University of Alberta

Quality of colonoscopies performed by Primary Care Physicians

by

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Dedication

I would like to dedicate this work to my wife Loraine and three children Nicholas, Kate and Mark. Without their support and sacrifices, the completion of this thesis would not have been possible.

Abstract

This thesis examines the quality of colonoscopies performed by primary care physicians.

Methods: A systematic review examined existing evidence pertaining to the quality of colonoscopies performed by primary care physicians. Subsequently, a prospective, multi-centre observational study (the Alberta Primary Care Endoscopy study) examined cecal intubation rates, adenoma detection rates, serious adverse event rates and patient satisfaction with colonoscopies performed by Albertan primary care physicians.

Results: The systematic review demonstrated that primary care physicians perform safe and likely perform quality colonoscopic exams. In the APC-Endo study, the overall adjusted cecal intubation rate was 96.5% (95% CI: 94.6, 97.8). Age and sex-specific adenoma detection rates reached recommended targets. One perforation and three post polypectomy bleeds occurred, and patient satisfaction was exceptionally high.

Conclusion: Primary care physicians are able to perform high quality colonoscopic exams. Training primary care physicians in gastrointestinal medicine and endoscopy may help with the colonoscopic shortage in Canada.

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I wish to thank all those who played a role, big or small, in the completion of this thesis project.

Firstly, I wish to thank my thesis supervisor, Dr. Brian Rowe, for his advice, wisdom, encouragement, and motivation in transforming ideas from concept to completion.
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The Alberta Primary Care Endoscopy study would not have been possible without the tremendous efforts of the participating physicians and their assistants. The physicians had the courage to participate in a study which analyzed the quality of colonoscopies they were performing themselves. I would also like to thank all the patients who provided valuable insight into patient satisfaction with primary care endoscopy through completion of the patient satisfaction survey.

The Alberta Primary Care Endoscopy study was funded by the Alberta Rural Physician Action Plan (RPAP). I wish to thank David Kay, the executive director of RPAP for all his support of primary care endoscopy both recently and over the past 12 years.

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Abbreviations

AAPCE	American Association of Primary Care Endoscopy
ACG	American College of Gastroenterology
AGA	American Gastroenterological Association
AHS	Alberta Health Services
APC-Endo	Alberta Primary Care Endoscopy
ASGE	American Society of Gastrointestinal Endoscopy
CIR	cecal intubation rate
cm	centimetre
CI	confidence interval
CRF	Case report form
CT	computerized tomography
FOBT	Fecal occult blood testing
GHAA-9	Group Health Association of America 9
HREB	Health research ethics board
IQR	interquartile range
KT	Knowledge transfer
NA	Not applicable
OR	odds ratio
PSA	Procedural sedation and analgesia
PAGE	Practice Audit in Gastroenterology
RPAP	Alberta Rural Physician Action Plan
SAE	Serious adverse event
SD	standard deviation
USMSTF	United States Multi-Society Task Force on Colorectal Cancer

Chapter 1
Gastrointestinal disease, colorectal cancer screening and primary care colonoscopy in Canada

1.1 Burden of gastrointestinal disease in Canada

Gastrointestinal disease affects approximately 20 million Canadians.(1) It includes diseases such as peptic ulcer disease, gastroesophageal reflux disease, inflammatory bowel disease, celiac disease, diverticulitis and colorectal cancer. Gastrointestinal complaints are common in primary care, with up to 18% of primary care patients reporting substantially bothersome gastrointestinal symptoms.(2) Patients with gastrointestinal symptoms experience impairments in social functioning and their activities of daily living while waiting for their gastrointestinal investigations and treatment.(3)

Approximately 1 in 2 Canadians will develop a cancer, and 1 in 4 will die from a cancer.(4) In Alberta and in Canada, colorectal cancer has the fourth highest incidence of any cancer, and next to lung cancer, is the most common cause of death from a malignancy.(5,6) Colorectal cancer affects both men and women is responsible for an estimated 9,100 annual deaths per year in Canada.(6)

Most Canadians have a 6% lifetime risk of developing and a 3% risk of dying from colorectal cancer.(7,8) This risk increases if one has a family history of colorectal cancer or polyps, underlying inflammatory bowel disease or if one belongs to a Lynch syndrome or familial adenomatous polyposis family.(9)

1.2 Colonoscopy definition and uses

A variety of diagnostic tests are available to investigate patients with gastrointestinal symptoms or to screen asymptomatic individuals for colorectal cancer. These tests commonly include: fecal occult blood testing (FOBT), radiographic imaging such as computerized tomography (CT scans), barium studies or virtual colonoscopy, and endoscopy including gastroscopy, sigmoidoscopy or colonoscopy.(10)

Colonoscopy is a procedure whereby a flexible fibre optic tube (the colonoscope) **{See figure 1.1}** is inserted into the anus and advanced from the rectum through the large intestine to the cecum or terminal ileum by a skilled operator.(11) Colonoscopy is performed to visualize the colonic mucosa **(See figures 1.2, 1.3)** to investigate patients with lower gastrointestinal tract symptoms(12) and to screen asymptomatic patients for colorectal cancer.(13,14) A sigmoidoscopy differs from a colonoscopy in that it only examines the rectum, sigmoid and a variable length of the colon.(15) Most colonoscopies are performed under procedural sedation and analgesia (PSA), commonly involving benzodiazepines +/- narcotics.(16)

The goals of a colonoscopy are to document, and if indicated and possible, to remove any abnormalities (for example polyps). Biopsies and photographs are also taken when appropriate. The aim is to achieve these goals while minimizing complications such as bleeding, colonic perforation or complications related to procedural sedation.(11)

A quality colonoscopy involves not just the technical performance of the procedure (including documentation of the quality of the bowel preparation, cecal intubation, procedural and withdrawal times, the detection of adenomas and cancers, and endoscopic

removal of adenomas when possible) but also pre and post procedure parameters. Pre colonoscopy quality indicators include appropriate indication and patient selection (including appropriate surveillance intervals) and obtaining informed consent. Post colonoscopy quality markers include determining and comparing complication rates to accepted standard rates and could also include patient satisfaction.(17)

1.3 Screening for colorectal cancer

Colorectal cancer is a disease that warrants population-based screening. Essentially all colorectal cancers develop from adenomatous polyps, with the conversion from a benign polyp to a cancer taking at least 10 years.(18) Detection and removal of these polyps should theoretically prevent colorectal cancer. Clinical symptoms of colorectal cancer are often non-specific and appear late, with up to 43% of cases having advanced disease at the time of diagnosis.(10,19) Even the classic alarm features of colorectal cancer including bleeding, abdominal mass, change in bowel habits, anemia and weight loss have limited sensitivity and specificity.(20)

Screening for colorectal cancer using fecal occult blood, sigmoidoscopy or colonoscopy have been shown to decrease colorectal cancer mortality.(21-24) The evidence demonstrating that colonoscopy decreases colorectal cancer mortality is from cohort studies,(21,22) while both fecal occult blood testing and sigmoidoscopy have evidence from randomized controlled trials.(23-24)

Colorectal cancer stages and survival rates

The aim of colorectal cancer screening is to decrease colorectal cancer rates through polyp detection and removal and to improve the stage of individuals diagnosed with colorectal cancer.

Colorectal cancer is staged according to the penetration of the primary lesion, nodal status and whether organ metastases exist.(25) Stage 1 colorectal cancer includes local tumor which has not invaded through the muscularis mucosa, stage 2 involves local tumor which has invaded through the muscularis mucosa into the pericolorectal tissues, stage 3 involves disease of local or regional lymph nodes, and stage 4 involves distant organ metastases.(26) The overall five-year survival for patients with colorectal cancer is 62%, which is substantially lower than both prostate cancer (95%) and breast cancer (87%).(27) Prognosis also worsens with increasing stage of cancer. Stage 1 has a 93% five year survival, but survival rates decrease with advancing stages to a five-year survival rate of 8% for those with stage 4 disease.(28)

Colorectal cancer screening guidelines

Current Canadian guidelines recommend colorectal cancer screening for all people between 50-75 years,(8,29-31) and timely access to endoscopy (including colonoscopy) for patients with lower gastrointestinal symptoms.(32)

For average risk population-based colorectal cancer screening, current Canadian guidelines recommend fecal occult blood testing or sigmoidoscopy, followed by a colonoscopy if either is positive.(31,33) Average risk persons include those patients 50 years and older without additional risk factors for colorectal cancer, such as: a personal history of colorectal

adenomatous polyps, colorectal cancer or inflammatory bowel disease or a family history of colorectal cancer.(30,31) For those with personal or familial risk factors for colorectal cancer, colonoscopy is the diagnostic test of choice.(8,30)

Current colorectal cancer screen rates

Unfortunately, only 14.3% of eligible Albertans are up to date with colorectal cancer screening, and 23% have had any type of colorectal cancer screening.(34) Other Canadian provinces have similarly low colorectal cancer screen rates.(35) As a likely result of these low screen rates, only about 6% of colorectal cancers are diagnosed by screening and most are diagnosed during an evaluation of gastrointestinal symptoms.(19)

Colorectal cancer screen rates are substantially lower than breast cancer screen rates.(7) In the past 18 years, breast cancer mortality rates have decreased by 30%,(4,36) while mortality rates from colorectal cancer have only diminished marginally.(36) By substantially increasing screening rates, the Alberta Cancer Board's goal is to decrease the mortality of colorectal cancer by 30% by the year 2025 (Dr. H. Yang, Alberta Cancer Board, personal communication; 2009).

While patients appear to be willing to be screened for colorectal cancer,(34,37,38) Alberta physicians are concerned with lack of endoscopic capacity for follow-up of patients with a positive FOBT.(39) These concerns may further contribute to low colorectal cancer screening rates.

1.4 Who performs colonoscopy?

In Canada, 97% of colonoscopies are performed by gastroenterologists or general surgeons,(40) while few family physicians or general internists perform colonoscopies.(41) Gastroenterologists are specialists in internal medicine with a minimum of two additional years of sub-specialty training in gastrointestinal medicine and endoscopy. General surgeons normally spend three months of their five year surgical residency acquiring their endoscopy skills.(11) The means by which other physicians achieve training in gastrointestinal medicine and endoscopy is variable. Family medicine residency programs in Canada do not have specific training in gastroenterology. Most currently practicing primary care colonoscopists in Alberta were proctored by gastroenterologists with a view to help service their rural communities. Internal medicine residency programs in Canada generally have a gastrointestinal block, but residents are not often encouraged to become proficient at endoscopy.(15)

Shortage of colonoscopists

Recent campaigns aimed at increasing colorectal cancer screening rates have substantially increased the demand for colonoscopies.(42-44) Excessive wait times illustrate a shortage of colonoscopists(45,46) and wait times are worsening as more colonoscopies are being done for screening purposes.(47) Endoscopic wait times, depending on the indication, are up to 7.2 times longer than recommended targets,(46) and only 41% of patients with a positive FOBT underwent a colonoscopy within the consensus guidelines of two months.(32,46)

Patients experience impairments in social functioning and in their activities of daily living while waiting for gastrointestinal investigations and treatment.(3) Consequently, the

current strategy of using gastroenterologists and general surgeons almost exclusively to perform colonoscopies is insufficient to satisfy the current and future colonoscopy demands in Canada.

Are primary care colonoscopists a potential solution to the colonoscopist shortage?

Solutions to the issue of insufficient manpower to perform timely endoscopy are varied. Training or importing additional gastroenterologists or surgeons can be expensive and time consuming in terms of length of training. However, providing focused training in gastrointestinal medicine and endoscopy to alternative practitioners such as family physicians, general internists or nurse practitioners may help improve the relative shortage of endoscopists in Canada.

Physicians and nurses who have trained in formal, but shortened GI and endoscopy training programs have demonstrated an ability to competently perform endoscopic exams.(48,49) As a result, the possible solution of increasing these types of training programs is especially appealing.

1.5 Existing evidence on the quality of colonoscopies done by primary care physicians

The first published reports on primary care physicians performing colonoscopy were from the United States from the early 1990s. These early studies demonstrated suboptimal quality outcomes.(50,51) Current research, including a case-series from Canada,(48) a systematic review,(52) and other studies published since the systematic review(53,54) however do demonstrate that trained primary care physicians can achieve quality benchmarks in colonoscopy. Despite this research, controversy surrounding the quality of

colonoscopies being performed by family physicians and general internists still exists and many gastroenterologists do not believe that primary care physicians should be performing colonoscopies.(55)

Issues with studies on the quality of colonoscopies performed by primary care physicians

A previous systematic review on the quality of colonoscopies performed by primary care physicians(52) was publically criticized by the gastroenterological community(56) for including results from a large study (responsible for the majority {73.1%} of all colonoscopies analyzed) where an on-site gastroenterologist was able to assist the primary care colonoscopists if needed.(57)

Many of the original studies that examine the quality of primary care colonoscopies also have methodological issues including: single endoscopist reporting,(48,50,51,53,54,58-61) retrospective data collection,(48,50,53,54,59-64) use of older monocular endoscopes,(50,51,58-60) or potentially suboptimal outcome ascertainment. Some studies did not report how cecal intubation was confirmed.(58,59,61) Other studies used inaccurate methods of confirming cecal intubation,(65) such as visualizing the colonoscopic light in the right lower quadrant(60,66) or measuring the length the colonoscope was inserted.(50)

Only three studies calculated age and sex-specific adenoma detection rates, which would enable comparisons to benchmark targets.(48,62,67) The adenoma detection rate is a likely more meaningful marker of quality colonoscopy than cecal intubation rates as it evaluates both the technical competency of the colonoscopist, and indirectly measures appropriate patient selection and colonoscopy intervals.

Other literature questions the long term outcomes of colonoscopies performed by primary care physicians. Recent Canadian studies, utilizing administrative databases and physician billing codes, claim that future cancer rates are higher when colonoscopies are performed by non-gastroenterologists, including family physicians and general internists.(68-70)

Clearly additional research is required, given the burden of colorectal cancer and gastrointestinal symptoms in primary care, ongoing campaigns to increase colorectal cancer screen rates, the relative shortage of colonoscopists, and the uncertainty surrounding the quality of colonoscopies performed by primary care physicians.

1.6 The thesis proposal

This program of research rigorously investigates the quality of colonoscopies performed by primary care physicians. First, using accepted methods, this proposal presents an updated systematic review of studies reporting on colonoscopies performed by primary care physicians. The systematic review includes studies since the last systematic review as well as sensitivity analyses to determine whether using older monocular endoscopes, having a gastroenterologist to potentially assist primary care physicians, and the volume of procedures performed affects colonoscopy quality outcomes. In addition, the thesis reports the methods and results of a multi-centre, multi-physician prospective observational study examining the quality of colonoscopies performed by Albertan primary care physicians. The thesis also reports on a process of assessing and reporting serious adverse events associated with colonoscopies performed by Albertan primary care physicians.

The Alberta Primary Care Endoscopy (APC-Endo) study is the first Canadian study that examines the quality of colonoscopies performed by primary care physicians at a provincial level. Cecal intubation rates, adenoma detection rates, serious adverse event rates and other quality outcomes are reported and compared to standard benchmarks in colonoscopy quality. Based on the outcomes reported in the research of this thesis, recommendations for training future endoscopists, goals of future colorectal cancer screening and future endoscopy research are outlined.

The Alberta Primary Care Endoscopy (APC-Endo) study was funded by Alberta Rural Physician Action Plan (RPAP) and was registered as a clinical trial at www.clinicaltrials.gov (NCT01320826).

Figure 1.1: The colonoscope

Figure 1.2: Endoscopic picture of a polypectomy

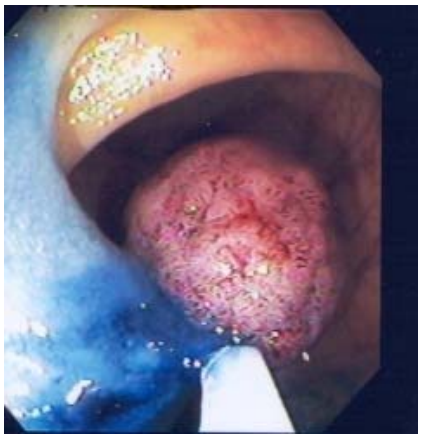
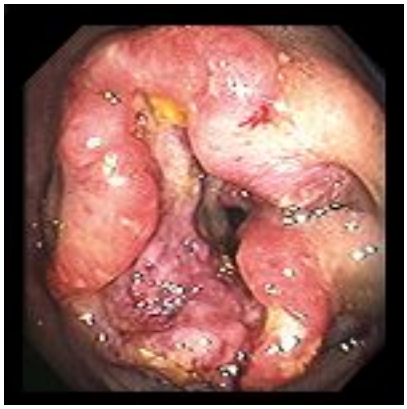


Figure 1.3: Endoscopic picture of a colorectal cancer



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Chapter 2
Systematic review of the quality and safety of colonoscopies performed by primary care physicians

2.1 Background

Description of the condition

In North America, colorectal cancer has the fourth highest incidence of any type of cancer and is second only to lung cancer as a cause of cancer deaths.(1-4) Colonoscopy is a cost-effective tool in screening asymptomatic patients for colorectal cancer and can be used to investigate patients with gastrointestinal symptoms.(5-7) Unfortunately, less than 20% of Canadians are up to date with colorectal cancer screening(8,9) and 43% of colorectal cancers are advanced at the time of diagnosis.(10)

Recent campaigns aimed at increasing colorectal cancer screening rates have substantially increased the demand for colonoscopies.(11,12) Gastroenterologists and general surgeons perform the majority of colonoscopies in Canada and the United States,(11,13) while few primary care physicians are known to perform them.(14-16) Excessive wait times demonstrate a current shortage of colonoscopists,(17,18) which will invariably worsen as our population ages, and more people participate in colorectal cancer screening.

Description of the intervention

Training family physicians and general internists in gastrointestinal medicine and colonoscopy may help improve the relative shortage of colonoscopists. Discrepant data exists, however, regarding the quality of colonoscopies being performed by these primary care physicians.

While some studies demonstrate that trained family physicians and general internists can perform quality colonoscopic exams,(19-21) other studies claim increased future colorectal cancer rates in colonoscopies performed by non-gastroenterologists.(22-24)

A previous systematic review and meta-analysis concluded that primary care physicians are able to perform quality and safe colonoscopies.(25) This review was publically criticized by the gastroenterological community for including results from a large study, (responsible for the majority {73.1%} of all colonoscopies analyzed) where an on-site gastroenterologist was able to assist the primary care colonoscopists, if needed.(26,27)

Why it is important to do this review?

If primary care physicians are to be considered a legitimate option for performing colonoscopies, evidence should conclusively demonstrate that current primary care colonoscopists can perform quality colonoscopies.

What is new

This systematic review includes studies published since the last systematic review. It also utilizes improved methodology, including an *a priori* decision not to perform a meta-analysis due to the differences in study characteristics, including differing endoscopic systems used. A thorough search for grey literature was performed and authors were contacted for unpublished data. Finally, sensitivity analyses were performed to determine whether technological advances in endoscopic systems, unique practice models, or the volume of colonoscopies performed per physician could explain any heterogeneity observed between studies.

Objectives

The purpose of this review was to evaluate the evidence of the quality and safety of colonoscopies performed by primary care physicians. Crude and adjusted cecal intubation rates, age and sex stratified adenoma detection rates as well as complication rates were compared to current evidence and consensus based standards of quality colonoscopy.

2.2 Methods

Criteria for considering studies for this review

Types of studies

There are no randomized controlled studies comparing the quality and safety of colonoscopies performed by primary care physicians to those performed by gastroenterologists or general surgeons. All types of studies that contained original data and reported outcomes of colonoscopies performed by self-defined primary care physicians were considered.

In addition, there are no systematic reviews that examine the quality of colonoscopies performed by gastroenterologists or general surgeons. Outcomes derived from this systematic review were compared to standards of colonoscopy quality developed by the U.S. Multi-Society Task Force on Colorectal Cancer (USMSTF), which are endorsed by the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society of Gastrointestinal Endoscopy (ASGE).(28,29)

Types of participants

We included patients, symptomatic or asymptomatic, of any age or sex, who had a colonoscopy performed for any reason by a self-defined primary care physician.

Types of interventions

Colonoscopies performed by a self-defined primary care physician including family physicians or general internists.

Outcome measures

Primary outcomes

The primary outcome was the cecal intubation rate, expressed as either the crude cecal intubation rate or the adjusted cecal intubation rate. The adjusted cecal intubation rate is the preferred primary outcome and was used when reasons for incomplete colonoscopies were described.(28,29) Adjusted cecal intubation rates do not count incomplete colonoscopies due to poor quality bowel preparation or severe endoscopic colitis,(28,29) and can also exclude incomplete colonoscopies due to a colonic stricture or obstruction or equipment failure. Poor quality bowel preparation and equipment failure are beyond the responsibility of the endoscopist, while advancing a colonoscope through severe endoscopic colitis or a colonic stricture may increase the risk of a perforation.

Secondary outcomes

The proportion of patients with at least one adenoma was determined and then analyzed by sex and age-specific groups.

Safety was assessed by the overall rate of serious adverse events including bleeding, perforation, complications with procedural sedation, and death.

Search methods for identification of studies

Electronic searches

Using search strategies developed in collaboration with a University of Alberta Health Sciences librarian, electronic searches of MEDLINE, EMBASE, PUBMED, SCOPUS and Web of Science were performed **(See appendix 2a)**. The search was performed on March 3, 2010 and was repeated April 23, 2011. The second search revealed no new studies, but Sweeney's study initially published as an abstract was now a full manuscript.(30)

Searching other resources

Abstracts and thesis dissertations from the past 10 years were also searched using OCLC Proceedings First, BIOSIS Previews, and Web of Science. Efforts were made to contact all authors for unpublished data and other potentially relevant presentations, abstracts or articles. Finally, citation lists and Google Scholar were hand searched, and contact was made with the American Association of Primary Care Endoscopists (www.aapce.org) for any additional data or manuscripts. Language of publication and non-publication was not a reason for exclusion.

Data collection and analysis

Selection of studies

Studies were considered for inclusion if they contained original data reporting on outcomes of colonoscopies performed by primary care physicians. Studies were excluded if the colonoscopies were performed by non-primary care physicians, trainees, or any other health care professionals, if less than 100 colonoscopies were analyzed, or if outcomes for primary care physicians were not reported separately from other types of physician colonoscopists.

MRK screened the titles and abstracts of eligible studies. Two independent reviewers (MRK and TL) then reviewed full manuscripts of potentially relevant studies to determine inclusion status. Disagreements were resolved by consensus. TL independently reviewed MRK's own published paper to determine inclusion status.

Data extraction and management

Data was extracted using specially designed data extraction forms and was entered into Revman 5™. We extracted data on: study design, methods, the participants (patients) and the primary care physicians, outcomes, and type of endoscopic system used. Since an *a priori* decision was made not to perform a meta-analysis, overall point estimates for the cecal intubation or adenoma detection rates are not reported.

Assessment of risk of bias

Risk of bias in individual studies

To assess the quality of the case-series studies, we adapted criteria from Chambers (31) and determined the following for each study that met inclusion criteria:

1. Was selection / eligibility criteria adequately reported?
2. Were the patients representative of that seen in normal practice?
3. Were the patients recruited consecutively?
4. Were the patients recruited prospectively?
5. Was cecal intubation determined accurately?

Reporting the selection / eligibility criteria was important to determine whether colonoscopies were performed for only colorectal cancer screening or for both screening

and the investigation of symptomatic patients. This designation determines the appropriate cecal intubation rate target and whether the study was representative of normal primary care colonoscopy practice. Consecutive and prospective patient recruitment decreases the risk of selection bias. Appropriate methods of confirming cecal intubation are identifying landmarks of the cecum (appendiceal orifice, tri-folds and ileocecal valve) or intubating the terminal ileum. Photographing or videoing these landmarks are considered the gold standards for cecal confirmation.(29) Unreliable methods of confirming cecal intubation include visualizing the colonoscopic light in the right lower quadrant and measuring the length of colonoscope insertion.(32) For the one cohort study, risk of bias was explored using the Newcastle-Ottawa quality assessment scale.(33)

Risk of bias at the review level

Double counting subjects in case series studies can lead to overestimating or underestimating outcomes.(34) We contacted authors to specifically address the potential of double counting if: more than one article was authored or co-authored by the same person, or if more than one trial collected data from the same geographical setting.

As we did not perform a meta-analysis in this systematic review, we did not perform a funnel plot to evaluate for publication bias.

Measures of treatment effect

Cecal intubation rates

Cecal intubation rates (crude and adjusted) and adenoma detection rates were expressed in percentages with 95% confidence intervals. The crude cecal intubation rate was calculated by dividing the total number of colonoscopies where cecal intubation was achieved by the

total number of colonoscopies performed. The adjusted cecal intubation rate was calculated by dividing the total number of colonoscopies performed where cecal intubation was achieved by the total number of colonoscopies performed minus the procedures limited by a poor bowel preparation, colonic stricture or obstruction, equipment failure or severe endoscopic colitis. Our adjusted cecal intubation rates were calculated slightly differently than the USMSTF calculations.(28,29) We considered colonoscopies aborted due to colonic stricture or obstruction or equipment failure to be legitimate reasons for incomplete colonoscopies since primary care colonoscopists do not normally dilate strictures and equipment failure is beyond the control of the colonoscopist.

The USMSTF recommended targets for adjusted cecal intubation rates are ≥ 90% for all colonoscopies and ≥ 95% if only screening colonoscopies are being performed.(28,29) Adjusted cecal intubation rates were used to determine whether each study met cecal intubation targets, with crude cecal intubation rates being used when studies did not report reasons for incomplete colonoscopies. Primary care colonoscopists achieving mean cecal intubation rates equal to or greater than aforementioned targets were considered to be meeting quality standards in cecal intubation.

Adenoma prevalence rates

For patients 50 years and older who are having their first colonoscopy, USMSFTF recommends that the proportion of males and females that have a pathologically confirmed adenoma should be 25% and 15%, respectively.(28,29) Endoscopists achieving these targets were considered to be meeting quality standards in adenoma detection.

Potentially serious adverse events

Serious complications in colonoscopy were defined from the Standards of Practice Committee of the American Society of Gastrointestinal Endoscopy (ASGE)(35,36) as follows:

Bleeding: Bleeding which subsequently resulted in admission to hospital, a blood transfusion, a second colonoscopy or surgery. Bleeding should occur in less than 1/100 colonoscopies in which polypectomies are performed.(28,29,37)

Perforation: Clinical and radiographic (free air on plain abdominal films or CT scan) evidence of a perforation. Perforation rates should be no greater than 1/500 and ideally less than 1/1000 colonoscopies.(28)

Procedural sedation adverse events: Occurred when the colonoscopy was stopped prematurely, reversal agents were used, the patient required artificial ventilation, or the patient was admitted to hospital after the procedure for any new cardiac or respiratory condition related to the sedation agents. Complications related to procedural sedation should be less than 1/100.(28,29)

Death: A death directly resulting from a complication related to the colonoscopy, which occurs in approximately 1/10,000 colonoscopies.(38,39)

If the complication rates observed in the systematic review were less than the above defined rates, we would conclude that primary care colonoscopists perform safe colonoscopies.

Unit of analysis

For each study, 95% confidence intervals around given point estimates of cecal intubation and adenoma detection rates were calculated using the formula:

(95% CI = X +/- 1.96 (SD/$\sqrt{n}$) where SD = $\sqrt{p}$ (1-p) and verified using a statistical calculator from Dimension Research Inc.™

Missing data

For studies with prospective data collection, we examined the percentage of incomplete data. Any study that had greater than 10% incomplete data would be considered at high risk of attrition bias.

Assessment of heterogeneity

Due to differences among the studies in terms of years of data collection and therefore differences in endoscopic systems used, an *a priori* decision was made not to perform a meta-analysis and therefore we did not perform a statistical analysis of heterogeneity.

Assessment of reporting biases

Since none of the studies had protocols, it was not possible to completely determine selective reporting biases. The methods section of each study, however, was reviewed to ensure all patients and variables that were identified in the methods were reported in the results.

Data synthesis

We did not perform a meta-analysis and therefore summary point estimates of cecal intubation rates and the adenoma detection rates were not provided. Since serious complications of colonoscopies are rare, we determined the overall and complication specific complication rates.

Subgroup analysis and investigation of heterogeneity

Sensitivity analysis

To explore potential heterogeneity between studies, sensitivity analyses were performed for: the type of endoscopic system used, unique practice models, and the annual volume of colonoscopies performed per physician.

We hypothesized that studies that used the older monocular endoscopic system, would have lower cecal intubation rates compared to studies that used the newer video fibreoptic systems. In response to the aforementioned criticism of the previous meta-analysis (that primary care colonoscopists do not normally have the luxury of having an onsite gastroenterologist), a sensitivity analysis comparing this unique practice model to standard practice models was performed. Finally, a sensitivity analysis was performed to explore the hypothesis that higher volume colonoscopists have better quality outcomes than lower volume colonoscopists.

2.3 Results

Results of the search

From 711 records identified through electronic database searching and five found via hand searching, after removing duplicates, we identified 449 potentially relevant articles. Fifty-eight full-text articles were assessed for eligibility by two independent reviewers (MRK, TL). Authors were contacted to clarify questions pertaining to inclusion criteria when necessary. TL independently determined whether MRK's publication met criteria for inclusion. Forty-three (43) articles were excluded leaving 15 articles included in this review **(See figure 2.1)**.

Reasons for study exclusions were: twenty-eight did not report original data; eight studies had colonoscopies performed by non-primary care physicians; in three studies we were unable to determine physician subtypes; two studies did not separate outcomes by primary care vs. non-primary care physicians; and two analyzed fewer than 100 colonoscopies. There were no disagreements on study inclusion between the two reviewers.

Included studies

Fifteen studies met inclusion for the review, four of which were published since the last meta-analysis.(19-21,40) The fifteen studies reported on 115,018 colonoscopies, with 94,870 from one large population based cohort(40) and 20,148 from 14 case-series studies. Overall, 13,366 of the 20,148 colonoscopies from the case-series literature were from one abstract currently pending publication as a full manuscript(27) **(See table 2.1)**.

Study design

All fifteen studies gathered data on consecutive patients, however, only three studies gathered data prospectively.(41-43) In the included abstract, it was unclear whether data was collected prospectively or retrospectively.(27)

Study settings

All of the studies were from North America; eleven from the United States(20,21,27,41,43-49) and four from Canada.(19,40,42,50) Eight studies were from rural centres.(19,41-43,46-48,50) In five studies at least some of the colonoscopies were performed outside a hospital setting(44-46,48) with one study utilizing a dedicated endoscopy centre.(27)

Participants

All studies reported performing colonoscopies for both symptoms and screening except Sweeney(27) (only performed screening colonoscopies) and Cotterill(42)(performed both symptomatic and screening colonoscopies, but reported outcomes for only screened patients). For these two studies, the cecal intubation target was ≥ 95%, while for all other studies the target was ≥90%.

All but two studies(27,42) reported the mean age of their patients, with the average age of patients in each study ranging from 53.5 years(19) to 67.4 years.(41) Details on sex of patients were reported in eleven of the fifteen studies **(See table 2.1).**

Intervention

All studies included family physician colonoscopists, while only two studies included internists.(27,40) Unfortunately, these two studies did not separate outcomes for family physicians and internists.

In the case-series articles, the number of colonoscopies performed per study ranged from 157 performed by one physician(44) to 13,366 performed by fifty-three physicians.(27) Nine of the studies reported on colonoscopies performed by one primary care colonoscopist,(19-21,41,44,45,47,48,50) while an unknown number of physicians performed 94,870 colonoscopies in the cohort study.(40) The average volume of colonoscopies performed per physician per year ranged from 25(44) to 200.(20) Only two studies had yearly averages greater than 125.(19,20)

Outcomes

Cecal intubation rates

All studies recorded crude cecal intubation rates, which ranged from 54.7% (95% CI: 47.9, 60.1)(48) to 98.6% (95% CI: 97.0, 98.9).(20) Only six studies either directly reported(19) or reported reasons for incomplete colonoscopies which allowed a calculation or estimate of the adjusted cecal intubation rate.(41,43,44,47,48) The adjusted cecal intubation rates ranged from 55.7% (95% CI: 48.8, 61.2)(48) to 98.6% (95% CI: 97.0, 98.9).(20) The median overall cecal intubation rate {crude or adjusted if available} for all the studies was 92.3% (IQR: 83.3, 96.2). Eight out of the fifteen studies reached USMSTF cecal intubation rate targets (19-21,27,43,46,47) **(See table 2.2)**.

Confirmation of cecal intubation differed substantially among the studies. Four studies used the gold standard of photographing or videotaping cecal landmarks,(19,20,27,43) while three used visualizing landmarks without photo or video documentation.(44,47,49) Three studies used a combination of landmarks, light in the right lower quadrant and length of scope insertion,(42,48,50) one study used physician billing data,(40) and four studies did not mention how cecal intubation was confirmed.(21,41,45,46)

Adenoma prevalence rate

The proportion of patients with at least one pathologically confirmed adenoma was reported in eight studies.(19,20,27,42,43,46,47,50) Only three studies reported age and sex-stratified adenoma detection rates,(19,20,46) with all three achieving USMSTF target adenoma prevalence rates of 25% for males and 15% for females 50 years and older **(See table 2.2)**.

Potentially serious adverse events

All fourteen case-series studies, totaling 20,148 colonoscopies, reported on complications, while the large population based cohort study, did not.(40) Seven studies reported having no complications (20,21,42-44,49,50) while the remaining studies reported a total of 76 potentially serious adverse events, for an overall rate of 1 serious adverse event in every 265 colonoscopies performed **(See table 2.2)**.

Sixty of the serious adverse events were related to procedural sedation (1/336 colonoscopies); however, 52 /60 (87%) of these complications stemmed from one physician using naloxone (Narcan) 52 times in 293 colonoscopies.(48) If that physician's naloxone use is excluded, a total of 24 serious complications occurred for a serious adverse event rate of 1 in every 839 colonoscopies.

There were seven bleeds (1/ 2878) and five perforations (1/4030) reported and no deaths attributed to having a colonoscopy. Of the seven bleeds, three were admitted to hospital overnight without requiring additional treatment,(41,46,47) one had a second colonoscopy, (19) and in three the details were not reported.(27) One of the five perforations resolved with conservative management,(19) while details on the other four were not reported.(27)

The overall complication rates were less than accepted complication rates of procedural sedation (1/100), bleeding (1/100), perforation (1/500-1/1000) and death (1/10,000).

Sensitivity analysis

Due to clinical differences among the older and newer studies, we did not pool our studies and perform a meta-analysis. However, in order to explore potential heterogeneity, three

sensitivity analyses were performed to determine whether it appeared that the type of endoscopic system used, unique practice model or volume of colonoscopies performed per physician per year explained heterogeneity. Formal statistical analysis was not performed in the sensitivity analyses and results are provided only for illustrative purposes.

Sensitivity analysis: Endoscopic system used

Endoscopic systems advanced from monocular viewing through the end of the colonoscope to fibreoptic video projection on a monitor, around the late 1980s in the United States (personal communication, Richard Pierzchajlo) and early to mid 1990s in Canada (personal communication, Richard Fedorak). From dates of data collection,(45,48,50) date of publication,(44) or personal communication with the author,(41) we determined that five studies likely performed some of their colonoscopies with the older endoscopic system. Pierzchailo personally confirmed that although his data collection started in the late 1980s, all his procedures were performed using the newer fibreoptic system.(47)

All five studies in which the monocular endoscopic system was used did not achieve cecal intubation rates targets. The studies using monocular systems also appeared to have lower cecal intubation rates (median CIR = 80.4%; IQR: 74.7, 83.3) compared to studies using only the newer video fibreoptic systems (median CIR = 94.4%; IQR: 92.3, 98.0) **(See figure 2.2)**.

Sensitivity analysis: Unique practice models

In response to criticism of the previous meta-analysis and the fact that most primary care colonoscopists do not have an onsite gastroenterologist, a sensitivity analysis was performed comparing Sweeney's unique practice model to standard practice models.(27) As Sweeney's cecal intubation rate (98.4%) compares favorably to the median CIR of the

other studies which do not have an on-site gastroenterologist (92.1%; IQR: 83.3, 94.8), it appears that having an onsite gastroenterologist does improve cecal intubation rates. There are insufficient published data, however, to state this conclusively **(See figure 2.3)**.

Sensitivity analysis: Annual volume of colonoscopies performed per physician

Evidence suggests that inexperienced physicians who perform a higher annual volume of colonoscopies may have higher completion rates compared to those who perform fewer colonoscopies.(51) To explore this hypothesis, we compared physicians who averaged over 125 colonoscopies per year to those performing less than 125 colonoscopies per year. The volume of colonoscopies performed per year did not appear to significantly influence cecal intubation rates. For example, low volume endoscopists had a median CIR = 92.6% (IQR: 83.3, 96.2) while high volume endoscopists had a median CIR = 95.5% (IQR: 92.3, 98.6). Again there are insufficient data to state this conclusively as only two studies had annual colonoscopic volumes of > 125 **(See figure 2.4)**.

Risk of bias in included studies

Due to inconsistent and incomplete reporting in the case-series papers, it was difficult to assess the risk of bias. Sixty-six (66) colonoscopies performed in the same Canadian rural community were included in two studies.(42,50) Despite contacting the authors, it remained unclear which of the 66 colonoscopies were counted twice.

The cohort study had acceptable ascertainment of exposure, and demonstrated that the outcome of interest was not present at the start of the study, but assessment of completion of colonoscopy was based on physician billing data.(40)This self-reported data, directly tied to financial compensation (depending on how far the colonoscope was inserted), was not

cross-referenced to other records and may have resulted in inaccurate ascertainment of colonoscopy success.

Incomplete outcome data

For the three trials with prospective data collection, the number or proportion of patients with incomplete data were not reported.

Selective reporting

As none of the studies reported their protocols, we were unable to completely determine if selective reporting existed. By comparing each study's methods to results section, two studies were discovered to use selective reporting. In one study, both symptomatic and asymptomatic patients underwent colonoscopy; however, outcomes were only reported for the asymptomatic patients who underwent colonoscopy for colorectal cancer screening.(42) While 293 colonoscopies were performed in the other study, only the outcomes of 253 sedated colonoscopies were reported.(48)

Other potential sources of bias

No studies were funded by makers of endoscopic equipment.

2.4 Discussion

Summary of main results

This review is the largest and most rigorous systematic review about the quality of colonoscopies performed by primary care physicians. This study illustrates that primary care physicians perform safe colonoscopic examinations which are likely of high quality.

Although only eight out of fifteen studies reached cecal intubation rate targets, explanations exist for those that did not achieve quality standards. Firstly, in nine studies crude cecal intubation rates were compared to adjusted cecal intubation rate targets. Incomplete colonoscopies occur not only for technical limitations of the colonoscopist but also due to poor bowel preparation, stricture or obstructions, equipment failure or severe colitis. If more studies calculated adjusted cecal intubation rates, then perhaps more studies would have reached cecal intubation targets. For example, Cotterill's study involving screening colonoscopies had a crude cecal intubation rate of 94.0% (95% CI: 91.4, 96.6).(42) If four of the incomplete colonoscopies occurred due to poor quality bowel preparation, equipment failure, stricture or obstruction or severe colitis, the adjusted cecal intubation rate would have been ≥ 95%.

It also appears that the type of endoscopic system used influences cecal intubation rates. All five studies which had colonoscopies performed with the technically challenging older monocular endoscopic systems did not meet cecal intubation targets. In the studies that used the newer fibreoptic systems, 8/10 reached cecal intubation targets. Other literature, has also illustrated that technological improvements in colonoscopy equipment may be partly responsible for improving colonoscopy outcomes over time.(40,52)

In addition, most current colonoscopies are performed using procedural sedation. Hopper's overall crude cecal intubation rate was 74.7% (95% CI: 71.3, 76.7),(45) however; 32% of his colonoscopies were performed without sedation. When only sedated colonoscopies were analyzed, the cecal intubation rate improved to 92.8% (95% CI: 90.0, 94.0). Conversely, one study utilized an onsite gastroenterologist. It remains unclear how many procedures the gastroenterologist assisted the primary care colonoscopist with. These

‘assisted colonoscopies' may have contributed to overestimating cecal intubation rates in this study.(27)

Accurate assessment of outcomes is imperative in any research. Confirmation of cecal intubation differed between many studies, which may have also affected true cecal intubation rates.

Recent literature also reports that even gastroenterologists may have difficulties achieving cecal intubation targets.(53-55) Only when systematic reviews of other types of physician colonoscopists are performed will a true understanding of whether these targets are reasonable and achievable in normal clinical practice occur.

The adenoma prevalence rate may be a more useful quality outcome than cecal intubation rates; however, this may not be a universal belief. In addition to evaluating technical competency of the colonoscopist, adenoma detection rates also indirectly measure the appropriateness of patient selection and intervals for repeat colonoscopy. Only three studies reported age and sex-specific adenoma prevalence rates, with all three achieving USMSTF targets.

Seventy-six serious complications occurred. Fifty-two of these complications were due to one physician's almost routine use of the reversal agent naloxone (Narcan). Excluding this physician’s naloxone use, the rate of serious complications was significantly lower. Irrespective of this exclusion or not, complication rates were less than the accepted complication rates of bleeding and perforation and related to procedural sedation. Therefore we concluded that primary care physicians provide safe colonoscopic exams.

Overall completeness and applicability of evidence

There are no standardized templates for reporting of colonoscopic outcomes and as a result, reporting was inconsistent and often incomplete.

Specific areas for improved reporting for future studies include:

1. Reporting patient demographics: to allow a better understanding of the applicability of findings and for calculation of age and sex specific adenoma detection rates.
2. Reporting reasons for incomplete colonoscopies: to allow direct comparisons of study adjusted cecal intubation rates to adjusted cecal intubation rate targets.
3. Using gold standard techniques (photo or video documentation) to ensure accurate ascertainment of cecal intubation.

In addition, once Sweeney's abstract is published as a full manuscript, questions regarding the validity of this study will likely be answered.(27)

Three studies were considered non-representative of normal primary care colonoscopic practice. Two studies had a high rate of unsedated colonoscopies(45,48) while one study used a practice model which employs a consultant gastroenterologist to potentially aid primary care colonoscopists.(27)

Quality of the evidence

Although case series are not the highest level of evidence, they are meaningful in examining non-pharmacological interventions and adverse events and can be meaningful for systematic reviews.(31) Unfortunately, as previously described, many studies had

methodological issues or incomplete reporting and therefore overall quality of the evidence in this review could be considered either unclear or have a high risk of bias.

Potential biases in the review process

The author screened the titles and abstracts of eligible studies, which could possibly result in selection bias. Also, no papers or abstracts from outside of North America were identified. This may be due to primary care physicians not performing colonoscopies outside North America, or possibly that primary care colonoscopists outside North American are not publishing their results.

Agreements and disagreements with other studies or reviews

Our conclusion that primary care physicians are able to perform safe colonoscopies and likely able to perform quality colonoscopic exams is similar to the conclusions of the previous meta-analysis. This review differs in concluding that future research with complete and standardized reporting is required before definitive statements about the quality of colonoscopies performed by primary care physicians can be made.

Authors' conclusions

Implications for practice

This review supports the conclusion that primary care physicians do perform safe colonoscopies and are likely able to perform quality colonoscopic exams. As shown in this review, it is likely that even after adjusting for the type of endoscopic system used, unique practice models and volume of colonoscopies performed, individual variation in the quality of colonoscopies performed exists. All physicians who perform colonoscopies should collect

and report their quality markers to get a true understanding of this variability and whether quality targets are truly achievable for all endoscopists.

Implications for research

All primary care physicians who are performing colonoscopies should be encouraged to collect and report on their outcomes in a consistent and complete format. Reporting on patient demographics, reasons for incomplete colonoscopies, pathologically confirmed age and sex specific adenoma detection rates, and conclusive documentation of cecal intubation with photographs or video will offer a better understanding about the true quality and safety of colonoscopies performed by primary care physicians.

Due to the substantial difference between the newer fibreoptic and the older monocular endoscopic systems, future reviews on this topic should only include studies using newer video fibreoptic systems which better reflects the current rather than past practices.

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Declaration of interest

MRK authored one of the included studies that examined the quality of his endoscopic practice, which included colonoscopies.

Table 2.1: Characteristics of the 15 individual studies included in the systematic review

Reference	Years of data collection	Number of endoscopists	Number of colonoscopies (total)	Average # colonoscopies per physician per year	Mean patient age (years)	% female	Indications: Screening, symptoms, or both	Endoscopy system used	Data collection	Recruitment	Study representative of normal practice?	Cecal intubation confirmation
Carr 1998	1991-1994	1	250	63	67.4	38.4	both	old and new	prospective	consecutive	yes	not mentioned
Cotterill 2005	2001-2003	2	324	81	NA	48.7	screening	new	prospective	consecutive	yes	landmarks, light RLQ
Eckert 2009	2003-2007	1	800	200	56.1	52.6	both	new	retrospective	consecutive	yes	photograph
Edwards 2004	2000-2002	4	200	25	62	45.5	both	new	prospective	consecutive	yes	photograph
Godreau 1992	NA	1	157	NA	58	54.8	both	old and new	NA	consecutive	yes	landmarks
Hopper 1996	1985-1994	1	1048	116	57	41.3	both	old and new	retrospective	consecutive	no, 32% unsedated	not mentioned
Kirby 2004	1992-2003	1	618	62	58	NA	both	old and new	retrospective	consecutive	yes	landmarks, light RLQ
Kolber 2009	1999-2007	1	1178	157	53.5	58.8	both	new	retrospective	consecutive	yes	photograph
Newman 2005	1996-2001	2	731	73	62.7	51.6	both	new	retrospective	consecutive	yes	not mentioned
Pierchzajalo 1997	1988-1995	1	751	107	53.8	NA	both	new	retrospective	consecutive	yes	landmarks
Rodney 1993	1985-1990	1	293	59	67	NA	both	old and new	retrospective	consecutive	no, 13% unsedated	landmarks, light RLQ, length of scope inserted
Shah 2007	1999-2003	Unknown	94,870	NA	60.8	53.5	both	new	retrospective	consecutive	unclear	physician billing
Short 2007	2003-2005	1	182	108	57	58.2	both	new	retrospective	consecutive	yes	not mentioned
Strayer 2004	2000-2002	4	250	31	55.3	45.9	both	new	retrospective	consecutive	yes	landmarks
Sweeney 2007	2001-2006	53	13,366	50	NA	NA	screening	new	unclear	consecutive	no, GI supervising	photograph

Table 2.2: Outcomes of the 15 individual studies included in the systematic review

Study	Number of colonoscopies (total)	Crude Cecal Intubation Rate (% with 95% CIs)	Adjusted Cecal Intubation Rate (% with 95% CIs)	Cecal Intubation Rate Target Met*	Adenoma Detection Rate Females ≥ 50 years (proportion with 95%CIs)	Adenoma Detection Rate Males ≥ 50 years (proportion with 95%CIs)	Potentially Serious Adverse Events
Carr 1998	250	82.0 (77.2, 86.8)	86.0 (81.6, 90.4)	No	NA	NA	1 bleed
Cotterill 2005	324[a]	94.0 (91.4, 96.6)	NA	No	NA	NA	0
Eckert 2009	800	98.6 (97, 98.9)	NA	Yes	21.6 (16.8, 25.2)	33.7 (27.7, 38.3)	0
Edwards 2004	200	96.5 (93.2, 98.7)	98 (94.6, 99.4)	Yes	NA	NA	0
Godreau 1992	157	82.8 (76, 88)	83.3 (77.1, 88.9)	No	NA	NA	0
Hopper 1996	1048	74.7 (71.3, 76.7)	NA	No	NA	NA	1 other
Kirby 2004	618	80.4 (76.9, 83.2)	NA	No	NA	NA	0
Kolber 2009	1178	88.3 (86.1, 90.0)	92.3 (90.4, 93.6)	Yes	18.4 (14.4, 21.6)	29.7 (24, 34)	1 bleed, 4 PSAE, 1 perforation,
Newman 2005	731	91.8 (88.9, 93.1)	NA	Yes	21.6 (16.6, 25.4)	27.2 (22.1, 31.9)	1 bleed
Pierchzajalo 1997	751	91.5(89.0, 93.1)	93.4 (91.2, 94.8)	Yes	NA	NA	1 bleed, 3 PSAE
Rodney 1993	293[b]	54.7 (47.9, 60.1)	55.7 (48.8, 61.2)	No	NA	NA	52 PSAE
Shah 2007	94,870	86.2 (85.8, 86.2)	NA	No	NA	NA	N/A
Short 2007	182	96.2 (93.2, 98.6)	NA	Yes	NA	NA	0
Strayer 2004	250	94.8 (91.8, 97.5)	NA	Yes	NA	NA	0
Sweeney 2007	13, 366	98.4 (97.8, 98.4)	NA	Yes	NA	NA	3 bleeds, 1 PSAE, 4 perforations, 3 others

CI = confidence intervals; PSAE = Adverse event related to procedural sedation ; NA = not applicable / available

[a] Reported on only 152 screening colonoscopies

[b] Reported on only 253 colonoscopies where procedural sedation used

* Adjusted CIR used when available, otherwise crude CIR used

Figure 2.1: Flow of papers through review

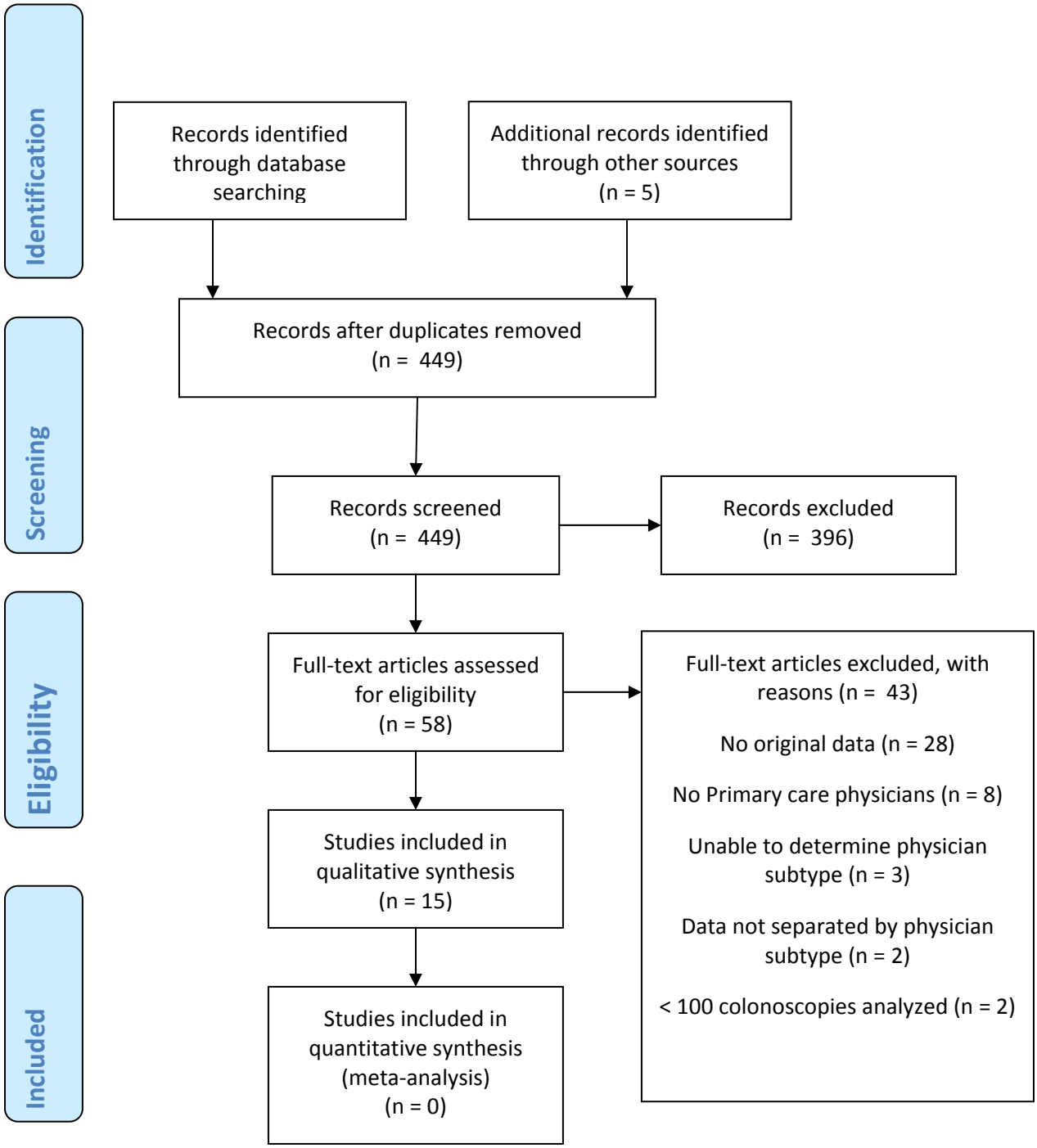


Figure 2.2 (Analysis 2.1)

Forest plot of comparison: 2 Sensitivity Analysis, outcome: 2.1 Endoscopic system used

Study or Subgroup	Adjusted or Crude CIR	SE	Cecal Intubations Total	Colonoscopies Total	Adjusted or Crude CIR IV, Random, 95% CI
2.1.1 Older (monocular) system					
Carr 1998	0.86	0.024	205	238	0.86 [0.81, 0.91]
Godreau 1992	0.833	0.03	130	156	0.83 [0.77, 0.89]
Hopper 1996	0.747	0.014	783	1048	0.75 [0.72, 0.77]
Kirby 2004	0.804	0.016	498	618	0.80 [0.77, 0.84]
Rodney 1993	0.557	0.03	137	246	0.56 [0.50, 0.62]
2.1.2 Newer (video fibreoptic) system					
Cotterill 2005	0.941	0.014	143	152	0.94 [0.91, 0.97]
Eckert 2009	0.986	0.005	789	800	0.99 [0.98, 1.00]
Edwards 2004	0.98	0.012	193	197	0.98 [0.96, 1.00]
Kolber 2009	0.923	0.008	1040	1127	0.92 [0.91, 0.94]
Newman 2005	0.918	0.008	671	731	0.92 [0.90, 0.93]
Pierzchajlo 1997	0.934	0.008	687	735	0.93 [0.92, 0.95]
Shah 2007	0.862	0.001	81761	94870	0.86 [0.86, 0.86]
Short 2007	0.962	0.015	175	182	0.96 [0.93, 0.99]
Strayer 2004	0.948	0.015	237	250	0.95 [0.92, 0.98]
Sweeney 2007	0.984	0.001	13146	13366	0.98 [0.98, 0.99]

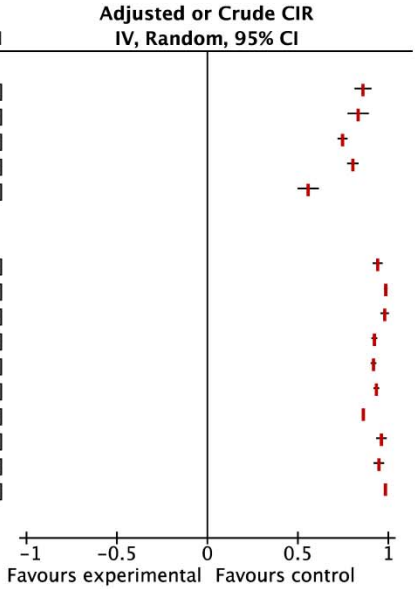


Figure 2.3 (Analysis 2.2)

Forest plot of comparison: 2 Sensitivity Analysis, outcome: 2.2 Unique practice model

Study or Subgroup	Adjusted or Crude CIR	SE	Cecal Intubations Total	Colonoscopies Total	Adjusted or Crude CIR IV, Random, 95% CI
2.2.1 Standard Practice Models					
Carr 1998	0.86	0.024	205	238	0.86 [0.81, 0.91]
Cotterill 2005	0.941	0.014	143	152	0.94 [0.91, 0.97]
Eckert 2009	0.986	0.005	789	800	0.99 [0.98, 1.00]
Edwards 2004	0.98	0.012	193	197	0.98 [0.96, 1.00]
Godreau 1992	0.833	0.03	130	156	0.83 [0.77, 0.89]
Hopper 1996	0.747	0.014	783	1048	0.75 [0.72, 0.77]
Kirby 2004	0.804	0.016	498	618	0.80 [0.77, 0.84]
Kolber 2009	0.923	0.008	1040	1127	0.92 [0.91, 0.94]
Newman 2005	0.918	0.008	671	731	0.92 [0.90, 0.93]
Pierzchajlo 1997	0.934	0.008	687	735	0.93 [0.92, 0.95]
Rodney 1993	0.557	0.03	137	246	0.56 [0.50, 0.62]
Shah 2007	0.862	0.001	81761	94870	0.86 [0.86, 0.86]
Short 2007	0.962	0.015	175	182	0.96 [0.93, 0.99]
Strayer 2004	0.948	0.015	237	250	0.95 [0.92, 0.98]
2.2.2 Unique Practice Model					
Sweeney 2007	0.984	0.001	13146	13366	0.98 [0.98, 0.99]

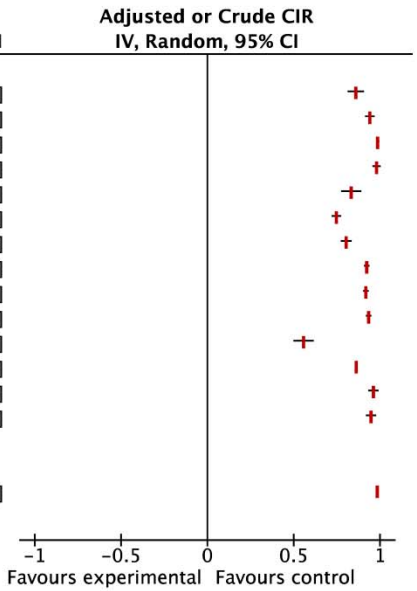
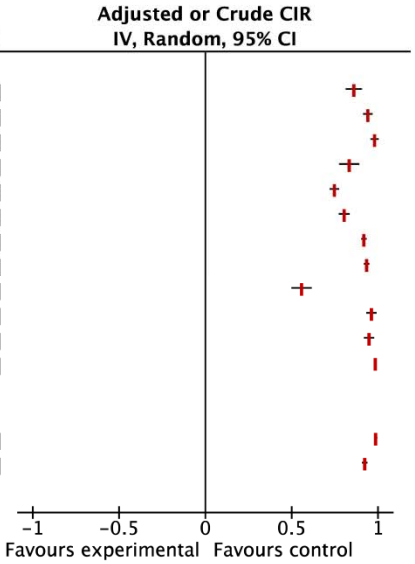


Figure 2.4 (Analysis 2.3)

Forest plot of comparison: 2 Sensitivity Analysis, outcome: 2.3 Annual volume of colonoscopies performed per physician

Study or Subgroup	Adjusted or Crude CIR	SE	Cecal Intubations Total	Colonoscopies Total	Adjusted or Crude CIR IV, Random, 95% CI
2.3.1 Lower volume endoscopists < 125 per physician per year					
Carr 1998	0.86	0.024	205	238	0.86 [0.81, 0.91]
Cotterill 2005	0.941	0.014	143	152	0.94 [0.91, 0.97]
Edwards 2004	0.98	0.012	193	197	0.98 [0.96, 1.00]
Godreau 1992	0.833	0.03	130	156	0.83 [0.77, 0.89]
Hopper 1996	0.747	0.014	783	1048	0.75 [0.72, 0.77]
Kirby 2004	0.804	0.016	498	618	0.80 [0.77, 0.84]
Newman 2005	0.918	0.008	671	731	0.92 [0.90, 0.93]
Pierzchajlo 1997	0.934	0.008	687	735	0.93 [0.92, 0.95]
Rodney 1993	0.557	0.03	137	246	0.56 [0.50, 0.62]
Short 2007	0.962	0.015	175	182	0.96 [0.93, 0.99]
Strayer 2004	0.948	0.015	237	250	0.95 [0.92, 0.98]
Sweeney 2007	0.984	0.001	13146	13366	0.98 [0.98, 0.99]
2.3.2 Higher volume colonoscopists > 125 per physician per year					
Eckert 2009	0.986	0.005	789	800	0.99 [0.98, 1.00]
Kolber 2009	0.923	0.008	1040	1127	0.92 [0.91, 0.94]



Appendix 2a

MEDLINE search strategy

1. (colonoscop* or coloscop*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

2. (((family physician* or general practitioner* or general internist* or primary) adj3 care) or family practice or internist*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]

3. exp Total Quality Management/ or exp Quality Assurance, Health Care/ or exp "Quality of Health Care"/ or exp Quality Indicators, Health Care/ or exp Quality Control/

4. 1 and 2 and 3

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Chapter 3
Prospective Study of the Quality of Colonoscopies Performed by Primary Care Physicians in Alberta, Canada
The Alberta Primary Care Endoscopy (APC–Endo) Study
Study Design and Methods

3.1 Introduction

In Alberta and Canada, colorectal cancer is the second most common cause of death from a malignancy,(1,2) and gastrointestinal complaints are common in primary care.(3) Colonoscopy is a cost-effective tool in screening asymptomatic patients for colorectal cancer and can be used to investigate patients with gastrointestinal symptoms.(4-6)

Controversy exists regarding the quality of colonoscopies performed by primary care physicians. While some studies demonstrate that trained family physicians and general internists can perform quality colonoscopic exams (7-10), other studies claim increased future colorectal cancer rates in colonoscopies performed by non-gastroenterologists.(11-13) In Canada, gastroenterologists and general surgeons perform 97% of colonoscopies.(14) Excessive wait times highlight a shortage of colonoscopists, which are worsening as our population ages and colorectal cancer screening rates increase.(15) One appealing alternative is to train primary care physicians in gastrointestinal medicine and endoscopy to mitigate this relative shortage. Before future primary care colonoscopists are trained in endoscopy, it must be shown that currently practicing primary care colonoscopists are able to meet benchmarks in colonoscopy competency. Additional research on quality outcomes of colonoscopies performed by primary care physicians is required to support this initiative.

The Alberta Primary Care Endoscopy (APC-Endo) Study

The Alberta Primary Care Endoscopy (APC-Endo) study was the first prospective, multi-center, multi-physician study that examined the quality of colonoscopic procedures performed by a group of primary care physicians at a provincial level in Canada.

The primary objective of the study was to determine whether family physicians and general internists in Alberta who perform colonoscopies are achieving quality assurance benchmarks in cecal intubation and adenoma detection rates. Secondary objectives included determining: serious adverse event rates, procedural and withdrawal times, patient comfort level during the colonoscopy, the percentage of patients who, after their colonoscopy, are subsequently referred to a specialist for their gastrointestinal problem, and patient satisfaction related to the colonoscopy. Results were compared to standards of quality colonoscopy developed by the United States Multi-Society Task Force on Colorectal Cancer (USMSTF).(16,17)

3.2 Methods

Study overview

The study prospectively examined the quality of colonoscopies performed by Albertan primary care colonoscopists over a two-month period. All eligible physicians completed a baseline assessment questionnaire **(See appendix 3a)**. Participating endoscopy physicians completed case report forms (CRF) at the time of the colonoscopy **(See appendix 3b)**. Corresponding pathology results were reviewed and all significant lesions (e.g., adenomas, cancers, inflammatory bowel disease) required pathological confirmation for analysis. A patient satisfaction telephone survey was completed approximately one month after the colonoscopy **(See appendix 3c)**.

Competency in colonoscopy was determined by comparing group and individual physician's rates of cecal intubation, adenoma detection, and complications to published benchmarks in colonoscopy quality.

Ethical approval was granted by the Health Research Ethics Board (HREB) at the University of Alberta, and operational approval was obtained from each study site before data collection commenced. The study was funded by the Alberta Rural Physician Action Plan (RPAP).

Study participants

Study physicians

Provincial physician regulatory agencies and government health organizations were unable to assist in identifying Albertan primary care colonoscopists. Identification of these colonoscopists occurred by contacting primary care physicians, primary care endoscopists, gastroenterologists, surgeons and health care administrators in Alberta. All identified physicians were subsequently contacted to confirm that they were family physicians or general internists and currently performed colonoscopies.

All confirmed primary care colonoscopists were mailed study information including study protocols and forms and were invited to voluntarily participate in the study. To explore the characteristics and colonoscopic experience of Albertan primary care colonoscopists, a questionnaire was also sent to these physicians **(See appendix 3a)**. This questionnaire collected information about demographics, endoscopic training and experience, current practice patterns and skill set of each physician. In addition, two teleconferences were held to explain the study to interested physicians and their staff.

Upon enrolling in the study, physicians provided written informed consent before participating. The study coordinator attempted to visit each study site on the first day of data collection or early in the study period.

Study patients

Consecutive patients were enrolled in the study if they were undergoing a colonoscopy for any reason with one of the participating primary care colonoscopists. Patients were excluded from the study if they were: under 18 years of age, unlikely to be able to be contacted for the post procedure telephone survey, did not understand or speak basic English, or were cognitively impaired rendering them unable to complete the initial consent for their colonoscopy.

Prior to having their colonoscopy, patients were approached to consent to the patient satisfaction telephone survey. Data was collected on colonoscopies performed by the study physicians during the two-month study period using a CRF developed by the author **(See appendix 3b)**. The case report form was piloted by the author prior to commencing the study to ensure all clinically relevant colonoscopy quality markers were captured. Patient consent was not required for the collection of the coded case report forms and pathology results.

The overall study process is summarized in a flow diagram **(See figure 3.1)**.

Data procurement

Each study site collected data on all colonoscopies performed over a two-month period. Due to staggered local site start dates, data collection occurred between March 15, 2010 and June 14, 2010 and patient satisfaction phone surveys were completed by August 2010.

Both the study physicians and his or her endoscopy assistant completed the CRFs at the time of colonoscopy. Corresponding patient pathology results, with patient identifying features removed, were faxed to the study centre at the University of Alberta, Department of Emergency Medicine. Master lists containing the patient's name and study identification number were kept in locked filing cabinets at each local study site and centrally at the University of Alberta. Consenting patients had their patient satisfaction telephone surveys completed by centrally located study assistants approximately one month after the colonoscopy **(See appendix 3c)**.

3.3 Outcomes measured

Primary outcomes

Cecal intubation rate

Colonoscopy completion was determined by the visualization of cecal or ileal landmarks including: appendiceal orifice, cecal trifold, ileocecal valve, or intubation of the terminal ileum. Visualization of the light in the right lower quadrant was included as a cecal landmark to determine if any physicians were utilizing this inaccurate method of verifying colonoscopy completion.(18) Analysis of the number of cecal landmarks observed per case, the proportion of cases in which the terminal ileum was intubated and whether photographs of the cecal landmarks were performed was also determined. Photographing cecal landmarks was not necessary for confirming cecal intubation.

The crude cecal intubation rate was calculated by dividing the total number of colonoscopies where cecal intubation was achieved by the total number of colonoscopies performed. The adjusted cecal intubation rate was calculated by dividing the total number of colonoscopies where cecal intubation was achieved by the total number of colonoscopies performed minus the number of procedures limited by a poor bowel preparation, colonic stricture, equipment failure or severe endoscopic colitis. In this study, the adjusted cecal intubation rates were calculated slightly differently than the United States Multi-Society Task Force on Colorectal Cancer (USMSTF) adjusted cecal intubation rates. The USMSTF only excludes incomplete colonoscopies due to poor bowel preparation and severe endoscopic colitis, while the present study also excluded colonoscopies aborted due to colonic stricture or obstruction or equipment failure. Primary care colonoscopists do not normally dilate strictures and equipment failure is beyond the control of the colonoscopist.

Competency in cecal intubation was determined by comparing adjusted cecal intubation rates to the USMSTF targets of ≥ 90% or ≥ 95% if only screening colonoscopies were performed.(16,17)

Adenoma detection rates

For all polyps found, the location, size, method of polyp removal and whether the polyp was retrieved was recorded on the case report form. Polyp size was estimated using the open biopsy forceps technique.(19-21) The largest diameter of the polyp was measured with the colonoscope 3-4cm away from the polyp. All study sites measured the width of their biopsy forceps before the study commenced.

All adenomas required confirmation by a certified pathologist to be included in the analysis. Serrated adenomas, an evolving pathological entity of polyps initially thought to be hyperplastic, but now shown to have distinct pathological architecture and potential for dysplasia(22) were grouped with adenomas for analysis. Any adenoma greater than 1cm (measured by the endoscopist or described in the pathology report), contained villous components or high-grade dysplasia on pathology, was classified as an advanced adenoma.

The adenoma detection rate was determined by dividing the total number of pathologically confirmed adenomas by the number of colonoscopies performed. Differences between physician adenoma detection rates were explored.

The proportion of patients with at least one adenoma was also determined and then analyzed by sex and age specific groups. As per USMSTF benchmarks, adenoma detection targets were achieved if ≥ 25% of males and ≥15% of females, 50 years and older and having their first time colonoscopy had an adenoma.(16)

Secondary outcomes

Potential serious adverse events

All potential adverse events, recorded on the CRF or reported by the patient during the satisfaction telephone survey, were investigated.

The lead author performed an initial review of all reported adverse events **(See appendix 3d)**. Additional information was requested from the APC-Endo study physicians for all potentially serious adverse events **(See appendix 3e)**. Potentially serious adverse events were then sent for external review by two independent adjudicators using a standard form

(See appendix 3f). The adjudicators determined whether a serious adverse event occurred, whether the event was related or possibly related to the colonoscopy, and the outcome of the adverse event. Disagreements between adjudicators were reconciled by a third independent adjudicator (a gastroenterologist).

Definitions of serious adverse events of colonoscopy were derived from the American Society of Gastrointestinal Endoscopy (ASGE).(23,24) Bleeding was defined as blood loss, which resulted in admission to hospital, a blood transfusion, a second colonoscopy or surgery. Perforations required clinical and radiographic evidence. Procedural sedation adverse events occurred when the colonoscopy was stopped prematurely, reversal agents were used, the patient required artificial ventilation, or the patient was admitted to hospital after the procedure for any new cardiac or respiratory condition related to the sedation agents.

Serious adverse event rates were compared to published standards of bleeding (< 1/100) (16,17), perforation (1/500 to 1/1000)(16) and procedural sedation (< 1/100).(17)

Additional outcomes measured

Patient demographics

Patient age, sex, inpatient or outpatient status, first time colonoscopy, bowel preparation product used and predominant indication for the colonoscopy were collected. As more than one indication often exists for a colonoscopy, the study physician chose the most important reason for the procedure. Colonoscopy indications were derived from a validated list of colonoscopic indications.(6)

Procedure and withdrawal times

Procedural time was defined as the time from the first insertion of the colonoscope until it was removed from the anus. Withdrawal time was defined as the time between leaving the cecum until the colonoscope exits the anus. All times were recorded by a local endoscopic assistant who was present during the colonoscopy and rounded up to the nearest minute.

We evaluated whether physicians with average withdrawal times (when no lesions were present) of ≥ 6 minutes had higher adenoma detection rates than physicians with average withdrawal times of ≤ 6 minutes.(25)

Quality of bowel preparation

Although many complicated bowel preparations scales exist,(26,27) a simple scale (e.g., excellent, good, satisfactory, poor) of the overall impression of the bowel preparation was used in the study.(28) The definitions of each bowel preparation category were described on the CRFs.

Patient comfort level and sedation

Patient comfort level during the colonoscopy was recorded using the Global Rating Score from the Joint Advisory Group on Gastrointestinal Endoscopy from the United Kingdom.(29) Sedation agents and dosages used were also recorded.

Post colonoscopy referral rates

The percentage of patients who, after having a colonoscopy, are referred to another specialist for their gastrointestinal problem was used as a proxy to ensure that primary care

colonoscopists possess not only technical skills, but also the cognitive ability to deal with their colonoscopic findings. A specialist was defined as a physician more specialized than the person performing the colonoscopy, and a referral was counted if the physician, at the time of colonoscopy, sent or anticipated sending the patient to a specialist for any reason.

Patient satisfaction survey

The final component of the study involved a patient satisfaction telephone survey, approximately one month after the procedure. The satisfaction survey was adapted from the Group Health Association of America 9 (GHAA-9)(30) and the University of Calgary Gastrointestinal Endoscopy Unit Patient Satisfaction Questionnaires.(31) The survey examined patient reported complications, patient satisfaction regarding their wait time for colonoscopy and visit to the hospital for the colonoscopy, the patient's perceived level of discomfort during the colonoscopy, and whether they would be willing to have another colonoscopy performed by the same physician.

3.4 Statistical considerations

It was determined that approximately fifteen primary care physicians currently perform colonoscopies in Alberta. A convenience sample of three of these physicians revealed they perform an average of 20 colonoscopies per month. Assuming that 12 out of the 15 physicians would agree to participate, approximately 240 procedures would be performed per month. Therefore, for our two-month study, there would be approximately 480 case reports to analyze. Assuming that 80% of patients agree to the post procedure telephone survey, 384 phone interviews would be performed. Estimating that the overall adjusted cecal intubation rate would be 90%, this sample size would provide 2.5% confidence

intervals (CI) around the point estimate. A significantly larger sample size would be required to provide CI within +/- 1%, which was not feasible.

Baseline characteristics were reported as means and standard deviations (SD) or medians and interquartile ranges (IQR) for continuous variables where appropriate. Binary outcomes, such as cecal intubation rates or age and sex-specific adenoma detection rates were presented as percentages with 95% CI and then compared to the quality standards using z statistics.

Logistic regression analysis was performed to determine which variables were associated with incomplete colonoscopies. Variables explored included the quality of the bowel preparation, patient sex and age, inpatient status, colonoscopy indication, type of physician (family physician or general internist) and volume of the colonoscopies performed per physician. Purposeful selection model building was used. The final model included variables consistently shown to be associated with incomplete colonoscopies in the literature and variables with a p value < 0.05. Hosmer-Lemeshow goodness of fit statistic was used to test the goodness of fit of the final model.

Data management

Data collection occurred locally at the study sites, was forwarded to the investigators and then inputted into Excel at the study centre located at the University of Alberta. Data was analyzed using STATA™ (version 11). To ensure data accuracy, double data entry on the first 100 procedures was performed as well as manual random audit of 10% of the charts.

All outcomes were calculated collectively and for each individual endoscopist. Anonymized individual physician results with peer group comparisons were presented to all participating physicians after the completion of the study.

3.5 Avoidance of bias

Since this study consists largely of self-reported data, there is a risk of reporting bias. To minimize this potential bias, both the endoscopy assistants and the physician endoscopist were involved in completing and signing the case report form. Bias in timing and CRF completion is a legitimate concern in this study, since the endoscopists have a vested interest in maintaining their current procedural status. To mitigate this concern, the study coordinator provided on-site training at the start of the study. We assumed the study sites included all patients in a consecutive fashion; however, we were unable to objectively verify this, as we did not externally review each site's endoscopy slate. Finally, under-reporting of the SAEs was a concern; however, having both patients and physicians report potential complications, as well as having an adjudication panel, reduced the bias associated with this determination.

3.6 Miscellaneous

Study status

This study was registered as a clinical trial with ClinicalTrials.gov (NCT# NCT01320826). The study is now completed and the results are reported in Chapter 4.

Competing interests

The lead author was one of the participating primary care colonoscopists in the study and served as the study coordinator.

Funding

The Alberta Rural Physician Action Plan (RPAP), an independent not-for-profit company funded by Alberta Health & Wellness, funded the Alberta Primary Care Endoscopy study.

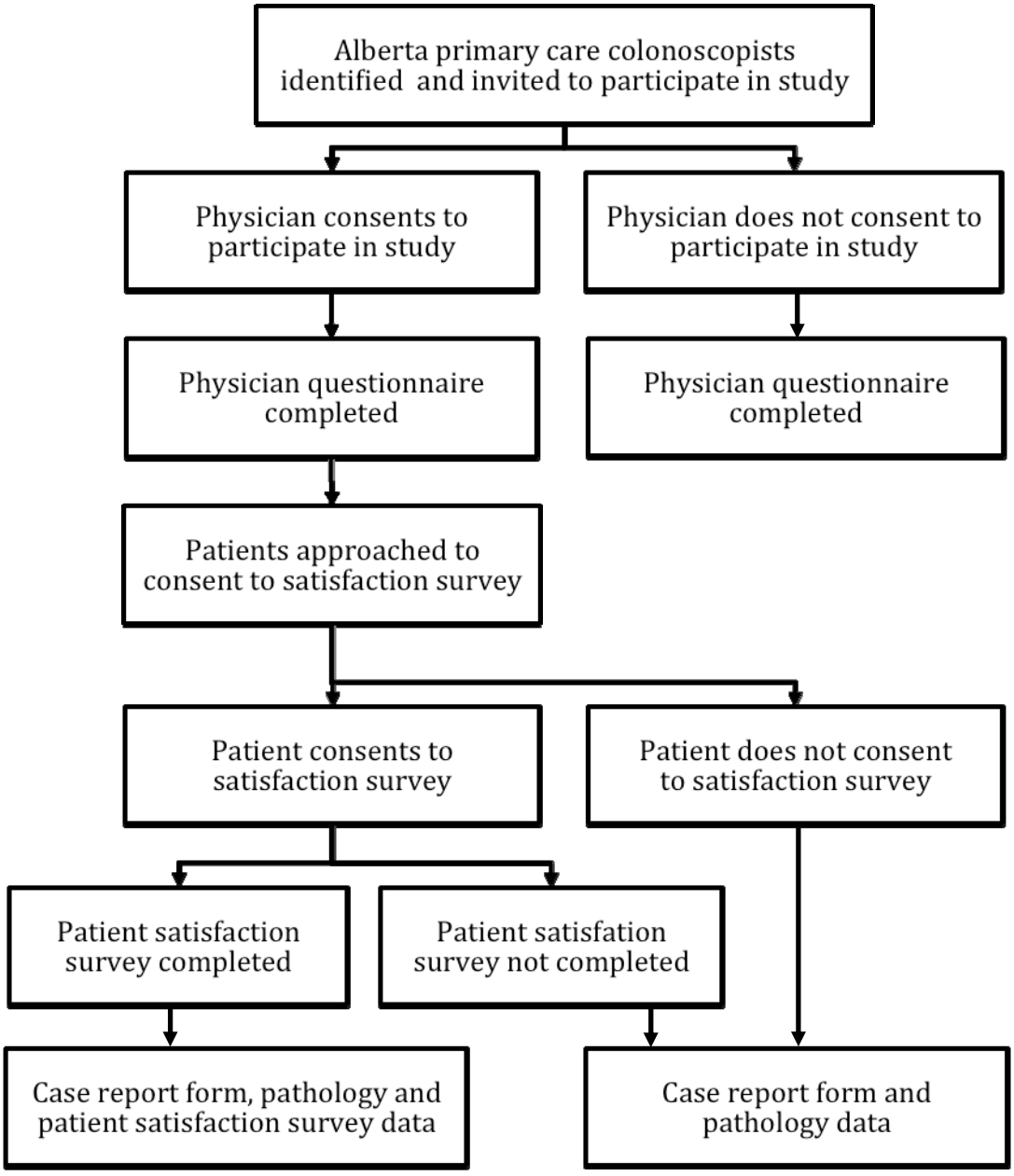

Figure 3.1: Alberta Primary Care Endoscopy Study Flow Diagram

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Chapter 4
Prospective study of the quality of colonoscopies performed by primary care physicians in Alberta, Canada
The Alberta Primary Care Endoscopy (APC-Endo) Study
Results

4.1 Introduction

Due to the increasing demand for colonoscopies for colorectal cancer screening and investigation of lower gastrointestinal symptoms, a relative shortage of colonoscopists exists in Canada. Wait times for endoscopy are increasing,(1) which can impact patient outcomes(2) and quality of life.(3) In Canada, gastroenterologists and general surgeons perform 97% of all colonoscopies,(4) and few primary care physicians perform endoscopy.(5)

Training primary care physicians in gastrointestinal medicine and endoscopy may improve patient access and wait times for endoscopy, particularly for rural patients. Due to the discrepancy in existing literature regarding the quality of colonoscopies performed by primary care physicians, a high quality study examining the colonoscopic outcomes of a group of primary care endoscopists is necessary.

The Alberta Primary Care Endoscopy (APC–Endo) Study

The Alberta Primary Care Endoscopy (APC-Endo) study is the first Canadian, prospective, multi-center, multi-physician study, to specifically examine the quality of colonoscopic procedures performed by a group of primary care physicians at a provincial level. The primary objective of the study is to determine whether Albertan family physicians and general internist colonoscopists achieve colonoscopy quality assurance benchmarks by comparing their cecal intubation and adenoma detection rates to standards defined by the

United States Multi-Society Task Force on Colorectal Cancer (USMSTF).(6,7) Secondary objectives include: determining serious adverse event rates, procedural and withdrawal times, patient comfort level during the procedure, the percentage of patients referred to a specialist for their gastrointestinal problem, and patient satisfaction related to the colonoscopy.

4.2 Methods

The study methods are described in detail in Chapter 3 and will only be briefly described here.

Study design

This was a prospective, observational study examining the quality of colonoscopies performed by Albertan primary care colonoscopists over a two-month period in 2010.

Study protocol

All physicians completed a baseline assessment questionnaire. Case report forms were completed at the time of the colonoscopy on consecutive colonoscopies performed by study physicians over the study period. Pathology results were reviewed, and patient satisfaction telephone surveys were completed approximately one month after the colonoscopy. All significant lesions required pathological confirmation by certified pathologists. Independent study collaborators externally adjudicated all potentially serious adverse events.

4.3 Outcome measures

Cecal intubation rate

Crude and adjusted cecal intubation rates were calculated. Since all study physicians performed colonoscopies for both symptom investigation and colorectal cancer screening, adjusted cecal intubation rates were compared to USMSTF targets of ≥ 90%.(6,7)

Adenoma detection rates

The adenoma detection rate was determined by dividing the total number of adenomas by the number of colonoscopies performed. In addition, the proportion of patients 50 years and older who were having their first colonoscopy, with at least one adenoma was compared to USMSTF benchmarks of 25% for males and 15% for females.(6,7)

Potential serious adverse events

All potentially serious adverse events were investigated and externally adjudicated. Serious adverse event rates were compared to published standards of bleeding (< 1/100)(6,7), perforation (1/500 to 1/1000),(7) and procedural sedation (< 1/100).(6)

Baseline characteristics are reported as means and standard deviations (SD) or medians and interquartile ranges (IQR) for continuous variables, where appropriate. Binary outcomes, such as cecal intubation rates or age and sex-specific adenoma detection rates are reported as percentages with 95% confidence intervals (CI) and then compared to the quality standards using z statistics. Logistic regression analysis was performed to determine which variables predicted incomplete colonoscopies.

4.4 Results

Study physicians

Ten of a total of 17 identified Albertan primary care physicians participated in the study; eight were family physicians and two were general internists **(See table 4.1)**. The physicians had a median of 10 years (IQR: 4, 15) of colonoscopy experience and performed a median of 1850 colonoscopies (IQR: 1400, 4000) colonoscopies before the study started. All physicians performed polypectomies and nine out of ten physicians administered their own procedural sedation.

Study locations

The ten physicians performed colonoscopies at thirteen different locations (i.e. three physicians performed endoscopy at two sites) and all procedures were performed in hospitals. Eleven study sites were rural and only three had local general surgery back up.

Patient enrollment

During the study, a total of 579 colonoscopies were performed. Two cases were excluded for being performed on patients under 18 years of age, resulting in 577 colonoscopies available for analysis.

Patient demographics

Each physician performed a median of 52 colonoscopies in the study (IQR: 38,78). The overall mean patient age was 57.6 (SD 13.3) and females accounted for 51.1% of the patients **(See table 4.2)**. For 65% of patients, the colonoscopy in the study was their first ever colonoscopy, and 1.9% of colonoscopies were done as inpatients. The most common indications for colonoscopy were screening for colorectal cancer (45.9%) and investigation

of gastrointestinal symptoms (40.2%) All study physicians performed screening and diagnostic colonoscopies.

Outcomes

Cecal intubation rates

Cecal intubation was achieved in 550 of 577 colonoscopies for a group crude cecal intubation rate of 95.3% (95% CI: 93.3, 96.9) **(See table 4.3)**. Individual physician's crude cecal intubation rate ranged from 87.8% to 100%. After seven cases were excluded for reasons of stricture / obstruction (4), poor bowel preparation (2) and severe inflammatory bowel disease (1), the overall adjusted cecal intubation rate was 96.5% (95% CI: 94.6, 97.8). All ten physicians achieved adjusted cecal intubation targets of ≥ 90%.

Cecal landmarks identified

The terminal ileum was intubated in 41.3% (95% CI: 36.9, 45.1) of completed colonoscopies. All four cecal landmarks (terminal ileum, ileocecal valve, trifold and appendiceal orifice) were visualized in 22.7% (95% CI: 19.5, 26.5) of the cases, while three and two landmarks were visualized in 38% (95% CI: 33.9, 42.1) and 23.6% (95% CI: 20.4, 27.6) of the cases respectively. Although 36 cases recorded visualizing the light in the right lower quadrant, no cases relied on this alone to confirm cecal intubation.

Photography of cecal landmarks

Photographs of cecal landmarks were performed in 57.1% (95% CI: 52.7, 61.6) of cases in which photographic capabilities existed. Five physicians photographed cecal landmarks in 269/276 (98.5%: 95% CI: 95.6, 99.3) of their procedures, while four physicians photographed cecal landmarks in only 4/204 (2.0%) of their cases. One physician, who

worked in two different locations, did not have the necessary equipment to take photographs in either location.

Predictors of incomplete colonoscopies

The odds of an incomplete colonoscopy was significantly increased in patients with poor bowel preparations (OR = 4.5: 95% CI: 1.2, 17.2), and patients over the age of 65 years (OR = 2.9: 95% CI: 1.3, 6.3). Female patients were also at higher risk of having an incomplete colonoscopy, but this was not statistically significant (OR = 2.2: 95% CI: 0.97, 5.15). The type of physician endoscopist, volume of colonoscopies performed, indication for colonoscopy or inpatient status did not significantly influence the proportion of successful cecal intubations.

Adenoma detection rates

A total of 360 adenomas were pathologically confirmed (272 adenomas, 50 advanced adenomas, 34 serrated adenomas and 4 advanced serrated adenomas). The overall adenoma detection rate was 360/577 or 0.62 adenomas / colonoscopy. Individual physicians' adenoma detection rates varied from 0.13 to 1.54 adenomas / colonoscopy.

At least one adenoma was found in 46.4% (95% CI: 38.5, 54.3) of males and 30.2% (95% CI: 22.3, 38.2) of females who were 50 years and older and who were undergoing their first colonoscopy. These rates were significantly greater than the USMSTF benchmarks of 25% and 15% ($p < 0.0001$ for both).(6,7)

Colon cancer detection rates

Twelve cancers of colorectal cancer were pathologically confirmed for a colorectal cancer incidence rate of 2.1%.

Procedure and withdrawal times

The average procedure time was 23. 6 minutes and the average withdrawal time in procedures without lesions was 7.0 minutes. Five physicians had average withdrawal times greater than six minutes and five physicians had average withdrawal times less than six minutes. Physicians whose average withdrawal times were ≥ 6 minutes had similar adenoma detection rates (0.65 vs 0.58: p = 0.28) compared to those who averaged < 6 minute withdrawal times.

Patient comfort level

Patients tolerated the colonoscopies, experiencing only one or two well-tolerated episodes of discomfort in 45.1% of the cases and no discomfort in 40.4% of cases.

Sedation agents and doses

Midazolam (Versed) was the most commonly used sedation agent (n = 570), followed by Fentanyl (n = 494) and propofol (Diprivan) (n=140). Overall, only five physicians used propofol. Three endoscopists (two who were also general practice- anesthetists and one who had sedation administered by an anesthetist) accounted for 86.4% of the propofol use. One case was performed without any sedation.

Referral to specialist

Twenty-eight patients (4.8%) were referred to a specialist for their gastrointestinal problems: 71% of the time for definitive surgical management and 25% of the time for ongoing disease management.

Potential serious adverse events

A total of 18 potential adverse events were reported (9 patient and 9 physician reported), and five cases were sent for external adjudication. Four serious adverse events (three bleeds and one perforation) occurred.

All three bleeds occurred after snare cautery for advanced adenomas in patients over 50 years of age. These three patients were admitted to hospital (mean of 2.3 days). One patient was transfused packed red blood cells, while no patients required a repeat colonoscopy or surgery.

The perforation occurred during rectal retroflexion in a 79 year old male with radiation proctitis. The perforation was recognized during the procedure, and the patient had surgery and was discharged home from his local hospital five days later.

The risk of post-colonoscopy bleeding (3/577) was less than the target of ≤ 1/100(7) and the perforation rate (1/577) was between the accepted targets of 1/500 and 1/1000.(6,7) There were no serious complications related to procedural sedation and no deaths in the study.

Patient satisfaction survey

Five hundred and thirty of 577 (91.8%; 95% CI: 89.3, 93.9) study patients consented to the patient satisfaction phone survey and 443 (83.5%) of the surveys were completed **(See figure 4.1)**. Inability to contact the patient (55 cases) and withdrawal of consent (21 cases) were the most common reasons for not completing the satisfaction survey.

Seven point Likert scales were used to measure patient satisfaction. The median wait time satisfaction score was 7 (IQR = 5-7) while the median patient score for the hospital experience for their colonoscopy was 7 (IQR = 6-7). Only three patients reported they would not be willing to have a repeat colonoscopy performed by their study colonoscopist.

4.5 Discussion

The Alberta Primary Care Endoscopy Study (APC-Endo) demonstrates that a group of primary care physicians can achieve standard benchmarks in colonoscopy performance.

The group adjusted cecal intubation rate was 96.5%, and all ten study physicians achieved adjusted cecal intubation rates targets of ≥ 90%. We calculated our adjusted cecal intubation rate differently than the USMSTF; however, our approach is transparent and reflects the skills of the endoscopist (do not dilate strictures) and accounts for equipment malfunction, which is also outside of the control of the endoscopist.(6,7) Using the USMSTF definition, which only excludes incomplete colonoscopies due to poor bowel preparation and severe endoscopic colitis, the group adjusted cecal intubation rate was 95.8% (95% CI: 93.8, 97.3). Using the USMSTF definition, only one physician, whose USMSTF rate was 88.9%, did not achieve an adjusted cecal intubation rate of ≥ 90%.

Recent literature demonstrates that even gastroenterologists may have difficulties achieving cecal intubation targets. A study of 17,868 colonoscopies performed by gastroenterologists in the United States and Canada found only 55% achieved cecal intubation rates ≥ 90%.(8) A study from the United Kingdom revealed cecal intubation rates of 76%, which improved to 83.6% when only consultant gastroenterologists were analyzed.(9) Another American study of 5,477 colonoscopies performed by 10 American gastroenterologists revealed USMSTF adjusted cecal intubation rates of 89.8%.(10)

In Canada, the PAGE (Practice Audit in Gastroenterology) program demonstrated overall crude cecal intubation rates of 92%, but provincial averages ranged from 86-94%.(11) Another similar Canadian study collected data on 1279 colonoscopies performed by 62 endoscopists (46 gastroenterologists and 16 general surgeons). The mean cecal intubation rate was 94.9%, but 10% of endoscopists had cecal intubation rates of < 85%.(12)

Predictors of incomplete colonoscopy

Several variables that were associated with an incomplete colonoscopy in the APC-Endo study were also found to be predictors of incomplete colonoscopies in other studies. In the APC-Endo study, elderly patients and those with a poor quality bowel preparation were at increased risk of an incomplete colonoscopy. Incomplete colonoscopies were not statistically more likely to occur in female patients, and the volume of colonoscopies performed by the physician or type of physician endoscopist also did not affect cecal intubation rates.

A population-based study of over 300,000 colonoscopies from Ontario explored factors associated with an incomplete colonoscopy.(13) Patient factors associated with an

incomplete colonoscopy included those who were older and female and those with previous abdominal or pelvic surgery. The type of physician endoscopist (e.g., surgeon, gastroenterologist or family physician / internist) did not significantly affect colonoscopy completion rates. While physicians who performed more colonoscopies had fewer incomplete colonoscopies, another study found that cecal intubation rates were more related to the number of years of colonoscopy experience the physician had rather than the volume of colonoscopies performed.(14)

Similar to our study, unsatisfactory bowel preparations have also been shown to be associated with incomplete colonoscopies.(15)

Adenoma detection rates

The adenoma detection rate may be a more meaningful marker of quality colonoscopy than cecal intubation rates. In addition to evaluating the technical competency of the colonoscopist, the adenoma detection rate indirectly measures appropriate patient selection and colonoscopy intervals, as well as qualities of the bowel preparations. The APC-Endo study overall adenoma detection rate was 0.62 adenomas per colonoscopy, while individual physician adenoma detection rates ranged from 0.13 to 1.54 adenomas per colonoscopy. Some of the variability in the adenoma detection rate may be explained by the patient age and indication for the colonoscopy; however, existing literature has also demonstrated inter-physician variability in adenoma detection.

Barclay evaluated the adenoma detection rates of 12 experienced gastroenterologists who performed 2053 screening colonoscopies.(16) The overall adenoma detection rate was 0.47 adenomas / colonoscopy while the individual physician's rate ranged from 0.1 – 1.05

adenomas / colonoscopy. After introducing quality improvement measures, the same group's adenoma detection rate improved to 0.61 adenomas / colonoscopy and the inter-physician variability decreased to 0.31 – 1.05 adenomas / colonoscopy.(17)

Another study of over 10, 000 colonoscopies performed by nine gastroenterologists concluded that the colonoscopist affects adenoma detection rates more than the patient's age or gender.(18) In this study the adenoma detection rates in female and male patients 50 years and older were 0.26 and 0.42 / colonoscopy respectively with individual physician's results ranged from 0.21 to 0.86 adenomas / colonoscopy.

Other studies have demonstrated that physicians who average > six minutes for withdrawal times have higher adenoma detection rates.(16,17) Our study, however, demonstrated that physicians who averaged > six minutes for withdrawal times had similar adenoma detection rates compared to those who averaged < six minutes.

Proportion of patients over 50 years with an adenoma

In this study, the proportion of males and females, over 50 years old, undergoing their first colonoscopy, with at least one adenoma was 46.4% and 30.2% respectively. These results significantly exceed the USPMTF minimum benchmarks of 25% and 15%, but are comparable to rates observed in an Albertan colorectal cancer screening facility (Jonathon Love, personal communication; Jan. 2011).

Of note, similar to many primary care studies, many studies evaluating gastroenterologists' colonoscopy outcomes do not report the proportion of patients 50 years and older undergoing their first time colonoscopy who have adenomas. In these studies, direct

comparisons to the USMSTF benchmarks in adenoma prevalence rates are not possible.(11,12,19-21)

Serious adverse event rates

Serious adverse event were not statistically different than suggested targets and were comparable to results seen in larger Canadian population-based studies. For example, the proportion of patients with post colonoscopy bleeding was not statistically different than the suggested target of 1/100 ($p = 0.40$). Canadian studies report overall bleeding rates between 1.0 - 1.6 / 1000 colonoscopies, (13,22) which increase to 6.4 / 1000 in cases were polypectomies were performed.(13) The observed bleeding risk of 5.2 / 1000 cases was within these margins.

The perforation rate of 1/577 was between the accepted 1/500 to 1/1000, and is comparable to results seen in Canadian clinical practice.(22-24) Recent Canadian studies report perforation rates ranging from 1/769 at a single academic centre in Alberta(23) to 1/833 at four hospitals in Winnipeg(24) to 1/1176 from a database involving colonoscopies in four provinces.(22)

APC-Endo study physicians also demonstrated competency in procedural sedation as evidenced by the fact that there were no complications reported related to procedural sedation.

Patient satisfaction

Patient satisfaction is an important, albeit infrequently, measured variable in quality assessment studies. In the APC-Endo study, patients were extremely satisfied with both

their wait time for colonoscopy, and with their hospital experience during the colonoscopy, scoring medians of 7 on a 7 point Likert scale for both variables. Previous satisfaction studies involving gastroenterologists demonstrated that many patients were dissatisfied with their wait time for their consultation(3) and for their endoscopy.(25) In Alberta in 2005, the median wait time for a gastroenterology consult was 107 days (IQR: 35, 172), and the median wait time from referral to endoscopy was 134 days (IQR 42, 282).(26) Alberta has the longest gastrointestinal wait times of any province in Canada.(26) Although wait time data were not collected in the APC-Endo study, it is hypothesized that wait times for consultation and endoscopy by Alberta primary care endoscopists are significantly less than wait times for Alberta gastroenterologists.

When comparing willingness to return for a repeat colonoscopy, the patients in the APC-Endo study were more willing to have a repeat colonoscopy by their primary care endoscopist (99.3%) than patients who had their colonoscopies performed by a cohort of gastroenterologists in Edmonton (83.9%).(27)

Referral to specialists

Less than 5% of cases were referred to specialists, illustrating that primary care colonoscopists are able to effectively manage most patients they see. The majority of patients referred were sent for definitive surgical management of their gastrointestinal condition. This referral pattern (from primary care colonoscopist to surgeon) may be an avenue of improved patient flow through the health care system. Ultimately, this referral pattern may improve the time between symptom onset and definitive care for diseases like colorectal cancer.

4.6 Limitations

Only 10 of 17 identified Alberta primary care colonoscopists participated in the study. Physicians who chose not to participate may have different endoscopy practices and outcomes than the ten physicians who did participate. Also, the APC-Endo physicians were an experienced group of colonoscopists. Whether similar results would be seen in less experienced primary care colonoscopists is not known. Since there is no organized group of primary care colonoscopists in Alberta or Canada, it is also possible that not all primary care colonoscopists in Alberta were identified. This is, however, highly unlikely given the various methods used to identify primary care colonoscopists and that to date we have not been made aware of any other primary care colonoscopists in Alberta.

Having both an endoscopy team member and the physician endoscopist complete and sign the case report forms minimized reporting bias. Whether any residual reporting bias existed in the self-reported data is not known. As the physicians were obviously aware of being enrolled in a study evaluating the quality of colonoscopies, the "Hawthorne Effect" may have been operating, which may have inflated the results of the study. It is also unclear whether the subset of patients who did not complete the satisfaction survey would have similar patient satisfaction results as those that completed the satisfaction survey.

Finally, data collection occurred for only two months, resulting in a relatively small sample size and only a snapshot of the outcomes of primary care colonoscopists in Alberta. While short evaluations of quality outcomes in endoscopy are not uncommon in Canada(11,12) the logical progression would be to collect and report on outcomes over a longer term.

4.7 Conclusion

The APC-Endo study is the most comprehensive study to date to report on the quality of colonoscopies performed by a group of primary care physicians. Participating colonoscopists achieved quality benchmarks in cecal intubation and adenoma detection with a low complication rate and high patient satisfaction. Based on the favorable results of the APC-Endo study, training additional primary care physicians in gastrointestinal medicine and endoscopy should be strongly encouraged. Increasing the number of primary care endoscopists may improve patient access and decrease endoscopic wait times, especially in non-urban settings.

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Conflict of interest

The author and study coordinator was one of the participating primary care colonoscopists in the study. RF and CW are gastroenterologists; however, they declare no conflict of interests. BHR, an emergency physician, declares no conflict of interest with this study.

Table 4.1: Participating physician and practice characteristics for the Alberta Primary Care Endoscopy study

Physician	Physician Gender	Physician Group	Location	Number of Colonoscopies in Practice	Years Performing Colonoscopies	Perform Polypectomies	Sedation Administration	Local Surgical Backup
1	M	FM	Rural	1700	10	Yes	Self	No
2	M	FM	Rural	4000	10	Yes	Self[a]	No
3	M	FM	Rural	8000	21	Yes	Self	No
4	M	GIM	Regional	2800	14	Yes	Anaesthesia	Yes
5	F	GIM	Regional	60	1	Yes	Self	Yes
6	M	FM	Rural	1500	6	Yes	Self	No
7	M	FM	Rural	2000	15	Yes	Self	No
8	M	FM	Rural	4000	15	Yes	Self[a]	Yes
9	M	FM	Rural	1400	4	Yes	Self	No
10	M	FM	Rural	1000	3	Yes	Self	No
Totals	**90% M**	**80% FM**	**80% Rural**	**Median: 1850**	**Median: 10**	**100%**	**90% Self**	**30%**

M = male; F = female; % = percentage
FM = Family Medicine; GIM = General Internal Medicine
[a] General practice – Anaesthetists (Gp-A)

Table 4.2: Patient characteristics for the Alberta Primary Care Endoscopy study

Physician	Colonoscopies Performed	Mean Patient Age (years)	Female (%)	Inpatient (%)	First-time Colon (%)	Indications (%)	
						Screening	Symptoms
1	54	56.4	59.3	5.6	51.9	37.0	42.6
2	72	57.0	52.8	2.8	66.7	48.6	36.1
3	95	59.3	59.0	0.0	66.3	63.2	26.3
4	31	60.8	32.3	0.0	64.5	38.7	41.9
5	38	47.3	42.1	2.6	68.4	29.0	47.4
6	40	57.8	52.5	0.0	62.5	52.5	35.0
7	38	58.3	57.9	0.0	73.7	36.8	52.6
8	82	61.5	45.1	2.4	59.8	42.7	47.6
9	78	59.4	46.2	1.3	69.2	57.7	30.8
10	49	52.3	55.1	4.1	69.4	24.5	61.2
Overall Totals / Means*	**577**	**57.6 (SD = 13.3)**	**51.1 (47.0, 55.2)**	**1.9 (0.7, 3.2)**	**65.0 (61.1, 69.0)**	**45.9 (41.8, 50.0)**	**40.2 (36.1, 44.3)**

% = percentage; SD = standard deviation

* Overall totals / means : reported with 95% confidence intervals except age reported with standard deviations

Table 4.3: Colonoscopy Quality Outcomes for the Alberta Primary Care Endoscopy Study

Physician	Colonoscopies Performed	Crude Cecal Intubation Rate (%)	Adjusted Cecal Intubation Rate (%)	USMSTF Adjusted Cecal Intubation Rate (%)	Adenoma Detection Rate[a]	ADR Males ≥50years[b] (%)	ADR Females ≥50years[c] (%)	Average Procedural Times (min)	Average Withdrawal Time[d] (min)	Serious Adverse Events (#)
1	54	96.3	96.3	96.3	0.46	60.0	20.0	24.4	8.4	1
2	72	100	100	100	1.01	57.9	33.3	24.6	5.2	0
3	95	96.8	98.9	97.9	0.35	23.8	20.0	21.6	9.7	0
4	31	96.8	100	96.8	0.36	27.3	0.0[e]	20.7	4.9	0
5	38	89.5	94.4	91.9	0.13	25.0	0.0[f]	19.7	4.1	0
6	40	92.5	92.5	92.5	0.6	57.1	37.5	26.3	5.7	0
7	38	94.7	94.7	94.7	0.37	50.0	30.0	21.5	3.8	0
8	82	87.8	90.0	88.9	0.31	30.4	14.3	23.6	6.2	2
9	78	97.4	97.4	97.4	1.54	66.7	57.9	27.7	9.1	0
10	49	100	100	100	0.61	70.0	50.0	23.2	7.8	1
Overall Means*	**58 (SD = 22.3)**	**95.3 (93.3, 96.9)**	**96.5 (94.6, 97.8)**	**95.8 (94.1, 97.5)**	**0.62 (0.51, 0.74)**	**46.4 (38.5, 54.3)**	**30.2 (22.3, 38.2)**	**23.6 (22.7, 24.5)**	**7.0 (6.6, 7.4)**	**4**

[a] Number of pathologically confirmed adenomas / number of colonoscopies
[b] Proportion of males[b] or females[c] ≥ 50 years old, first time colonoscopy with pathologically confirmed adenoma
[d] Average withdrawal time of procedures where no lesions were detected
[e] Only 2 colonoscopies performed on this patient cohort; [f] Only 3 colonoscopies performed on this patient cohort
ADR = adenoma detection rate; % = percent; min = minutes; # = number
Serious adverse events reported as totals
* Overall means reported with 95% confidence intervals except age reported with standard deviations

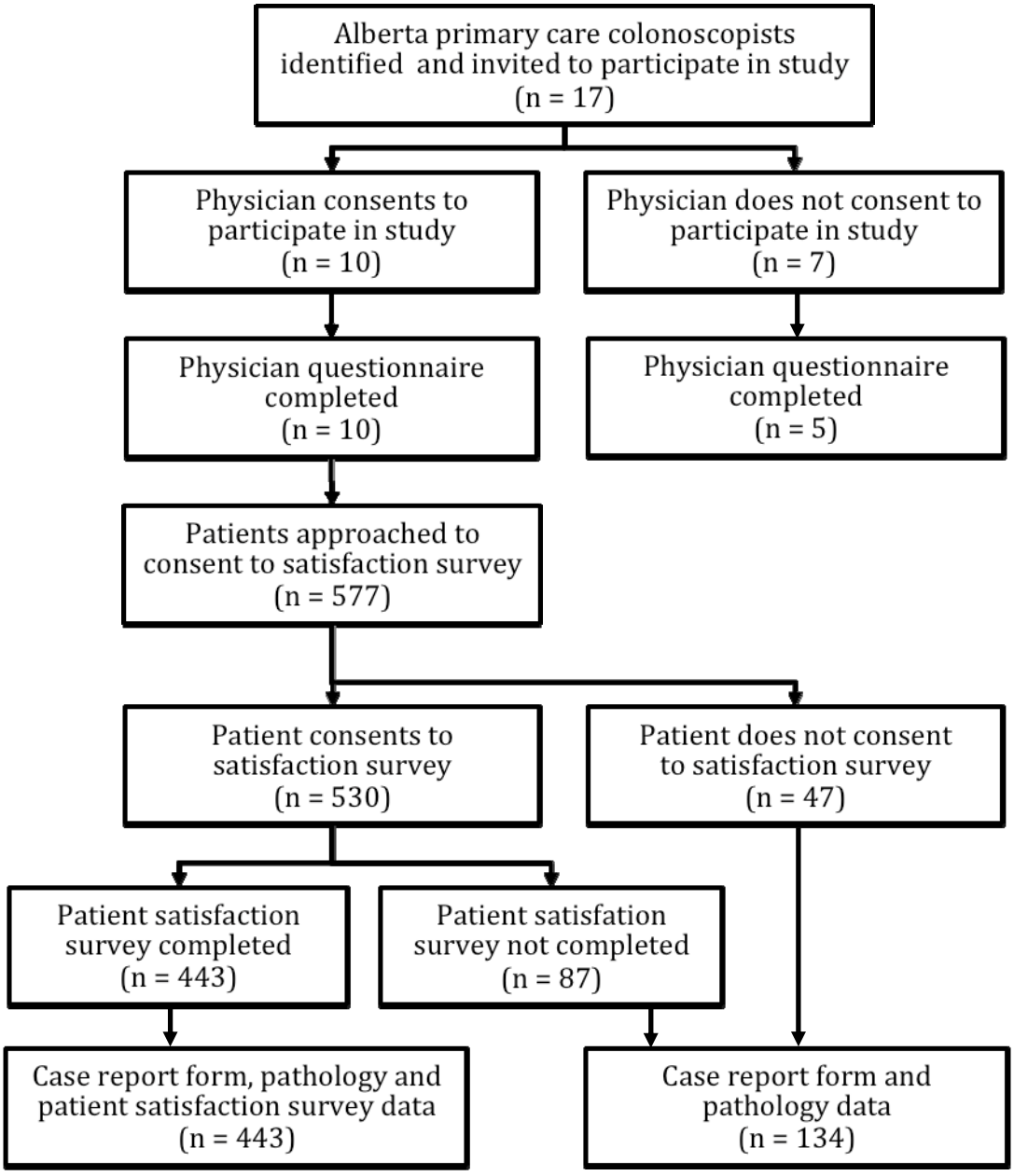

Figure 4.1: Alberta Primary Care Endoscopy Study Flow Diagram (Results)

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Chapter 5
Future of primary care endoscopists in Canada

5.1 Introduction

Endoscopy, including colonoscopy, is an integral part of investigating patients with gastrointestinal symptoms and screening for colorectal cancer. Unfortunately, the current shortage of endoscopists is contributing to diagnostic and treatment delays for patients with gastrointestinal diseases.(1-3) One solution is to train more primary care endoscopists to help with the current and future endoscopic demand that exists in Canada.

Primary care endoscopists are well positioned to positively affect the well being of patients with gastrointestinal symptoms or in need of colorectal cancer screening. They have the opportunity to improve colorectal cancer screen rates, provide timely access to endoscopy, collaborate with and learn from other primary care endoscopists, gastroenterologists, and surgical colleagues, and provide high quality research.

The program of research reported here provides the best evidence to date pertaining to the competency of primary care colonoscopists. The Alberta Primary Care Endoscopy (APC-Endo) study combined with the systematic review illustrates that primary care physicians can perform high quality and safe colonoscopies, detect high rates of adenomas and cancers, and that patients are extremely satisfied with their wait times and colonoscopy experience. This information is intended for dissemination to physicians and health care administrators to allow for informed decisions regarding future primary care endoscopy training programs in Alberta and across Canada. In addition, this research, which promotes current and future primary care endoscopy programs, ultimately aims to assist the health care system in improving the care of patients with gastrointestinal diseases or concerns.

5.2 Discussion

Future studies on the quality of colonoscopies performed

To continue to build on the favorable results of the APC-Endo study, further studies that evaluate quality of colonoscopies performed by primary care physicians should be undertaken. These, and other studies examining the quality of colonoscopies performed, should collect larger numbers, increase the follow-up to examine clinical outcomes of importance, and involve prospective and consecutive data collection, pathological confirmation of lesions and photographic documentation of cecal landmarks to confirm cecal intubation.

Furthermore, as the evolution of quality outcomes in colonoscopy research occurs, the adenoma detection rate (number of adenomas / number of colonoscopies) will replace the cecal intubation rate as the most informative outcome measure. In addition to evaluating the technical competency of the colonoscopist, the adenoma detection rate indirectly measures appropriate patient selection and colonoscopy intervals, as well as other variables such as qualities of the bowel preparations. Therefore, all future studies on quality outcomes in colonoscopy should measure the group and individual physician's adenoma detection rates. Data collection should also allow for the comparison of age and gender specific adenoma prevalence rates to target benchmarks. Only then will it be known if the USMSTF adenoma prevalence benchmarks (4,5) are reasonable, or in fact too low.

In addition, research that examines quality colonoscopy may also wish to determine whether the miss rate of adenomas or cancers in colonoscopies performed by primary care physicians is different than in colonoscopies performed by other physician groups. To determine the adenoma miss rate, patients who had a colonoscopy performed by a primary

care physician could undergo either a subsequent second colonoscopy by a gastroenterologist or a virtual colonoscopy. To determine the cancer miss rate, a cohort of patients who had colonoscopies performed by primary care physicians would need to be followed for up to three to five years to determine whether any interval cancers occurred.

Further work to appropriately define adjusted cecal intubation rates for primary care physicians must occur. Reasons for incomplete colonoscopies should be recorded as well, in order to calculate these adjusted cecal intubation rates.

Analyzing procedural times continues to be important for endoscopy bookings, and withdrawal times can provide insight if physicians or programs report low adenoma detection rates. Incorporating patient satisfaction is a valuable part of any future research endeavor.

To improve the generalizability of the APC-Endo study, all practicing primary care colonoscopists in Alberta should be encouraged to participate in future studies. Electronic data entry or mobile electronic devices (using the CRF), or utilizing standard endoscopy system software with central data collection would improve the logistics of such a study.

Finally, future research should include repeating and expanding the systematic review including the results from the Alberta Primary Care Endoscopy study as well as other future studies that examine the outcomes of colonoscopies performed by primary care physicians.

Primary care colonoscopists mentoring program

All primary care colonoscopists should be able to perform polypectomies and intubate the terminal ileum. Colonoscopists without these skills would benefit from time spent being mentored from an expert colonoscopist to achieve these skills. Furthermore, all primary care endoscopists, regardless of their skill set, could benefit from collaborating with gastroenterologists for ongoing feedback, support and the exchange of ideas regarding medical and endoscopic advancements.

The goal of primary care colonoscopists is not to replace gastroenterologists. Rather the goal is to improve access and care of patients, especially rural Canadians, with gastrointestinal symptoms or those patients who require colorectal cancer screening. To that end, advanced colonoscopic procedures such as stricture dilation and endoscopic mucosal resection of large polyps should be left to those who routinely perform these maneuvers. Again the skill set of physician groups should be referenced when defining adjusted cecal intubation rates.

Continuing quality improvement

The results of the APC-Endo study, including overall and anonymized individual physician results, have been shared with the study physicians and their teams as non-judgmental "report cards". These report cards were designed for use by the endoscopy teams to reflect upon their endoscopy program(s) and to facilitate and encourage future data collection to allow continual quality improvement.

Any endoscopist who is not meeting quality outcome targets could explore potential explanations for their substandard results and make necessary changes to improve quality

outcomes. For example, physicians with low adenoma detection rates could initially evaluate procedural and withdrawal times, as well as intervals between repeat colonoscopies.

Knowledge translation (KT)

One of the important products of the APC-Endo study is the case report form, which could become the standard of care for endoscopy recording by primary care physicians. Physician practice in the entire province is now under the direction of Alberta Health Services (AHS) and endorsement of the CRF at the provincial level would expedite ongoing data collection and quality assessment programs.

Study newsletters, sent electronically to participating physicians, were another important initiative of the APC-Endo study. In addition to updating physicians on the status of the study, these newsletters incorporated important medical papers or information pertaining to colonoscopy practice.

The author, with support of APC-Endo study physicians and Alberta gastroenterologists, has initiated "Endoscopy Skills Day for Practicing Endoscopists", a continuing professional learning event aimed at the needs of primary care endoscopists. This one-day conference was held in Banff, Alberta in January 2011 in conjunction with the University of Calgary's Emergency Medicine for Rural Hospitals conference. Over 25 primary care endoscopists, general surgeons, gastroenterologists and endoscopy nurses from across Canada attended. The goals of this event are to educate participants about best practices in gastroenterology and endoscopy, to support collaboration amongst primary care endoscopists, and to further develop relationships between primary care endoscopists, gastroenterologists and

surgeons. Collaboration between these physicians is essential for improving the lives of patients with gastrointestinal disease. In addition, conference attendees created an email group and now routinely post information and discuss questions or cases pertaining to gastrointestinal medicine and endoscopy. The conference will be an annual event and plans are currently underway for the 2012 event.

Collaboration between Canadian and American primary care endoscopists is also occurring. Four Canadians attended the 2010 American Association of Primary Care Endoscopy (AAPCE) annual conference and one of the APC-Endo physicians is now on the executive of the AAPCE. The APC-Endo study results were presented at the AAPCE annual meeting in November 2010 and at Endoscopy Skills Day for Practicing Endoscopists conference in January 2011. Eight of 10 APC-Endo participating physicians were present at the Endoscopy skills day presentation.

Finally the Alberta Primary Care Endoscopy study will be submitted for publication in a peer-reviewed journal in the upcoming year. Following publication of the APC-Endo study, the systematic review will likely be updated and published.

Equipment

All endoscopy suites require equipment to efficiently and safely perform diagnostic and therapeutic colonoscopies and to effectively communicate endoscopic findings.

All endoscopy units must be able to take photographs of cecal landmarks and abnormalities encountered during the procedure.(4,5) Two sites were unable to take photographs during the study. After the study completion and the endoscopy educational event, both sites have

since acquired the equipment necessary to take photographs. It is the goal to have all primary care colonoscopists take photographs that unequivocally demonstrate cecal landmarks and also take pictures of any abnormalities seen.

The systematic review demonstrated that the type of endoscopic system used (older monocular or newer video fibreoptic systems) affected cecal intubation rates. Recent technological advances in endoscopy equipment, including high definition, wide-angle lenses and advanced imaging techniques will also affect adenoma detection rates. For future comparisons between physicians or physician groups' adenoma detection rates, all groups should be using the latest advances in endoscopic technology.

Quality colonoscopy reporting

Variability in the quality of endoscopy reports generated by endoscopists exists.(6) All endoscopists must be encouraged to perform complete endoscopy reporting using consistent nomenclature.(7,8) Again, the APC-Endo study case report form records all important quality indicators and could be used as a template for the colonoscopy report.

Additional research projects involving primary care colonoscopists

There are a number of potential research studies that could be proposed from the program of research presented here. In addition to extending the APC-Endo study beyond two months, other research involving primary care colonoscopists could include:

1. Comparing actual wait times for endoscopic procedures performed by primary care to current local, provincial and national wait times and to Canadian wait time targets.

2. Comparing times to definitive treatment for colorectal cancer patients between those who had their colonoscopy performed by a primary care physician to those who had their colonoscopy performed by other endoscopists.
3. Determine whether the stage of cancer diagnosed by primary care colonoscopists is different than the stage of cancers diagnosed by other endoscopist groups.

Research stemming from data already collected in the APC-Endo study could explore:

1. Correlation of patient perceived level of discomfort at the telephone survey to the patient discomfort score recorded at the time of colonoscopy.
2. Whether using propofol (Diprivan) improved patient discomfort scores compared with the traditional use of narcotics and benzodiazepines.
3. Determining how accurately primary care physicians can predict the pathological type of the polyp visualized during colonoscopy.
4. Whether and how participating in the APC-Endo study changed the study physician's endoscopic practice.

Resource solution

Primary care physicians are a logical resource to assist with the increasing "endoscopic burden" of screening an aging population for colorectal cancer as well as providing timely investigations for patients with gastrointestinal symptoms. Leaders of provincial population-based screening programs must decide whether colorectal cancer screening programs are going to recommend only fecal occult blood (or fecal immune testing) or fecal testing and sigmoidoscopy. If sigmoidoscopy is going to be encouraged for screening average risk patients for colorectal cancer, then primary care physicians who are planning

on practicing in rural Canada should undergo sigmoidoscopy training in their residency programs.

Furthermore, many of the primary care colonoscopists in Alberta are within 5-10 years of retirement. Without a committed plan to replace these physicians, access for rural patients needing colonoscopy may actually worsen in the future. In Alberta, we should consider training one additional primary care physician in gastrointestinal medicine and endoscopy every 1-2 years for the next 5-10 years. This training should be a formal, funded and recognized additional skills training program in gastroenterology similar to current additional skills programs in emergency medicine, anaesthesia and geriatrics.(9) The length of training should be standardized, but could take into account previous training (family physician or general internal medicine) as well as previous endoscopy experience. Upon completion of this training, the physician could receive designation as an endoscopist from the College of Family Physicians of Canada or Canadian Society of Internal Medicine. Additional endoscopic time must also follow to support and enable these physicians to provide their service to the patients of rural Alberta. For physicians already performing colonoscopies, ongoing provincial accreditation and maintenance of competency in colonoscopy could be supported by documentation of quality outcomes as demonstrated in the APC-Endo study.

Finally, consideration may be given to training nurses and physician assistants in colonoscopy in the future. Subsequent research could evaluate the quality of endoscopic procedures performed by these alternate groups of endoscopists. Regardless of the endoscopists' level or type of training, documentation of the quality indicators in

colonoscopy is critical and should be emphasized. Research can then conclude whether quality colonoscopies are being performed for all patients.

5.3 Conclusion

The primary care endoscopy research presented in this thesis is the most comprehensive research pertaining to the quality of colonoscopies performed by primary care physicians. This body of knowledge should guide policy makers and physicians alike into utilizing an underused resource to help with current and future endoscopist shortages. Researchers and current endoscopists can also use this study to design future research projects or clinical quality practice improvements audits.

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Appendix 3a

Initial Physician Questionnaire

Alberta Primary Care Endoscopy Project (APC-Endo)

Initial Physician Questionnaire

Thank you for completing this physician questionnaire, which will allow a better understanding of the skill set of family physicians and general internists who perform colonoscopies in Alberta.

*The form is **only** to be filled out by a family physician or general internist who performs colonoscopies.*

I am a: ☐ Family Physician ☐ General Internist

Zone of endoscopy practice:

☐ North ☐ South ☐ Central ☐ Edmonton region ☐ Calgary region

Outline your colonoscopy training including time spent training:

☐ Formal training ☐ Self taught ☐ Other _____

_____

Estimated total number of colonoscopies performed in training: _____ Do not know

Number of years performing colonoscopies in practice: _____

Estimated number of colonoscopies performed per year: _____ Do not know

Estimated total number of colonoscopies performed in practice: _____ Do not know

Estimated number of complications in the past five years *(Complications are expected in routine care. This information is confidential, so please be honest)*

Perforation *(clinical and radiographic evidence):* _____

Bleeding *(requiring hospital admission, transfusion, repeat colonoscopy or surgery*): _____

Sedation (*requiring abandonment of procedure, use of reversal agents or artificial ventilation or admission to hospital for cardiac or respiratory complication of sedation):* _____

Other: _____

General Questions *(circle response)*

I (or my assistant) routinely meets the patient prior to colonoscopy Yes No

I most often obtain my own consent Yes No

I most often perform my own sedation Yes No

Most common agents used for sedation are: *(circle no more than three)*

Fentanyl Demerol Versed (Midazolam) Diazemuls Propofol Other

Alberta Primary Care Endoscopy Project (APC-Endo)

Initial Physician Questionnaire

I most often advance the colonoscope myself	Yes	No
I routinely perform biopsies	Yes	No
I routinely photograph cecal landmarks	Yes	No
I am able to intubate the terminal ileum most times if needed	Yes	No
I routinely perform polypectomies	Yes	No
♦ piecemeal (regular biopsy forceps)	Yes	No
♦ hot biopsy forceps	Yes	No
♦ hot snare (cautery)	Yes	No
♦ cold snare	Yes	No
I normally measure the size of polyps using biopsy forceps	Yes	No
I can perform saline injection prior to polypectomy	Yes	No
I use epinephrine for injection hemostasis	Yes	No
I use cautery (gold probe) for hemostasis	Yes	No
I am comfortable starting immunosuppressants for IBD	Yes	No
I feel that I am supported by specialists in GI medicine	Yes	No

My scheduled endoscopy days March 2010 – June 2010:

March 2010: _____ April 2010: _____

May 2010: _____ June 2010: _____

or my regular endoscopy day(s) are (ex. every Thursday): _____

Number of procedures performed per session: _____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Please fax the completed form to: Dr. M. Kolber fax # (780) 407-3982

Appendix 3b

Case Report Form

Alberta Primary Care Endoscopy Study (APC-Endo)
Case Report Form
*****To be completed by endoscopy nurse and physician endoscopist*****

Patient Code #: _____

Date _____ Patient's Age: _____ Sex: ☐ Male ☐ Female Inpatient: ☐Yes ☐No

Is this the patient's first time having a colonoscopy? ☐ Yes ☐ No

BOWEL PREPARATION USED: ☐ GoLytely (4 litres evening before) ☐ GoLytely split prep ☐ Pico-salax
☐ Milk of Magnesia ☐ Magnesium citrate ☐ Oral fleet Phospho-soda ☐ Other: _____

PREDOMINANT INDICATION: ***(circle only one** – the most compelling reason for the colonoscopy)*

CRC Screen:	Symptoms:	Follow Up Scope:	Other:
No FHx	Pain/diarrhea/constipation	IBD FU	Abnormal x-ray
FOBT +	Rectal Bleed	CRC FU	_____
FHx +	Anemia	Polyp FU	
HNPCC/FAP FHx			

PROCEDURAL TIMES: *(24 hour clock, round to nearest minute)*

Procedure Start time *(scope insertion into anus)*: __ __:__ __
Cecum identified: __ __:__ __
Leaving Cecum: __ __:__ __
Procedure End time: *(scope removed from anus)* __ __:__ __

QUALITY OF BOWEL PREPARATION AT END OF PROCEDURE: *(choose most appropriate response for entire colon)*

☐ Excellent (no more than small bits of adherent feces / fluid)
☐ Good (small amounts of feces or fluid, but not limiting exam)
☐ Satisfactory (enough feces or fluid that may have limited the exam)
☐ Poor (semi-solid waste could not be cleared resulting in poor views of mucosa)

CECAL INTUBATION: ☐ Yes ☐ No

If not, why:

☐ Technically difficult ☐ Poor bowel prep ☐ Stricture ☐ Equipment problem ☐Other

Cecal intubation verified by visualization of: *(tick all that apply)*

☐ Appendix ☐ Trifold ☐ Ileocecal valve ☐ Intubation of t. ileum ☐ Light in RLQ

Photo taken of cecal landmarks ☐ Yes ☐No

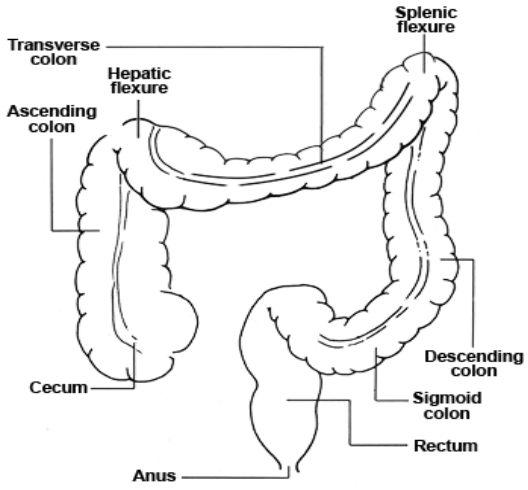
SEDATION USED: (AGENTS AND AMOUNTS): _____

PATIENT COMFORT LEVEL DURING PROCEDURE

☐ No discomfort-resting comfortably throughout procedure
☐ One or two episodes of discomfort, well tolerated
☐ More than two episodes of discomfort adequately tolerated
☐ Significant discomfort experienced several times during the procedure
☐ Extreme discomfort experienced frequency throughout the procedure

Alberta Primary Care Endoscopy Study (APC-Endo)

POLYP DETECTION



Type of polyp / lesion

H = hyperplastic

A = adenoma < 1 cm*

AA = adenoma > 1 cm*

C = cancer

Polypectomy Method

1. Regular Biopsy
2. Hot biopsy forceps
3. Cold snare
4. Hot (cautery) snare

Using nomenclature in boxes, mark the location of ALL polyps found.

Mark **X** if the polyp was not retrieved.

**Largest diameter of polyp estimated by endoscopist using outer width of open biopsy forceps normally = 8mm*

PREDOMINANT FINDING: *(circle the one most important clinical finding)*

Normal	Colorectal Cancer	
Adenoma polyp > 1 cm*	Adenoma polyp < 1 cm*	Hyperplastic polyp
IBD: old	IBD: new	Infectious colitis (incl. c. diff)
Diverticulosis**	Hemorrhoids / Fissure**	Other: _____

** Largest diameter of polyp estimated by endoscopist using outer width of open biopsy forceps normally = 8 mm*

** *To be considered as predominant finding, must be consistent with presenting symptoms*

IMMEDIATE COMPLICATIONS: *(see information sheet for definitions of complications)*

☐ None ☐ Bleeding ☐ Perforation ☐ Sedation ☐ Other: _____

ANTICIPATED REFERRAL TO SPECIALIST: ☐ Yes ☐ No

If Yes, reason for referral:

☐Surgery ☐Disease management ☐Repeat colonoscopy ☐Other:_____

ADDITIONAL NOTES: _____

_____

Endoscopist: _____ Nurse: _____

PLEASE FAX THE COMPLETED FORM TO DR. M. KOLBER AT (780) 407-3982

Appendix 3c

Post Procedural Satisfaction Survey

Alberta Primary Care Endoscopy Study (APC-Endo)
POST PROCEDURE TELEPHONE SURVEY
****Top section to be completed by endoscopy nurse or endoscopist****

Patient Code #: _____

Patient Consents to Participate in Post Procedure Telephone Survey: ☐ **Yes** ☐ **No**

If Yes, please complete the demographics section below and fax to Dr. M. Kolber

If No, please DO NOT complete the demographics section, but still fax form to Dr. M. Kolber

Patient Name _____ Patient DOB _____ **Patient AHC # _____**

Procedure date _____ Endoscopist _____

Patient preferred phone # _____ Preferred time to call: AM PM Evening

Patient alternate phone # _____ Preferred time to call: AM PM Evening

PLEASE FAX THIS FORM TO DR. M. KOLBER AT (780) 407-3982

POST PROCEDURE TELEPHONE SURVEY

SHADED SECTION TO BE COMPLETED ONLY BY DR. M. KOLBER or DESIGNATE

Date(s) attempted: _____ Date spoke to patient: _____

Patient reported Delayed Complications: Yes No

Perforation Bleeding Other: _____

Complication Verified: Yes No

Satisfaction Survey

1. How would you rate your satisfaction with the wait to have your colonoscopy:

   Extremely Dissatisfied 1 2 3 4 5 6 7 Extremely satisfied

2. How would you rate the level of discomfort you experienced during the colonoscopy:

   (0) No discomfort (1) Mild (2) Moderate (3) Severe (4) Extreme discomfort

   Do not remember

3. How would you rate your visit to the hospital for the colonoscopy:

   Poor 1 2 3 4 5 6 7 Excellent

4. Would you be willing to have a repeat colonoscopy performed by the same physician, if required?

   Yes No

5. Do you anticipate being referred to a specialist for your GI complaint? Yes No

6. If yes, for what reason? Surgery Management of disease Repeat colonoscopy Other

Notes: _____

Reviewer Name: _____ Date: _____

Appendix 3d

Potential Complication: Initial Review

ALBERTA PRIMARY CARE ENDOSCOPY (APC-ENDO) STUDY

POTENTIAL COMPLICATION – INITIAL REVIEW

TO BE FILLED IN BY STUDY COORDINATOR

APC-Endo Study #: _____

Date of procedure: _____ Date Reviewed (dd/mm/yr): / / 2010

Potential complication reported by: ☐ physician ☐ patient

REPORTED POTENTIAL COMPLICATION:

☐ **Bleeding**: bleeding related to the colonoscopy, which resulted in:

☐ Blood transfusion ☐ Admission to hospital ☐ Second colonoscopy ☐ Surgery

☐ Yes ☐ No ☐ Unsure

☐ **Perforation**: clinical and radiographic evidence (free air on plain films or CT scan) of a perforation:

☐ Yes ☐ No ☐ Unsure

☐ **Related to procedural sedation and analgesia (PSA)**:

☐ Physician stopped colonoscopy prematurely due to adverse effects of PSA

☐ Used reversal agents (nalaxone or flumazinil) ☐ Artificially ventilated the patient

☐ Admitted patient to hospital after the procedure for any cardiac or respiratory condition related to the PSA agents.

☐ Yes ☐ No ☐ Unsure

☐ **Minor Complication or Expected Symptoms**:

☐ Abdominal pain / cramping ☐ Nausea / vomiting

☐ Related to intravenous access

☐ **Other**: _____

Notes: _____

_____

Decision: Potentially serious complication? ☐ Yes ☐ No ☐ Unsure

Plan: ☐ File ☐ Send Information Request to physician ☐ Other: _____

Appendix 3e

Potential Serious Complication: Information Request

ALBERTA PRIMARY CARE ENDOSCOPY (APC-ENDO) STUDY

POTENTIAL SERIOUS COMPLICATION –INFORMATION REQUEST

According to the case report forms or patient telephone survey, a potential serious complication may have occurred on one of your patients in the APC-Endo study. Please fill in the form below detailing the complication and attach all relevant lab, x-ray, extra endoscopy or surgery records, emergency or clinic visits and hospital admission or discharge summaries.

APC Endo Study #: _____ Date of procedure: _____

Potential serious complication reported: _____

BELOW TO BE FILLED IN BY PARTICIPATING APC-ENDO PHYSICIAN

☐ **Bleeding**: any bleeding related to the colonoscopy, which resulted in:

☐ Blood transfusion ☐ Admission to hospital ☐ Second colonoscopy ☐ Surgery

☐ Yes ☐ No ☐ Unsure

Did the bleed occur after a polypectomy?

☐ Yes ☐ No ☐ Unsure

☐ **Perforation**:

Clinical and radiographic evidence (free air on plain films or CT scan) of a perforation:

☐ Yes ☐ No ☐ Unsure

Did the perforation occur after a polypectomy?

☐ Yes ☐ No ☐ Unsure

☐ **Related to procedural sedation and analgesia (PSA)**:

☐ Physician stopped colonoscopy prematurely due to adverse effects of PSA

☐ Used reversal agents (nalaxone or flumazinil)

☐ Artificially ventilated the patient

☐ Admitted patient to hospital after the procedure for any cardiac or respiratory condition related to the PSA agents.

☐ Yes ☐ No ☐ Unsure

☐ **Other:** _____

ALBERTA PRIMARY CARE ENDOSCOPY (APC-ENDO) STUDY

POTENTIAL SERIOUS COMPLICATION – INFORMATION REQUEST

Details about potential complication: _____

_____

_____

_____

_____

_____

_____

Was patient hospitalized due to potential complication: ☐ Yes ☐ No

If yes, length of stay in hospital: _____

Was patient transferred to another hospital? ☐ Yes ☐ No

If yes, length of stay in that hospital: _____

Pertinent Laboratory, x-ray, OR, hospital results attached ☐ Yes ☐ No

Outcome: ☐ Death ☐ Life threatening ☐ Involved or prolonged hospitalization

☐ Resulted in persistent or significant incapacity

☐ Resulted in another medically important condition

☐ Other: _____

Form completed by: _____ Date: _____

Please fill in and fax form and accompanying records (with name blackened out and APC-Endo study number added) to **APC – Endo study fax: (780) 407 – 3982.**

Please contact me if you have any questions.

Michael Kolber BSc, MD, CCFP
Study Coordinator APC-Endo study
(780) 616-8411 (cell)
(780) 407-3982 (APC-Endo study fax)
email: mkolber@ualberta.ca

Appendix 3f

Potential Serious Complication: Verification by Adjudicator

ALBERTA PRIMARY CARE ENDOSCOPY (APC-ENDO) STUDY

POTENTIAL SERIOUS COMPLICATION VERIFICATION

FOR ADJUDICATOR ONLY:

APC ENDO CHART # _____

Adjudicator Identification: ☐ BHR ☐ RT ☐ RF Date Reviewed (dd/mm/yr):___ / ___ / 2010

Potential serious complication:

☐ **Bleeding**: any bleeding related to the colonoscopy, which resulted in:

☐ Blood transfusion ☐ Admission to hospital ☐ Second colonoscopy ☐ Surgery

☐ Yes ☐ No ☐ Unsure

Did the bleed occur after a polypectomy? ☐ Yes ☐ No ☐ Unsure

☐ **Perforation**: Clinical and radiographic evidence (plain films or CT scan) of perforation:

☐ Yes ☐ No ☐ Unsure

Did the perforation occur after a polypectomy? ☐ Yes ☐ No ☐ Unsure

☐ **Related to procedural sedation and analgesia (PSA)**:

☐ Physician stopped colonoscopy prematurely due to adverse effects of PSA

☐ Used reversal agents (nalaxone or flumazinil) ☐ Artificially ventilated the patient

☐ Admitted patient to hospital after the procedure for cardiac or respiratory condition related to the PSA agents.

☐ Yes ☐ No ☐ Unsure

☐ **Other potential serious complication**: _____

Notes:

_____

_____

Outcome: ☐ Death ☐ Life threatening ☐ Involved or prolonged hospitalization

☐ Resulted in persistent or significant incapacity

☐ Resulted in another medically important condition

Causality: ☐ Related or possibly related ☐ Unknown / Uncertain ☐ Not related