative diagnosed with CRC before age 50 have a two fold increased risk for colon cancer.

Familial CRC constitutes a heterogeneous group of patients in whom the underlying molecular mechanism is still unknown. Predisposition to developing CRC in this setting is possibly due to common low-penetrance genetic components but the role of genetic testing in clinical practice has yet to be determined. [6] Novel genes and syndromes have been described which account for a small proportion of patients who have a phenotype/family history suggestive of a genetic syndrome including 'polymerase proofreading-associated polyposis' and mutations in the NTHL 1 gene.[7]

Sporadic colorectal cancers affect an older population (60 - 80 years of age) and occur in the absence of a family history, the key component separating them from familial cancers. Approximately 60-80% of all colon cancers occur sporadically. Sporadic colorectal cancers develop from neoplastic polyps through the adenoma-carcinoma sequence. [3] Genetic mutations associated with sporadic cancers are limited to the tumor itself, unlike in hereditary disease, in which a specific mutation is present in all cells of the affected individual. [3] Sporadic cancers result from somatic mutations, which are genetic alterations to a cell that can be passed on to the progeny of the mutated cell. Germ line mutations are inherited genetic alterations that occur in the germ calls (i.e., sperm and eggs).

Multiple other risk factors for colon cancer include obesity, inactivity, alcohol consumption, cigarette smoking, diet high in processed meats, diet low in fibre and inflammatory bowel disease.[2]

1.2 Colonic Polyps

Colonic polyps can be broadly classified into categories including adenomatous, inflammatory, hamartomatous, and serrated. It can be difficult to distinguish the type of polyp endoscopically, warranting removal for histologic examination.

The most prevalent neoplastic polyp is the adenoma, which can be subcategorized as tubular, villous and tubulovillous. [8] Risk factors for developing colorectal adenomas include increasing age, increased body mass index (BMI) and male gender. Some degree of dysplasia exists in all adenomas. Adenomatous polyps are classified histologically as having low-grade dysplasia or high-grade dysplasia. High-grade dysplasia is synonymous with intraepithelial carcinoma and represents an intermediate step in the progression from low-grade dysplasia to cancer. The incidence of invasive carcinoma being found in an adenoma is dependent on the size and histologic type of polyp. Only a small number of adenomas (five percent or less) progress to cancer. Advanced adenomas, defined as being $\geq$ 10mm in size, containing villous components or evidence of high-grade dysplasia, carry higher risk of progression. Adenomas should be resected completely when identified and published guidelines define follow up.

Inflammatory polyps are non-neoplastic intraluminal projections of mucosa consisting of stromal and epithelial components and inflammatory cells. Hamartomatous polyps, also non-neoplastic, are made up of tissue elements that are normally found at the site but are growing in a disorganized fashion.

Serrated polyps are a heterogeneous group of polyps with variable malignant potential. They include hyperplastic polyps, traditional serrated adenomas and sessile serrated polyps (with or without dysplasia). [9] Classification of serrated polyps is evolving

and variation exists among pathologists. Hyperplastic polyps are the most common non-neoplastic polyps of the colon. Hyperplastic polyps and are usually less than 5mm in size and are composed of cells showing dysmaturation and hyperplasia. They are typically located in the recto-sigmoid colon and can be biopsied for diagnosis, but require no specific follow up, as they have no potential to progress to adenocarcinoma.

Sessile serrated polyps (SSP) and traditional serrated adenomas (TSA) are often flat and coated with mucous making them difficult to identify endoscopically. [10] These polyps frequently exhibit dysplasia. SSPs are considered the likely precursor lesions to sporadic microsatellite instability colon cancer. [11] These polyps should be removed when identified with follow up as per published guidelines. There is evidence that these lesions may progress more quickly through the adenoma-carcinoma sequence, following an alternative pathway, and therefore disproportionally contribute to interval CRCs. [12] Interval CRC may be defined as "a colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected and before the date of the next recommended exam. [13]" Serrated polyposis syndrome (SPS) is a rare condition characterized by multiple large and/or proximal serrated polyps. The genetic basis of SPS remains unknown and current data support the existence of more than one genetic cause. Both sporadic and hereditary cases have been described.[11]

Traditional serrated adenomas are the least common type of serrated polyps, are more prevalent in the rectosigmoid colon and may be pedunculated or sessile. TSAs have diffuse, but often mild, cytologic dysplasia. They are thought to be likely precursor lesions to the biologically aggressive, *BRAF* mutated, microsatellite stable, colorectal cancer.[14]

A variety of submucosal lesions including lymphoid aggregates, lipomas, leiomyomas, fibromas, polypoid endocrine tumors, rectal carcinoids and metastatic lesions may impart a polypoid appearance to the overlying colonic mucosa. The most common of these, the lipoma, can be diagnosed endoscopically.

Morphologically, colorectal polyps arising from the intestinal mucosa are classified as pedunculated or sessile. Pedunculated polyps are on a stalk arising from the mucosa and sessile polyps are flat lesions without a stalk. [3] The Paris classification system was developed to describe polyp morphology. [15] The clinical implications of the Paris classification mainly involve the assessment of endoscopic resectability. The NICE classification is based on narrow-band images of polyps and uses staining, vascular patterns, and surface pit patterns to distinguish between hyperplastic and adenomatous polyps. [16] The Kudo pit pattern was also developed to predict polyp histology based on surface pit patterns. [17] Using such standardized descriptors is encouraged for synoptic reporting.[18]

Some challenges exist for detecting and removing polyps from the colon. Good colonic preparation prior to the exam is essential and a meticulous inspection by an experienced endoscopist provides the best results. Significant miss rates for detecting polyps (up to 28%), including adenomas, have been described in studies comparing back to back procedures. Specifically, small flat polyps are often associated with a higher miss rate. [19] We also know that screening colonoscopy is less effective at reducing the incidence of proximal colorectal cancers when compared to distal cancers. [20] Some proximal colon cancers may also be more biologically aggressive tumors, such as those that arise from HNPCC carriers.

1.3 Screening for CRC

For the purpose of colorectal cancer screening, the population is divided into average risk and high-risk individuals. High-risk individuals are those with a family history of CRC at a young age, a personal history of CRC or adenomas, inflammatory bowel disease and some inherited syndromes. For individuals in the high-risk group, screening guidelines exist based upon patient risk factors and require periodic colonoscopy.[21,22]

Average risk individuals are those aged 50-74 years and without high-risk features. Current recommendations are for a stool test every one to two years, which should be followed up by a colonoscopy if positive.[21] Stool tests include the guaiac-based fecal occult blood test (gFOBT) and the fecal immunochemical test (FIT). The gFOBT test is able to detect small amounts of blood in the stool and is slightly different than the FIT test, which uses specific antibodies to detect blood in the stool. The FIT test is a more sensitive screening tool than the gFOBT test but they have similar specificity.

1.4 Colonoscopy

Following pioneering work of Dr. Niwa and Dr. Yamagata, Dr. William Wolff and Dr. Hiromi Shinya invented the colonoscope in 1969.[23] These procedures were done looking through an eyepiece at the end of a scope. In 1983 the video endoscope was first introduced, enabling viewing of an image on a video screen. Multiple companies manufacture colonoscopes today including Karl Storz, Fujinon, Pentax and Olympus.

Colonoscopy is the endoscopic examination of the large bowel and the distal part of the small bowel with a camera on a flexible tube passed through the anus. It can

provide a visual diagnosis and grants the opportunity for biopsy or removal of suspicious lesions. Common indications for colonoscopy include gastrointestinal hemorrhage, unexplained changes in bowel habit and suspicion of malignancy. It is also used as a screening test for colon cancer. The day before, and sometimes the morning of, a colonoscopy the patient takes an oral laxative solution to cleanse the bowel. Colonoscopy frequently requires sedation, so may be performed as an outpatient procedure if the patient has an adult to accompany them.[24]

The procedure is performed with the patient recumbent, usually in the left lateral decubitus position. A colonoscope is inserted through the anus to the rectum and advanced through the colon. This is completed using dials that allow for deflection of the tip of the instrument, which includes a video chip to produce an image onto a screen. Air or carbon dioxide is inflated to stretch the large intestine and allow easier visualization while the colonoscope is slowly removed while performing meticulous inspection of the mucosa. There is one working port at the end of the scope that allows for the introduction of smaller devices to perform various interventions, such as taking a biopsy or removing a polyp. Photographs and videos can also be taken to document findings. Colonoscopy usually takes about 30 minutes to perform depending upon patient anatomy and findings. There is usually an endoscopy nurse present to assist the endoscopist during the procedure.

Complications of colonoscopy include complications related to the bowel preparation, the procedure itself, and to the use of sedative agents. Dehydration, patient discomfort and transient hypoxia are not uncommon. Post-polypectomy bleeding and colonic perforation (a hole in the large intestine) are rare but serious complications.

Patients are advised to present to the nearest emergency department for assessment if they develop severe abdominal pain or experience prolonged rectal bleeding.

1.4.1 Quality in Colonoscopy

Quality improvement for colonoscopy has been a recent focus in the endoscopy community. Colonoscopy plays a critical role in the early detection and prevention of CRC with a number of quality indicators identified. [25-28] Only adenoma detection rate (ADR) has been clearly associated with risk of interval CRC and death. [29,30] ADR may be defined as "the fraction of patients undergoing colonoscopy who had one or more adenomas detected. [31]" Other intra-procedure quality indicators have been identified including adequacy of bowel preparation, cecal intubation rate, patient comfort, withdrawal time and sedation use.[25]

Given variation in colonoscopy quality metrics among endoscopists, the Canadian Association of Gastroenterology (CAG) developed the Skills Enhancement for Endoscopy (SEE) program. [32] This program consists of three separate types of accredited programs: Train-the-Endoscopy-Trainer (TET), Colonoscopy Skills Improvement (CSI) and the Endoscopic Polypectomy Improvement Course (EPIC).

The TET program is designed to improve teaching skills and procedural conscious competence needed to teach endoscopy. Courses are led by SEE faculty and run for one and a half days with an instructor to student ratio of 1:3. The CSI program, which runs for one day, is designed to provide up-skilling for practicing colonoscopists. This is targeted towards endoscopists participating in provincial colon cancer screening

programs. Participants get hands on colonoscopy training under supervision with an instructor to student ratio of 2:3.

Traditionally and often presently, the teaching of colonoscopy is performed by instructors who were self-taught using a trial and error approach to skills acquisition with little time for self-reflection or formative feedback. [33] Given this training model, these instructors struggle teaching colonoscopy as they failed to develop the tools needed to deconstruct what happens during a colonoscopy. That is, they failed to become consciously competent colonoscopists. Conscious competence originates from the 'Four stages for Learning Any New Skill,' a theory developed in the 1970s by psychologist Noel Burch. According to this theory, learning progresses from unconscious incompetence through conscious incompetence and conscious competence to unconscious competence. Prior to the SEE program, many colonoscopists became unconsciously competent without first becoming consciously competent. The SEE program strives to develop conscious competence in its trainees such that these individuals can better describe colonoscopy to others.

Coaching is a proven approach for performance improvement in both surgery and professional sports. Basic principles of facilitated learning, autonomous and individualized goal setting and constructive feedback can apply to both trainees and surgeons in practice. [34] This can be applied for the most simple or complex procedures depending on the level of the trainee. The CSI program follows many of the same principles to improve performance in colonoscopy, with CSI faculty functioning as coaches to participants. Faculty observe and critique procedures and provide constructive feedback on technique in a non-confrontational manner.

1.5 Purpose

A study showing poorer than expected safety outcomes following colonoscopy in St. John's, NL, along with the launch of the provincial colon cancer screening program, prompted Eastern Health to join the CAG SEE program. Training in St. John's has been ongoing since 2014. [35] The purpose of this study was to evaluate the CAG CSI course as an educational intervention to improve colonoscopy quality in St. John's, NL. The primary outcome was change in endoscopist ADR. Secondary outcomes included APC, cecal intubation rate, sedation usage and dosing and withdrawal time.

Null Hypothesis

H_0: CSI training has no effect on ADR.

CHAPTER 2 REVIEW OF LITERATURE/BACKGROUND

2.1 Quality Measures in Colonoscopy

Quality indicators or measures are tools that help to quantify healthcare processes. [26] They allow researchers to quantify processes, facilitating analysis and comparison of the results of various interventions. Common quality indicators include: adenoma and polyp detection, cecal intubation, withdrawal time, bowel preparation, medication usage and patient comfort.

An important outcome measure after colonoscopy is the prevention of colorectal cancer (CRC), however, cancer occurrences are so infrequent that their use is limited as a quality indicator. Adenoma detection, which correlates well with colorectal cancer prevention, is used as an outcome measure.[26]

2.1.1 Adenoma & Polyp Detection

For screening colonoscopy in average risk individuals, ADR performance targets are ≥25% for all patients (≥30% for men and ≥20% for women). [25] These thresholds were chosen based on the prevalence rate of adenomas detected in screening colonoscopy programs. ADR for a particular endoscopist can be determined by including both screening/surveillance and diagnostic procedures but minimum acceptable standards have been developed using primarily screening/surveillance procedures. Studies have found that endoscopists' ADR is significantly associated with the risk of interval cancer and death. [29,30] In fact, ADR is the only quality indicator that has been shown to be directly associated with interval CRC. [27] Each one percent increase in ADR has been associated

with a three percent decrease in the risk of interval cancer development. [29] Suggestions to explain interval cancer development have included missed lesions, new lesions, and incompletely resected lesions. Improvement in training and a creating a culture of quality improvement are cited as potential solutions.[36]

Polyp detection rate (PDR) is a surrogate for ADR that is easier to measure because it does not require histological review. [37] Although PDR correlates with ADR, it is a less desirable measure. PDR will include polyps with histologies that are benign and inconsequential. An additional problem with focusing quality improvement on PDR is the possibility that endoscopists inflate their PDR by intentionally removing small and clearly inconsequential polyps. [25] PDR is not currently endorsed as a quality indicator. [25] Adenoma per colonoscopy (APC) is another metric that may more accurately reflect inspection of the entire length of the colon and provide greater separation between endoscopists than ADR. [38] APC is calculated by dividing the total number of adenomas detected by the total number of colonoscopies performed. APC has not yet been shown to have a direct association with decreased interval CRC. The remainder of this section focuses on other quality indicators that are important but have not yet been associated with interval CRC.

2.1.2 Cecal Intubation

Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal caput is visible. A colonoscopy is only considered complete if the colonoscope is passed into the cecum. Confirmatory photo documentation and description of cecal landmarks should be done for each procedure.

Variations in cecal intubation rates exist in practice; inadequate cecal intubation could explain the proximal location of some interval cancers.[26] Indeed, cecal intubation rates below 80% have been associated with higher rates of interval proximal colon cancer.[39] Colonoscopists should be able to intubate the cecum in ≥90% of all cases and ≥95% of cases when the indication is screening in a healthy adult.[25]

2.1.3 Withdrawal Time

Mean withdrawal time for colonoscopies with normal results in a patient with intact anatomy should be greater than or equal to six minutes.[25] Studies have shown that a six minute minimum withdrawal time is associated with increased detection of significant neoplastic lesions. It is the minimum recommended time to conduct a thorough inspection of the colonic mucosa. Many studies that have examined the association between withdrawal time and quality were limited as they were performed in single centers with relatively few endoscopists.[26] Consequently, there is potential for further research to define optimal withdrawal time.

The primary utility of recording withdrawal time may be in correcting performance of colonoscopists with substandard ADRs.[40] In a study comparing endoscopists before and after instituting a minimum eight minute withdrawal protocol, ADR improved. Endoscopists with the highest rates of adenoma detection were those with intermediate mean withdrawal times. Furthermore, increases in ADR were apparent among all endoscopists whose baseline rates were at the low end of the spectrum.[40]

2.1.4 Bowel Preparation

Quality of bowel preparation directly impacts adenoma detection. Adequate preparation is critical to ensure full inspection of the colonic mucosa. There are several validated scales to rate preparation quality however none are widely adopted. As a general rule, if the preparation is inadequate to identify polyps greater than five millimeters in size, then the procedure should be repeated. Most centers use a Likert scale when describing preparation quality, rating preparations as: *excellent, good, poor or very poor.*

Preparations rated *poor* or *very poor* warrant an early repeat examination. A meta-analysis conducted in 2014 determined that poor preparation yielded significantly lower ADR than intermediate and high quality preparation but that each of the latter did not differ significantly from one another. [41] Poor preparation is also associated with prolonged cecal intubation and withdrawal times.[25]

Recently, split dosage bowel preparations have become common. Split dosage refers to taking half the dose of purgative the night before the exam and the second half the morning of the exam. Previously it was more common to administer the entire preparation the day before a colonoscopy and have the patient consume only clear fluids until their procedure. Split dosage bowel preparation has been found to improve ADR as well as preparation quality and colonoscopy completion rate. [42] Split dose bowel preparation is now considered the standard of care.

2.1.5 Medication Usage and Patient Comfort

There is great variation in the use of sedation and analgesia among colonoscopists.[27] Traditionally, colonoscopy has been performed using conscious sedation with a combination of a narcotic and a benzodiazepine. In this scenario the endoscopist is in control of medications administered by a nurse. In many countries, a large proportion of colonoscopies are now performed with little or no sedation.[43] There has been a recent trend in North America towards increased use of deep sedation for colonoscopy. This is often done using propofol and may negatively affect safety and quality while offering marginal benefits.[44] In North America propofol administration is usually done with anesthesia assistance.

The American Society of Anesthesiologists has defined a continuum of sedation including minimal, moderate, deep sedation and general anesthesia. Minimal sedation is a drug-induced relief of apprehension with minimal effect on consciousness. The patient is awake and alert. Moderate sedation (often referred to as conscious sedation) is a depression of consciousness in which the patient can respond purposefully to verbal or light tactile stimuli. Airway reflexes, spontaneous ventilation and cardiovascular function are maintained. Deep sedation is a depression of consciousness in which the patient cannot be aroused by voice or light touch but responds purposefully to repeated or painful stimuli. The patient may not be able to maintain airway reflexes or spontaneous ventilation but cardiovascular function is usually maintained. General anesthesia is a state of unconsciousness. Airway intervention is often required and cardiovascular function may be impaired.[45,46]

No direct association had been demonstrated between sedation usage and ADR but there is some suggestion that sedation can improve colonoscopy completion. [47] This is believed to be facilitated by improved patient comfort, which has been associated with improved cecal intubation, though there are conflicting reports.[48]

While sedation is used to improve patient comfort, optimal colonoscopic technique may also improve patient comfort and minimize sedation requirements. According to a recent study from the UK screening program, the medication practices of individual colonoscopists does not appear to be related to the occurrence of significant discomfort among patients.[49]

There has been recent interest in the type and level of sedation used for colonoscopy given the trend towards increased propofol usage in North America. Patient reported outcomes in terms of comfort and satisfaction were highlighted in a meta-analysis that suggested improved overall satisfaction with propofol sedation when compared to traditional agents. [50] Propofol has also been shown to have faster patient recovery and discharge times when compared to traditional agents.

Type of sedation may impact safety during colonoscopy procedures. Use of propofol provides deep sedation as opposed to the traditional narcotic and benzodiazepine combination, which provides mild-to-moderate sedation. Deep sedation for colonoscopy has recently been described as unnecessary and wasteful, citing increased cost, marginal benefits in comfort and negative impacts on safety and quality as justification. [44] Although studies have shown no difference in cardiopulmonary events when comparing propofol with traditional sedative agents, use of an anaesthesiologist has been associated with increased risk of serious but uncommon events. [51-53] The use of an

anaesthesiologist, who typically provides propofol sedation, has been associated with increased risk of perforation, haemorrhage, pneumonia and stroke. Deep sedation may also impair the endoscopist's ability to use optimal colonoscopy technique including prescribed patient position changes and water exchange. Deep sedation may prevent patients from expressing pain caused by excessive bowel distension and hence increase their risk of perforation.

2.2 Specialty and Experience

Studies have shown that gastroenterologists have higher ADRs than endoscopists from other specialties, such as surgeons, internists and family physicians. [54] However others have suggested that endoscopist annual procedural volume of greater than 200 colonoscopies per year may actually be more important than specialty when considering quality measures such as ADR, polyp detection and cecal intubation.[54-56]

The teaching of endoscopy can vary significantly based on specialty. In most major Canadian hospitals both gastroenterology fellows and general surgery residents learn colonoscopy as part of their training. Gastroenterology fellows undergo two years of training and typically get exposed to a higher case volume than their general surgery counterparts. General surgery residents typically have three to five months of dedicated endoscopy training and exposure to colonoscopy outside of that is variable. A study done in Western Canada in 2008 showed gastroenterology fellows performed an average of 248 colonoscopies during their training whereas general surgery residents performed an average of just 91 colonoscopies. [57] The American Society for Gastrointestinal

Endoscopy recommends that a minimum of 140 colonoscopies be performed to assess competency.

It is well recognized that completion of a specified number of colonoscopies does not necessarily imply competence. However, volume and accreditation have been shown to be more important than specialty in determining quality standards for colonoscopy for practicing endoscopists.[58]A recent study showed non-gastroenterologist specialty as a risk factor for perforation but cited that this result likely reflects volume and training style. [59] It is clear that in the relationship between colonoscopy quality and specialty, volume is a key factor.

2.3 Optimal Colonoscopy Technique

Training endoscopists to use optimal technique is a complex, multifaceted process that requires close collaboration between the trainer and the trainee. Aspects of training that are focused upon in the CSI course include room setup, scope handling, torque steering, patient positioning, insufflation technique, and loop recognition and reduction. This section intends to highlight some techniques recently debated in the literature.

2.3.1 Patient Positioning

Repositioning a patient during colonoscopy can facilitate insertion of the colonoscope and enhance visualization of the colon during withdrawal. Patient repositioning takes advantage of the gravity dependent distribution of fluid and air to optimize visualization of different colonic segments. There have been conflicting data published on whether prescribed patient position changes during the procedure can

influence ADR. [60,61] In one study, it was not shown to make a difference in those endoscopists with high baseline ADRs but did improve those endoscopists with ADRs less than 25%. A multi-center RCT published in 2016 demonstrated increased ADR and APC with position change on withdrawal.[62]

2.3.2 Insertion Technique

Water exchange, water immersion, CO_2 and air insufflation are different methods used to aid colonoscope insertion. The water exchange method involves infusion and removal of water predominantly during insertion. Using the water immersion technique, water is infused on insertion and removed during withdrawal. CO_2 and air insufflation also allow for visualization of the colonic mucosa on insertion.

Head to head comparison of air insufflation and water infusion has shown that water infusion can achieve significantly higher ADRs. [63] Water infusion colonoscopy has also been reported to reduce discomfort and to decrease the need for patient position change on insertion. [64,65] When comparing air and CO_2 insufflation, CO_2 significantly reduces abdominal pain during and following colonoscopy, lasting up to 24 hours. [66] CO_2 is more readily absorbed than air and use of CO_2, for both insertion and withdrawal is commonly recommended.

2.3.3 Magnetic Endoscopic Imaging

Magnetic endoscopic imaging (MEI) was first described in 1993 as a measure to improve appreciation of colonoscopic positioning. [67] MEI provides real-time three-dimensional views of the colonoscope configuration, allowing for identification of

looping during colonoscopy. MEI has been shown to be of benefit in training inexperienced endoscopists and improves cecal intubation rate for both experienced and inexperienced endoscopists.[68]

Looping occurs when the colonoscope stretches and distends the colon in response to the endoscopists efforts to advance the scope. This often causes pain and discomfort for the patient and may occur in up to 91% of colonoscopies[69] Looping may increase procedure time, as loops often need to be reduced before the scope can be advanced further. Reducing a loop is accomplished with a combination of patient repositioning, clockwise or anticlockwise torque on the shaft and withdrawal of the colonoscope shaft. MEI allows the endoscopist to identify the type of loop allowing him/her to apply the most effective reduction technique.

2.4 Previous Quality Improvement Programs/Initiatives

Establishing quality standards has become a recent focus in colonoscopy. Many centers conduct regular audits of overall performance and provide endoscopists with report cards on their individual performance in terms of common quality indicators. In the past five years there have been multiple quality improvement programs implemented worldwide. Most programs use changes in endoscopist ADRs as the primary outcome to measure quality and multiple RCTs have been published as a result. This section will provide a brief overview of the research that has been done in this area.

2.4.1 Education

There are multiple educational strategies currently used to target quality improvement. An educational intervention may consist of didactic teaching, a hands-on approach or a combination of the two. These interventions can target a large audience at once or can be done on an individualized basis. The most appropriate delivery method may vary depending on the content and intended result.

A program similar to the CAG SEE program was instituted for the National CRC Screening program in Poland during 2012, called the Train Colonoscopy Leaders program. [70] The first large multicenter RCT on a quality improvement program was subsequently published in 2015, showing improvement in ADR for participants by approximately four percent. The training of 38 screening centre leaders improved the performance of not only the individuals, but also the performance of their centres and these improvements in colonoscopy performance were sustained over the course of 18 months. [71] The intervention group in this study received a two-day intensive training course on skills improvement plus two half-day hands-on sessions tailored to their needs based on a pre-training assessment. The control group received email feedback on their individual pre-intervention screening colonoscopy quality indicators. Criticisms of the study include potential for Hawthorne effect, since leaders knew they were being monitored post intervention and generalizability as inclusion criteria selected only leaders who had a baseline ADR $\leq$ 25% (suboptimal performers).

Two smaller RCTs at the Mayo Clinic in the United Stated also showed improvement in ADR for endoscopists participating in both screening and surveillance colonoscopy after an educational intervention, called Endoscopy Quality Improvement

Program (EQUIP). [72,73] In the original EQUIP study, 15 endoscopists were randomized into two groups and both groups received feedback after an initial monitoring period but the intervention group also had two one-hour training sessions. The first session discussed methods and techniques proven to increase ADR and the second session focused on visually distinguishing neoplastic from non-neoplastic polyps. The intervention group also received monthly feedback on their ADR after the course while the control group did not. The intervention group saw an 11% increase in ADR while the control group ADR remained the same. Baseline ADR was 36% for both groups. Criticisms of this study included randomization (two endoscopists with the lowest baseline ADRs were assigned to receive training), co-interventions, and small sample size. The EQUIP intervention group consisted of mainly younger, less experienced endoscopists with some of the lowest baseline ADRs. The authors did address this in their subgroup analysis. The intervention group also received the training plus monthly feedback after the course, making it difficult to determine the benefit of the educational module relative to the monthly feedback on ADR.

The second study, EQUIP-II, was a follow up on the original and included the same 15 endoscopists. This study showed that improvements in ADR persisted for at least five months following the original study. However, in EQUIP II the control group was offered the educational intervention on a voluntary basis and all physicians received quarterly feedback on ADR. Criticisms of this study include crossover of the control group into the intervention group and a small sample size. The authors noted that APC rate did not change despite the study focusing on ADR, citing the possibility of a 'one and

done' phenomenon where endoscopists may not be as diligent about seeking additional adenomas after the first adenoma was found.[73]

2.4.2 Audit

A systematic review analyzing interventions to improve ADR in 2011 included seven papers and ten abstracts. [74] Only one study used a randomized, controlled trial design; [75] others used observational designs that contrasted adenoma and/or polyp detection rates before, during or after the intervention. Interventions across the studies varied but most were focused around providing feedback to endoscopists and lengthening withdrawal time by setting protocols. Only one paper showed improvement in ADR, which was attributed to a mandated withdrawal time ≥ eight minutes paired with training on enhanced mucosal inspection techniques. [40] The RCT included was the Evaluation of Formal Feedback on Endoscopic Competence (EFFECT) trial, demonstrating improved cecal intubation in gastroenterology trainees who received formal feedback versus those without feedback.

Audit and feedback interventions via physician report cards continue to be proposed as a strategy to improve colonoscopy quality. Physician report cards provide feedback on a number of quality metrics and are administered at regular intervals during the year. They are easy to produce if the unit has an electronic medical record and can be low cost. Implementation of an audit and feedback system must be thoughtful with attention paid to the concerns of recipients in order to achieve buy in because without accountability or motivation to change, they may have little or no impact. [76] A recent study combined audit and feedback with implementing standards of practice and saw

significant ADR improvement. [77] Standards of practice included minimum withdrawal times and minimum ADRs. These are similar to what has been done in the past. Another review on audit and feedback interventions cited mixed results with this technique in the past, largely due to study designs. [78]

2.4.3 Endoscopy Unit Review

In addition to studies on education-based quality improvement programs for endoscopists, there has been a mixed-methods review of quality improvement for colonoscopy in general, involving endoscopists as well as nurses, managers and patients. [79] The main findings of this review indicate that all user groups should be involved in the quality improvement process to ensure the appropriateness of the program and also that standards and guidelines must be reviewed and adapted locally to ensure feasibility. Considering patients as partners in the quality improvement process remains a challenge and future work might see them incorporated more often. It is noted that the most effective quality improvement initiatives are often in groups who have receptive attitudes and take ownership of the quality improvement process. Additionally, the confidentiality of the results for individual physicians was important and the most effective programs are focused on improving the quality of the colonoscopy unit as a whole and not targeting poor performers with negative consequences.[79]

The United Kingdom (UK) has developed a program called the Global Rating Scale (GRS), which is a web-based self-assessment quality improvement tool that underpins accreditation process for endoscopy services. [80] The GRS-UK was developed after an audit in 2004 revealed significant deficiencies in the quality of colonoscopy

services being performed at that time. [81] The outputs of the GRS provide a summary of progress towards quality standards as detailed by the Joint Advisory Group on GI Endoscopy. Progress is indicated by a score given in levels (A - D) in a number of areas of quality. Centres must obtain level B quality indicators if they want to be involved in colon cancer screening in the UK. Endoscopy services are required to submit the census annually to apply for accreditation.

The CAG developed an adaptation of the GRS-UK, the GRS-C, in 2013. [81] The goal was to improve endoscopic services in Canada by providing endoscopy units with a straightforward process to review the quality of the service they provide. The GRS-C uses a very similar rating scale to the GRS-UK. It is hoped the use of the GRS-C will help improve endoscopic services in Canada as it has in the UK. [82] No published reports of efficacy are available at this time.

2.5 CSI Course Overview

The CSI course was developed by CAG for all practicing endoscopists to provide up-skilling and improvement of colonoscopy skills. It allows for hands-on colonoscopy over the one-day course, with two SEE certified faculty teaching up to three delegates. The course was developed based on a framework for effective, efficient delivery of training skills in endoscopy. [83] This framework focuses on providing performance enhancing feedback to trainees using a structured approach and applying basic adult learning techniques. Educational goals are set at the beginning of the session to help align agendas between trainers and trainees. A dialogue continues during the hands-on component of the session aimed at enhancing performance and checking for

understanding using specific language and avoiding cognitive overload. At the end of each hands-on case, performance enhancing feedback is provided to the trainee along with one or two take home messages. Feedback is given in a non-judgmental fashion using a conversational approach. There has been no published evaluation of this course.

CHAPTER 3 METHODS

3.1 Literature Search

The PubMed, Embase, and Cochrane databases were searched to find relevant literature on the topics of colonoscopy quality indicators and quality improvement. Searches were performed using the keywords: “colonoscopy/standards” [MeSH], "quality indicators, health care" [Mesh], “adenoma detection” and “sedation usage” with the goal of finding research examining these quality measures for colonoscopy. Another search was done using the following keywords: “colonoscopy/standards” [MeSH] and “quality improvement” [MeSH] with the goal of identifying studies examining colonoscopy quality improvement programs. These searches revealed 687 and 77 English results published in the last five years, respectively. Relevant articles were then selected after reviewing all abstracts and only full publications were included. Seventeen articles with reference to colonoscopy quality indicators were identified which consisted of prospective and retrospective cohorts as well as review articles. Seven quality improvement articles were identified and included two randomized control trials (RCT), one follow up study, one systematic review, one prospective cohort studies and two review articles. The only limits placed on the literature search were published within the last five years and English only publications. Bibliographies of all selected studies were then screened to identify any additional resources missed in the original literature search.

3.2 Study Design

This was a retrospective cohort study designed to evaluate the impact of the CAG CSI course on colonoscopy quality in St. John's, NL. In October 2014, 3 Eastern Health endoscopists began training with the SEE program. This consisted of each completing the CSI and TET courses themselves and then leading CSI courses under the supervision of certified SEE faculty. After leading six courses, the EH endoscopists received CAG certification to provide courses independently. Subsequently, more CSI courses were offered to endoscopists throughout NL. Approximately eight courses were offered each year, with three endoscopists attending each one.

Our study included all local endoscopists who had taken the CSI course up until May 2016, including the three endoscopists that became certified SEE faculty. Short-term impacts were studied by looking at fifty procedures immediately before and after CSI training. An additional fifty procedures were then sampled eight months after training to identify the durability of any short-term effects.

Patients were identified using the EndoProse software package in the endoscopy unit at our institution. Colonoscopy procedures were selected based on the date of CSI training for each individual endoscopist. Data were collected from multiple sources including the software package and the Meditech system used at both hospitals. Data collected were converted into an excel document directly. Once collected, all data were entered into SPSS version 19.0 software for statistical analysis.[84]

Full approval was obtained from the provincial Health Research Ethics board (File no. 20170008). Local endoscopists were aware of the study.

3.2.1 Outcomes Measurements

The primary quality outcome was ADR. Secondary outcomes included APC, cecal intubation rate/completion, sedation usage and dosing, and withdrawal time. Pathology reports were used to classify polyp histologic type and determine ADR and APC. Cecal intubation was determined by review of the procedure report only. Withdrawal time in the procedure report included any intervention, where required.

Data were collected on patient age, gender and indication for procedure. Data regarding endoscopist experience, annual colonoscopy volume and specialty (gastroenterology or general surgery) were collected.

Adequacy of bowel preparation was also recorded from the endoscopy reports. Bowel preparation was not assessed using a standardized tool in the procedure reports. It was reported using a Likert scale.

3.2.2 Inclusion/Exclusion Criteria

We included fifty colonoscopies immediately before, immediately after and eight months after CSI training for each endoscopist who completed the CSI course. All procedures were included except those with indication 'Fecal immunochemical test (FIT) positive' since FIT positive patients have a higher prevalence of both CRC and adenomas which would bias the results. Procedures included screening and surveillance colonoscopies as well as diagnostic procedures based upon patient symptoms or abnormal laboratory and/or imaging studies.

3.3 Statistical Analysis

Students t test, chi squared tests, ANOVA and generalized linear effects model were used, where appropriate, to analyse the data. Students t test and ANOVA were used to assess continuous variables. Chi squared tests were used to assess categorical variables. We performed univariate analysis to identify factors associated with outcomes of interest including ADR, APC, procedure completion and medication dosing using a significance level of 0.10 as the cut-off. We then used logistic and linear regressions to identify factors independently associated with outcomes of interest, using a significance level of 0.05.

3.3.1 Sample Size Determination

In our analysis, the primary outcome was ADR before and after completion of the SEE program.

Baseline ADR for the endoscopist group in St. John's NL is 21.8% based on previous work. [54] We considered an absolute ADR improvement of six percent as clinically meaningful based on previous literature. [71] A sample size of 826 procedures per time point provides 80% power to detect a proportional difference in ADR improvement of six percent with a two-sided significance level (α) of 0.05. We planned to include 19 endoscopists with 50 procedures in each of the pre, post and late post groups.

CHAPTER 4 RESULTS

4.1 Endoscopist and Patient Characteristics

Of the 19 endoscopists included in the study, two were excluded in the final analysis. One had no logged procedures prior to taking the CSI course so there was no baseline comparison. The other had no data in the EMR due to a technical issue with that individuals' procedure logging. Additionally, one endoscopist only had 33 procedures before taking the course but was still included in the study. Data were collected on 2533 colonoscopies in total (833 pre CSI training, 850 immediately after CSI training and 850 eight months after CSI training).

Endoscopists predominantly had more than five years of experience and were a combination of gastroenterologists and general surgeons (Table 1). Annual case volume ranged from 64 procedures per year to 800 procedures per year. The majority of general surgeons had an annual volume of less than 300 procedures and most gastroenterologists had greater than 300 procedures.

Table 1 Baseline Characteristics of Endoscopists

Male sex - n (%)	12 (70.5)
Specialty - n (%)	
Gastroenterology	8 (47.1)
General Surgery	9 (52.9)
Annual case volume - n (%)	
≤150	4 (23.7)
150-300	6 (34.9)
301-599	4 (23.7)
≥ 600	3 (17.8)
Colonoscopy experience - n (%)	
≥ 5 years	13 (76.5)
< 5 years	4 (23.5)

Patient groups and indications for procedure were comparable at the pre, post and eight month follow up time points (Table 2). There was a statistically significant difference in the proportion of male patients between time points (p=0.042). The most common indications for colonoscopy were 'colon cancer screening' and 'history of polyps.' There was a significant difference noted in the number of screening procedures between groups (p=0.039). There were numerous stated procedural indications. For the purposes of statistical analysis, we re-categorized all indications into two categories: screening/surveillance procedures and diagnostic procedures.

Table 2 Patient Characteristics and Procedure Indications

Variable	Pre CSI	Post CSI	8-months	p value
Patient variables				
Age, mean (±SD)	60.1(12.5)	60.4(12.6)	60.5(13.0)	0.865
Male sex - n (%)	359 (43.1)	418 (49.2)	387 (45.5)	0.042
ASA Score				
1 - Normal healthy	95 (26.2)	73 (20.9)	70 (22.2)	0.051
2 - Mild systemic disease	225 (62.0)	231 (66.0)	205 (64.9)	0.272
3 - Severe systemic disease	34 (9.4)	42 (12.0)	37 (11.7)	0.682
4 - Severe systemic disease that is a constant threat to life	9 (2.5)	4 (1.1)	4 (1.3)	0.210
Total colonoscopies - n (%)	833	850	850	
Procedure indication - n (%)				
Not stated	2 (0.2)	2 (0.2)	6 (0.7)	0.207
Colon cancer screening	288 (34.6)	245 (28.8)	273 (32.1)	0.039
Known or suspected IBD	54 (6.5)	66 (7.8)	54 (6.4)	0.446
Diverticulitis follow up	14 (1.7)	20 (2.4)	14 (1.6)	0.486
History of CRC	54 (6.5)	66 (7.8)	59 (6.9)	0.582
History of polyps	150 (18.0)	160 (18.8)	151 (17.8)	0.839
Know carrier of a genetic CRC syndrome	6 (0.7)	5 (0.6)	12 (1.4)	0.185
Abnormal imaging/Unknown primary/Rectal mass	32 (3.8)	33 (3.9)	33 (3.9)	0.999
Lower GI bleed	85 (10.2)	94 (11.1)	86 (10.1)	0.783
Non-specific lower GI symptom	93 (11.2)	104 (12.2)	99 (11.6)	0.791
Anemia/FOB+	55 (6.6)	55 (6.5)	63 (7.4)	0.707

The American society of Anesthesiologists (ASA) score was recorded for only 1029 procedures. This score assesses the physical status of a patient before a procedure. The score ranges from one to six. A score of one represents a normal healthy patient

while a score of six represents a patient with declared brain death. There was no significant difference noted in ASA scores between groups (Table 2).

4.2 Procedural and Quality Outcomes

4.2.1 Bowel Preparation

For the purposes of our analysis bowel preparations were either considered 'adequate' or 'inadequate.' An 'adequate' preparation was rated as either *excellent* or *good* in the procedure record. 'Inadequate' preparations were those rates as *poor* and *very poor*. There was a significant difference in both adequacy of bowel preparations and type of bowel preparations used at the different time points (Table 3). We believe this change represents a change in practice of the group that occurred over the course of our study, independent of the training course itself. Adequacy of bowel preparation was kept in all multivariate analyses to account for any effect caused by this change.

Table 3 Bowel Preparation

Variable	Pre CSI	Post CSI	8-months	p value
Adequate preparation - n (%)	419 (50.3)	450 (52.9)	614 (72.2)	0.000
Type of preparation - n (%)				
Golytely	360 (43.2)	372 (43.8)	410 (48.2)	0.075
Peglyte	59 (7.1)	78 (9.2)	204 (24.0)	0.000
Picosalax	284 (34.1)	238 (28.0)	77 (9.1)	0.000
Purgodan	3 (0.4)	7 (0.8)	9 (1.1)	0.240
Not noted/Other	127 (15.2)	155 (18.2)	150 (17.7)	0.226

4.2.2 Withdrawal Time

Withdrawal time was recorded for 2320 (91.6%) of cases. Of those, 1333 procedures had some sort of intervention (e.g. polypectomy, biopsy), excluding them from our analysis of withdrawal time. In the baseline group 337 procedural withdrawal times were included with a mean withdrawal time of 8.64 minutes. Immediately following CSI training withdrawal time was included for 326 procedures and increased non-significantly to 8.77 minutes (P=0.599). At the eight month follow up withdrawal times for 324 procedures were included and the mean was 8.35 minutes (P=0.236). Since only 1200 of 2533 procedures included in the study had withdrawal times representing inspection time, withdrawal time was not included in regression analyses. Withdrawal time was above the minimum standard for quality for all groups.

4.2.3 Adenoma Detection Rate

Univariate and multivariate regression analysis was performed to identify variables independently associated with ADR. Univariate analysis was completed with chi squared tests and ANOVA using a cut-off of p=0.10. Variables associated with ADR in univariate analysis included patient age, patient gender, Fentanyl and Midazolam dosing, as well as procedure indication (Table 4).

Table 4 Univariate Analysis for ADR

Variable	Adenoma Detection	p value
Mean patient age (years)		
Adenoma detected	63.92	<0.001
Adenoma not detected	58.25	
Fentanyl dose (mcg)		
Adenoma detected	63.8	<0.001
Adenoma not detected	68.7	
Midazolam dose (mg)		
Adenoma detected	2.13	<0.001
Adenoma not detected	2.32	
Gender (%)		
Female	27.6	<0.001
Male	40.6	
Adequacy of bowel preparation (%)		
Adequate	34.3	0.358
Inadequate	32.6	
Preparation type (%)		
Golytely	34.7	0.215
Peglyte	33.1	
Picosalax	33.4	
Purgodan	21.1	
Specialty (%)		
General Surgery	33.3	0.764
Gastroenterology	33.9	
CSI training (%)		
Pre	31.8	0.131
Post	33.6	
8 months	35.3	
Indication (%)		
Screening/Surveillance	39.3	<0.001
Diagnostic	25.8	

Adequacy of bowel preparation was not significantly associated with ADR in univariate analysis but was included in the multivariate model as we saw a change in adequacy of preparations over time. Multivariate analysis was performed using binary logistic regression. Variables associated with ADR in the multivariate analysis included patient age, male gender, and indication screening/surveillance (Table 5). R square value for the model was 0.108.

Table 5 Multivariate Logistic Regression Model for ADR

Variable	Odds ratio	95% confidence interval	p value
Age	1.039	1.031 - 1.046	<0.001
Gender			
Female	Reference		
Male	1.704	1.435 - 2.023	<0.001
Indication			
Diagnostic	Reference		
Screening/Surveillance	1.860	1.556 - 2.223	<0.001

The overall ADR for endoscopists in the pre-training group was 31.8%. There was a non-significant increase in ADR to 33.6% after CSI training (P=0.423) with a further but non-significant increase at eight months to 35.5% (P=0.131) (Table 6). Endoscopists were broken into quartiles based on ADR at the pre-training time point. Endoscopists in the lowest ADR quartile (Q_1), had an overall pre-training ADR of 21.3%. This increased non-significantly to 26.0% (P=0.282) immediately following training and increased further to 27.5% at eight months but still remained non-significant (P=0.160). We would expect to see the most pronounced change in the lowest ADR quartile as they

often have the most room to improve. Similar but less pronounced, non-significant changes were seen in the remainder of the ADR quartiles. The general surgery group had a baseline ADR of 30.9% and showed a non-significant increase to 31.6% (P=0.829) immediately after training and significantly increased to 37.6% (0.035) at the eight month mark. Specialty, however, was not a significant predictor of ADR in univariate analysis (Table 4). The gastroenterology group had a slightly higher baseline ADR at 32.9 % that increased non-significantly to 36.0% immediately after CSI training (P=0.368). This increase in ADR did not persist at the eight month mark 32.8% (P=1.00). Variables 'ADR quartile' and 'specialty' were derived from the endoscopist variable. As such only one could be used in the regression analysis to prevent multicollinearity. Multicollinearity is a phenomenon in which one predictor variable in a multiple regression model can be linearly predicated from the others with a substantial degree of accuracy. A multivariate regression model with colinear predictors can still indicate how well the entire bundle of predictors predict the outcome variable but may not give valid results about any individual predictor. We chose specialty as it had the most clinical relevance.

Table 6 Procedural Quality Outcomes by Time Point

Variable	Pre CSI	Post CSI	8-months	p value
ADR - n (%)	265 (31.8)	286 (33.6)	300 (35.3)	0.131
ADR by quartile (%)				
Q_1 (≤24%)	21.3	26.0	27.5	0.160
Q_2 (25%-31%)	28.5	29.5	33.0	0.329
Q_3 (32%-35%)	32.7	36.7	30.0	0.467
Q_4 (≥36%)	40.0	40.0	44.7	0.247
ADR by specialty - n (%)				
General Surgery	139 (30.9)	142 (31.6)	169 (37.6)	0.035
Gastroenterology	126 (32.9)	144 (36.0)	131 (32.8)	0.361
APC - mean (±SE)	0.64 (0.05)	0.74 (0.05)	0.70 (0.05)	0.284
Completion rate - n (%)	94.1	94.2	94.7	0.858
PDR - n (%)	415 (31.6)	451 (34.4)	446 (34.0)	0.368
Sedation used - n (%)	805 (96.6)	812 (95.5)	820 (96.5)	0.437
Sedation dosing - mean (±SE)				
Fentanyl	72.8 (1.1)	64.8 (1.1)	63.5 (0.9)	<0.001
Midazolam	2.49 (0.03)	2.17 (0.03)	2.11 (0.03)	<0.001

Given that there appeared to be an association between ADR and CSI training for surgeons, we performed a subgroup analysis for this cohort of patients. We found the eight month time point following CSI training was associated with increased ADR for surgeons when accounting for patient age, gender, preparation adequacy and procedure indication (Table 7).

Table 7 Multivariate Logistic Regression Model for ADR for Surgeons

Variable	Odds ratio	95% confidence interval	p value
Age	1.036	1.026 - 1.047	<0.001
Gender			
Female	Reference		
Male	1.680	1.329 - 2.123	<0.001
Indication			
Diagnostic	Reference		
Screening/Surveillance	1.471	1.159 - 1.869	0.002
8 months post CSI	1.309	1.025 - 1.672	0.031

4.2.4 Adenomas Per Colonoscopy

Mean number of adenomas detected per colonoscopy showed non-significant changes immediately after CSI training and at the eight month mark (Table 6).

Univariate and multivariate regression analyses were performed to identify variables independently associated with APC. Univariate analysis was completed using ANOVA and correlations with a cut-off of p=0.10. Variables associated with APC in univariate analysis included patient age, patient gender, Midazolam dose, and indication (Table 8).

Table 8 Univariate Analysis for APC

Variable	Correlation coefficient	p value
Mean patient age (years)		
Pearson correlation coefficient	0.193	<0.001
Fentanyl dose (mcg)		
Pearson correlation coefficient	-0.050	0.012
Midazolam dose (mg)		
Pearson correlation coefficient	-0.069	0.001

Variable	APC rate	p value
Gender		
Female	0.51	<0.001
Male	0.91	
Adequacy of bowel preparation		
Adequate	0.67	0.321
Inadequate	0.73	
Preparation type		
Golytely	0.68	0.156
Peglyte	0.65	
Picosalax	0.69	
Purgodan	0.26	
Specialty		
General Surgery	0.67	0.764
Gastroenterology	0.72	
CSI training		
Pre	0.64	0.284
Post	0.74	
8 months	0.70	
Indication		
Screening/Surveillance	0.80	<0.001
Diagnostic	0.55	

Adequacy of preparation was again included in the model. Multivariate analysis was conducted using linear regression. Factors associated with APC in multivariate analysis included patient age, male gender, and screening/surveillance procedure (Table 9). R square value associated with the model was 0.059.

Table 9 Multivariate Linear Regression Model for APC

Variable	B	95% confidence interval	p value
Constant	0.351	0.002 - 0.669	0.049
Age	0.020	0.016 - 0.024	<0.001
Female gender	-0.359	-0.465 - -0.253	<0.001
Diagnostic procedure	-0.216	-0.323 - -0.109	<0.001

4.2.5 Completion

Completion rate for all procedures included in the study was 94.4%. There was no significant difference between procedure completion rates based on CSI training (Table 6).

Univariate and multivariate regression analysis was performed to identify variables associated with procedure completion. Univariate analysis was performed with chi squared tests and ANOVA using a cut-off of p=0.10. Variables associated with procedure completion in univariate analysis included patient age, patient gender, Fentanyl dose, specialty and indication (Table 10).

Table 10 Univariate Analysis for Completion

Variable	Completion	p value
Mean patient age (years)		
Procedure complete	59.97	0.003
Procedure incomplete	63.24	
Fentanyl dose (mcg)		
Procedure complete	66.6	0.003
Procedure incomplete	74.5	
Midazolam dose (mg)		
Procedure complete	2.25	0.333
Procedure incomplete	2.33	
Gender (%)		
Female	93.1	0.002
Male	95.9	
Adequacy of bowel preparation (%)		
Adequate	94.8	0.240
Inadequate	93.7	
Specialty (%)		
General Surgery	92.7	<0.001
Gastroenterology	96.3	
Indication (%)		
Screening/Surveillance	96.0	<0.001
Diagnostic	92.1	

Adequacy of preparation was again included in the model. Multivariate analysis was completed using binary logistic regression, identifying male gender, screening/surveillance indication and gastroenterology specialty as significantly

associated with procedure completion. Patient age and Fentanyl dosage were inversely related to completion rate (Table 11). R square value for the model was 0.061.

Table 11 Multivariate Logistic Regression Model for Completion

Variable	Odds ratio	95% confidence interval	p value
Age	0.975	0.961 - 0.990	0.001
Fentanyl dose	0.993	0.988 - 0.999	0.021
Gender			
Female	Reference		
Male	1.684	1.169 - 2.426	0.005
Indication			
Diagnostic	Reference		
Screening/Surveillance	1.948	1.378 - 2.754	<0.001
Specialty			
General Surgery	Reference		
Gastroenterology	1.749	1.196 - 2.557	0.004

4.2.6 Sedation Dosing

Sedation was given in 96.2% of cases. The only two medications used for sedation were Fentanyl and Midazolam. Sedation dosing decreased significantly for both Fentanyl and Midazolam after CSI training. This effect persisted at the eight month follow up (Table 6).

4.2.6.1 Fentanyl

Univariate and multivariate regression analysis was performed to identify variables associated with Fentanyl dosing. Univariate analysis was completed using ANOVA and correlations with a cut-off of p=0.10. Variables associated with Fentanyl dose in univariate analysis included CSI training, patient gender, patient age, specialty, procedure completion, polypectomy, and indication (Table 12).

Table 12 Univariate Analysis for Fentanyl Dose

Variable	Correlation coefficient	p value
Mean patient age (years)		
Pearson correlation coefficient	-.225	<0.001

Variable	Fentanyl dose (mcg)	p value
Gender		
Female	71.7	<0.001
Male	61.5	
Adequacy of bowel preparation		
Adequate	67.1	0.786
Inadequate	66.8	
Specialty		
General Surgery	72.6	<0.001
Gastroenterology	60.6	
CSI training		
Pre	72.8	<0.001
Post	64.8	
8 months	63.5	
Indication		
Screening/Surveillance	65.6	0.006
Diagnostic	69.0	
Procedure Completion		
Complete	30.2	0.003
Incomplete	36.5	
Polypectomy		
Yes	64.4	<0.001
No	69.6	

Multivariate analysis was conducted using linear regression. Variables associated with Fentanyl dose included CSI training, patient age, patient gender, procedure completion and specialty (Table 13). R square value for the model was 0.141.

Table 13 Multivariate Linear Regression Model for Fentanyl Dose

Variable	B	95% confidence interval	p value
Constant	141.708	127.908 - 155.508	<0.001
Age	-0.587	-0.675 - -0.498	<0.001
Female gender	9.254	7.024 - 11.484	<0.001
Gastroenterology specialty	-13.756	-15.992 - -11.520	<0.001
Complete procedure	-6.156	-10.974 - -1.338	0.012
Immediate post CSI	-7.197	-9.911 - -4.484	<0.001
8 months post CSI	-8.917	-11.628 - -6.206	<0.001

4.2.6.2 Midazolam

Univariate and multivariate regression analysis was performed to identify variables associated with Midazolam dosing. Univariate analysis was completed using ANOVA and correlations with a cut-off of p=0.10. Variables associated with Midazolam dosing in univariate analysis included CSI training, patient gender, patient age, specialty, and polypectomy (Table 14).

Table 14 Univariate Analysis for Midazolam Dose

Variable	Correlation coefficient	p value
Mean patient age (years)		
Pearson correlation coefficient	-.215	<0.001

Variable	Midazolam dose (mg)	p value
Gender		
Female	2.39	<0.001
Male	2.10	
Adequacy of bowel preparation		
Adequate	2.25	0.606
Inadequate	2.27	
Specialty		
General Surgery	2.29	0.025
Gastroenterology	2.21	
CSI training		
Pre	2.49	<0.001
Post	2.17	
8 months	2.11	
Indication		
Screening/Surveillance	2.23	0.104
Diagnostic	2.29	
Procedure Completion		
Complete	0.95	0.333
Incomplete	1.18	
Polypectomy		
Yes	2.18	<0.001
No	2.33	

Multivariate analysis was conducted using linear regression. Variables associated with Midazolam dosing included CSI training, patient age, patient gender and specialty (Table 15). R squared value for the model was 0.096.

Table 15 Multivariate Linear Regression Model for Midazolam Dose

Variable	B	95% confidence interval	p value
Constant	3.925	3.606 - 4.244	<0.001
Age	-0.016	-0.019 - -0.013	<0.001
Female gender	0.257	0.185 - 0.328	<0.001
Gastroenterology specialty	-0.139	-0.211 - -0.067	<0.001
Immediate post CSI	-0.294	-0.382 - -0.207	<0.001
8 months post CSI	-0.370	-0.457 - -0.283	<0.001

Given the association between gastroenterology specialty and sedation dosing, we performed subgroup analysis for both gastroenterologists and general surgeons. Both groups had significant decreases in sedation dosing at the immediate post and eight month time points.

CHAPTER 5 DISCUSSION

5.1 Quality Outcomes

This was the first formal evaluation of the impact of CAG CSI program on colonoscopy quality. Although we noted trends towards improvement in ADR there was no statistically significant association between ADR and CSI training for the entire group (Table 6). When we looked at endoscopists in the lowest ADR quartile we saw the same non-significant trend towards improvement in ADR. The subgroup analysis for general surgeons showed a significant improvement in ADR at the eight month time point. This finding suggests that the surgical group (lower volume endoscopists with less formal colonoscopy training) benefit more from CSI training than their colleagues in gastroenterology. One can only speculate why this occurred.

Based on previous work, overall ADR for our institution was 21.8% in 2012. [54] At the pre CSI training time point in our study, ADR was 31.8%. There had clearly been a significant improvement before the initiation of CSI training. We noted multiple practice changes over that time period. The endoscopy vendor changed from Fujinon to Olympus in 2014 and this included the addition of magnetic imaging. There had also been a change to split dose bowel preparation. Also, educational initiatives were undertaken to improve colonoscopy quality along with the introduction of the GRS-C. All of these factors may have influenced ADR. In addition, given that all endoscopists were aware their outcomes were being monitored, the Hawthorne effect may have played a role in the improvements seen between 2012 and the baseline measurements used for our study.

A possible explanation why the current study did not document significant changes in ADR for the entire group of endoscopists is the high baseline ADR. The accepted guideline for ADR in average risk patients is 25%, much lower than the baseline ADR for this group. Another possible explanation may be the CSI course itself. The training that occurs focuses more on helping the trainees navigate the colonoscope to the cecum in an ergonomic fashion that is comfortable for the patient. Although discussed, less emphasis is placed on finding and removing polyps.

No significant association was demonstrated between CSI training and APC. APC did show a non-significant trend towards improvement immediately after CSI training and remained higher at the eight month time point (Table 6). As expected, we noted patient age, patient gender and procedure indication to be associated with APC in multivariate analysis.

During the time period of our study we noted significant changes in bowel preparation type and quality. This likely reflects a practice change of the entire group towards split dose preparation given recent evidence of superiority. [42] This was included in all multivariate analyses since it is known to affect ADR and may affect other quality outcomes of interest. An improvement in bowel preparation could confound our results, biasing towards a higher ADR at eight months and potentially lead to false positive results.

No association was identified between procedure completion as defined by cecal intubation and CSI training. Our group had a high completion rate at the baseline time point of 94.1%. This is well above the acceptable standard of 90%.[25] Completion rate was higher in the gastroenterology group, which may again be attributed to the fact that most

general surgeons at our institution have a lower annual volume and the general surgery group contains more endoscopists with less than five years of experience.

CSI training appears to have improved quality at our institution primarily through reduced sedation dosing for both Fentanyl and Midazolam. These are the only two sedation agents used for colonoscopy at our institution. This change in practice persisted at the eight month time point.

The association between lower sedation dosing and CSI training may reflect improvement in colonoscopy technique associated with taking the course. The course focused on topics including scope handling, torque steering, patient positioning, insufflation technique, and loop recognition and reduction. All of these topics are discussed to help lessen patient discomfort and sedation requirements.[49]

Specifically, frequent patient repositioning is emphasized during the course, with a goal of having the patient in optimal position for colonoscope insertion and mucosal inspection in each segment of colon. This is a relatively new technique that most local endoscopists had not adopted prior to taking the course. To allow for frequent repositioning it is helpful to have an awake and alert patient that can respond to commands. Deep sedation would prevent this, making the repositioning much more difficult.

Less sedation may also be valuable in that it may reduce recovery time. Short recovery time and faster discharge is an argument provided for using propofol over a narcotic and benzodiazepine combination. [85] CSI training may reduce recovery and discharge time associated with a narcotic and benzodiazepine combination by reducing

doses of these agents. Although our study did not address this issue, it may be an area for future work.

Gastroenterology specialty was associated with lower Fentanyl and Midazolam dosing when compared to the general surgeons. The gastroenterologists at our institution have higher annual procedural volumes on average than the general surgeons. This fits with findings recently published in the UK showing that more experienced endoscopists use less sedation to complete the procedure. [48] In the subgroup analysis both gastroenterology and general surgery groups had significant reductions in sedation dosing after CSI training, which suggests the benefits are independent of annual volume.

In our multivariate models for both Fentanyl and Midazolam we demonstrated that there was no significant difference between mean dosage at the immediate post training and eight month time points. This further strengthens our findings and suggests that the change is related to CSI training rather than time of sampling.

This is the first study to show an association between an educational intervention to improve colonoscopy quality and lower sedation dosing. Previous studies have not assessed effects on sedation while focusing mainly on ADR. [71,72] A study done during 2012 showed that medication related adverse events were extremely common. [35] In that study one in ten patients suffered hypoxia (oxygen saturation ≤85%) and one in six patients suffered hypotension (blood pressure <20% of baseline). Although we did not assess the rate of these adverse events, given the significant reduction in sedation it is likely a decrease in the incidence of these adverse events would correspond.

5.2 Sample Size Calculation and Power

The sample size calculation performed for this study estimated a total number of procedures necessary to detect a 6% change in ADR. Procedural data were collected based on the date that each individual endoscopist participated in CSI training. Because of this, our sample size calculation may overlook clustering and correlation of outcomes within individual endoscopists. This is an issue we did not consider, but an important consideration for future research, as it would significantly increase the sample size necessary to detect a change in ADR.

Using the same baseline ADR of 21.8% and considering an ADR improvement of 6% as clinically meaningful, a sample size of 1330 procedures per time point would be necessary when accounting for correlation of outcomes using an intra-cluster correlation coefficient of 0.05. If we were to increase the correlation coefficient, the sample size would increase further. Another alternative to this would be to change our data collection strategy, sampling procedures at a time point before training was initiated in 2014 and again at the completion of all training. In this scenario, clustering and correlation of outcomes would not be an issue.

5.3 Limitations

Our study has some limitations. First, this is a retrospective study and we are relying on endoscopist records for our data. Not all data may be entered accurately or completely. Second, we cannot control for all confounding variables. We did identify and control for bowel preparation type and adequacy as possible confounders, including these in the multivariate analyses. Third, our cohort of endoscopists were highly experienced,

13 endoscopists in our study have been in practice for over five years and only three had an annual volume less than 150 procedures. This may partially account for our high baseline ADR and completion rate. In a less experienced group we may see more pronounced effects with CSI training. Fourth, our sample of procedures was heterogeneous in terms of indication. We did however account for indication in all regression analyses and FIT positive procedures were excluded. Fifth, a recent audit performed in 2012 may have improved ADR through a Hawthorne effect, making it more difficult to see change in our study. Lastly, procedures for two of the nineteen endoscopists were not included in our study and our study may be underpowered to detect small changes in ADR due to correlation of outcomes within individual endoscopists. At our institution CSI training was provided free of cost to the individual which enhanced uptake of the program.

To avoid bias in this study we chose a clear primary outcome variable that could be accurately measured and has been validated in the literature. Data on all cases were collected in the same fashion and a sample size calculation was performed at the outset of the study. This study was susceptible to selection bias in choosing patients to include. We standardized our method of case selection for each endoscopist to minimize this. The only procedures excluded were those with indication FIT positive. Being a retrospective study, confounding is a significant potential issue. Confounding occurs when differences in the baseline characteristics between the study groups result in difference in the outcome. In our study particularly it was important to account for patient age, gender and bowel preparation quality, which are all variables know to influence ADR.

5.4 Future Work

Our retrospective study has identified that training aimed at increasing the skills of the experienced endoscopist can improve quality. The next step to evaluate the impact of the CSI program may be a randomized controlled trial assigning endoscopists with no prior CSI training to take the course or not. Such an RCT may have ethical issues and if ethically permissible, would have considerable logistic challenges. An argument could also be made that such an RCT is not actually necessary given the results of our study. There may also be value in repeating a similar study with a less experienced group of endoscopists as more pronounced effects could be noted. It would be useful to study a group that has not previously undergone audit as that may have impacted our results. Additionally, given we identified significant changes in practice with just a one-day course, larger effects may be achieved with more training interventions or interventions specifically targeting ADR improvement.

Given the findings of our study it may be prudent to compare patient comfort between endoscopists who have completed CSI training and those who have not. It would be important to identify whether lower levels of sedation are correlated with higher levels of patient discomfort. We hypothesize that lower levels of sedation actually reflects improved technique causing less discomfort.

CONCLUSION

In summary, participation in CSI training was shown to be associated with improvements in quality, specifically with regards to sedation required. Specifically we

have identified that colonoscopy can be completed with less sedation in a sustained fashion with a brief training course. CSI training appears to improve ADR for surgeons.

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