NOVA SCOTIA RECTAL CANCER PROJECT: A POPULATION-BASED ASSESSMENT OF RECTAL CANCER CARE AND OUTCOMES

by

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ABSTRACT

Purpose: To describe patient & tumor characteristics among rectal cancer patients in Nova Scotia, to determine factors associated with permanent colostomy and oncologic outcomes and to determine the relationship between surgeon knowledge and oncologic outcomes.**Methods:** The Provincial cancer registry identified new rectal cancer patients from in Nova Scotia. A comprehensive review of inpatient, outpatient and cancer center medical records was used to assemble the cohort. Surgeon knowledge was assessed using a survey with questions pertaining to rectal cancer care.**Results:** Patient & tumor characteristics were similar between hospitals providing rectal cancer care. Patients treated by high volume cancer center surgeons are less likely to undergo a permanent colostomy or have a local recurrence compared to patients treated elsewhere. Patients treated by surgeons with a high survey score have improved clinical and oncologic outcomes.**Conclusions:** There is an opportunity to improve rectal cancer care in Nova Scotia.

LIST OF ABBREVIATIONS USED

APR	abdominal perineal resection
DSS	disease specific survival
LR	local recurrence
PC	permanent colostomy
SPS	sphincter-preserving surgery
TME	total mesorectal excision

GLOSSARY

Abdominal perineal resection (APR)
A surgical procedure involving resection of the lower sigmoid colon, rectum, anus and surrounding skin with formation of a permanent sigmoid colostomy.

Abscess
A contained collection of infected fluid

Adjuvant therapy
Radiation therapy, chemotherapy, or both given after surgical resection

Anastomosis
A new connection between two pieces of bowel after a segment has been resected

Anastomotic leak
Leakage of fecal material from an anastomosis

Anterior resection
A surgical procedure where part (or all) of the rectum is resected and an asatomosis is created between the colon and the low rectum or anus. A permanent colostomy is not required, however a temporary diverting ileostomy may be created.

Barium enema
Administration of barium (a radio-opaque material) through the rectum for an X-ray examination of the colon and rectum.

Colonoscopy
Visualization of the the entire colon and rectum using a fiberoptic endoscope.

Colostomy
A surgical procedure that involves exteriorizing part of the colon out through a defect created in the abdominal wall and securing it to the skin. The feces are then collected in a bag.

Disease specific survival
The length of time a patient survives without the disease of interest (rectal cancer).

Diverting Ileostomy
Refers to the creation of an ileostomy to divert the fecal stream away from a newly constructed anastomosis. This may prevent some of the severe consequences of an anastomotic leak.

***En bloc* resection**
If a cancer invades other organs the organs are resected together with the primary organ (ie rectum) in one complete piece.

Endoscopic Excision
Removal of a lesion from the colon or rectum (ie. rectal cancer) via the endoscope at the time of colonoscopy or flexible sigmoidoscopy. It does not involve and adominal incision and does not remove the lymph nodes.

Flexible sigmoidoscopy
Visualization of the rectum and part of the sigmoid colon using a fiberoptic endoscope. This differs from colonoscopy in that only the lower part of the colon is visualized

Laparotomy
An incision created to gain access to the abdominal cavity.

Leukocytosis
Elevated white blood cell count; indicative of an infectious or inflammatory process.

Local recurrence of cancer
After resection of a primary tumor, the re-appearance of a cancer in the same area that it had originally appeared.

Mesorectum
The fatty tissue envelope of the rectum that contains blood and lymph vessels, lymph nodes and autonomic nerves

Metastasis
The spread of cancer from the primary tumor to another body part.

Neo adjuvant therapy
Radiation therapy, chemotherapy, or both that is given prior to surgical treatment.

Pathologic margins
The distance between the tumor and the site of surgical dissection. For rectal cancer the proximal margin is the distance from the tumor to where the bowel was divided upstream from the cancer. The distal margin is the distance from the tumor to where the bowel was divided downstream from the tumor. The radial margin is the distance from the tumor to the site of lateral dissection.

Peri-operative
The period of time immediately after a surgery (usually up to 30 days after a surgery).

Radical excision
The surgical removal of a tumor mass, the surrounding connective tissues, and the lymph nodes.

Rectum
Part of the bowel between the sigmoid colon and the anus.

Sphincter-preserving surgery
A surgical procedure in which the anal sphincters are not removed (ie. APR is not a sphincter-preserving surgery; anterior resection is a sphincter-preserving surgery).

Synchronous cancer
A cancer that occurs at the same time as another cancer in the same organ.

Total mesorectal excision (TME)
Complete removal of the rectum together with its surrounding mesorectal lymphovascular fatty tissue by precise sharp dissection along the visceral pelvic fascia

Transanal excision
Excision of a rectal cancer through the anus that does not involve an abdominal incision and does not remove the lymph nodes.

CHAPTER 1: INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer in men and women and the second leading cause of cancer-related mortality in North America. The age-standardized incidence rate of CRC in Canada is among the highest in the world. Within Canada, Nova Scotia has the second highest incidence rates of CRC for both men and women. Of all CRC, rectal cancer accounts for approximately 25-30 percent of cases. Rectal cancer presents unique treatment challenges given the skeletal confines of the pelvis, the functional importance of the anal sphincter complex and the proximity of pelvic autonomic nerves. The treatment of rectal cancer is technically demanding and is associated with higher rates of local recurrence and functional disturbances compared to the treatment of colon cancer.

At present, most of the data regarding rectal cancer care and outcomes in North America have come from specialized treatment centers and clinical trials. While there are many facilities across Canada and the U.S. with clinical expertise and high volume experience in rectal cancer care, rectal cancer is a common disease and many patients, if not the majority, are treated in community and regional hospitals by general surgeons. It is unknown how much variation exists in the delivery of rectal cancer care in different geographic regions and clinical environments and how this may impact treatment outcomes. A limited number of population-based studies have examined rectal cancer care in North America with concerning results. These studies have reported that less than 50 percent of rectal cancer patients have an adequate lymph node harvest and only 40 percent undergo sphincter-preserving surgery[1,2]. In contrast, population based studies from Europe have reported sphincter preserving surgery in approximately 70 percent of rectal cancer patients[3,4] suggesting that there may be important deficiencies in North American rectal cancer care. In an attempt to improve rectal cancer care in the United States, quality indicators have recently been established and pay for performance has been recommended.

Most population-based data regarding rectal cancer outcomes in North America have come from administrative databases and/or cancer registries. While these databases provide for large sample sizes, they lack patient level data which may be important for proper interpretation of results. For example, it is difficult to use abdominoperineal resection (APR) rates as an indicator of quality care without details regarding the tumor (ie. sphincter invasion) and the patient (ie. patient preference, body habitus, pre-existing incontinence, etc). Accordingly, population-based studies using patient-level data are important for accurate assessment of rectal cancer care and outcomes.

The province of Nova Scotia provides a unique opportunity to evaluate the delivery of rectal cancer care because of its relatively small geographic and population size. The purpose of this study was to provide a population based assessment of rectal cancer care and outcomes in Nova Scotia. Specifically the project aimed to: 1) compare patient characteristics and tumor factors across all hospitals in the province; 2) describe the treatment of rectal cancer across the province and determine if there were hospital or surgeon associated differences in treatment; 3) compare oncologic outcomes for rectal cancer across all hospitals in the province; 4) compare the use of permanent colostomy in the management of rectal cancer across all hospitals in the province; and 5) determine if surgeon knowledge is associated with patient outcomes.

CHAPTER 2: LITERATURE REVIEW

Presentation and Staging

The majority of patients with rectal cancer present when they are > 60 years old[5] and the mean age is 67[6]. There is a higher proportion of male patients presenting with this disease compared to female patients[5-7]. Rectal cancer is typically detected either by screening colonoscopy or when patients present to medical attention with signs or symptoms of the disease. There is little research that has explicitly examined the presentation patterns for patients with rectal cancer. Most studies of presentation have included patients with colon cancer and patients with rectal cancer. Only 6.6% of new CRC cases are diagnosed with a screening test[8]. The majority of patients undergo investigations because they have developed symptoms. These may include abdominal pain, change in bowel habit, anorexia, nausea/vomiting, rectal pain, rectal bleeding, tenesmus, anemia and weight loss. Among patients with CRC, anemia, rectal bleeding and constipation are associated with a left sided tumors[9]. Previous population based studies of rectal cancer have found that rectal tumor height is equally distributed between low, mid and high rectal tumors[7]. The reported stage distribution among patients with rectal cancer varies, however the majority of patients have Stage II or III disease[5-7].

Among patients with CRC cancer who are symptomatic at the time of presentation, some may present to their family physicians while others may present to another specialist or to the emergency department. Patients who present to the emergency room with CRC are similar to those who present to their family physician in terms of age and gender, however patients who present to the emergency room and undergo emergent surgery are more likely to have obstruction or perforation of cancer[10].

Patients who undergo emergency surgery for their CRC are more likely to have an advanced tumor stage (T stage) than patients who present to their family physician[10]. It is currently unknown how many patients with rectal cancer present to the emergency department and if these patients differ from those who present to other clinical settings.

Patients with rectal cancer require staging investigations to determine the presence of synchronous cancers and metastatic disease. Synchronous lesions occur in 3% - 5% of patients with rectal cancer and patients require pre-operative assessment of the entire colon to exclude these lesions. Assessment of the colon should be done with a complete colonoscopy. If complete colonoscopy cannot be performed, then a barium enema should be performed in addition to the partial colonoscopy. Pre-operative workup for patients with rectal cancer should also include imaging of the pelvis (CT pelvis or pelvic MRI), imaging of the liver (CT abdomen or abdominal ultrasound) and imaging of the chest (Chest X-Ray or CT scan)[11]. These images will rule in or rule out distant rectal cancer metastases in the lung or liver which, if present, may change the management of the patient. Little is known about the extent to which staging investigations are used appropriately in patients with rectal cancer. An Ontario-based survey published in 2005 revealed significant variation in self-reported use of preoperative investigation among surgeons treating primary rectal cancer[12]. The survey indicated that while over 80% of respondents would perform a pre-operative colonoscopy, only 42% of surgeons said they would routinely order a pre-operative CT scan of the abdomen and pelvis and 59% said they would obtain imaging of the chest. Over half of survey respondents indicated that they did not order imaging because of lack of availability. The impact of inappropriate or incomplete staging investigations among patients with rectal cancer is not known.

Treatment and Oncologic Outcomes

Impact of volume on oncologic outcomes

Over the past decade there has been increasing interest in the quality of rectal cancer care. Much of this interest has focused on the impact of hospital procedure volume, surgeon procedure volume and surgeon training on oncologic outcomes. Surgeon procedure volume and type of training have been studied with regards to outcomes after resection of rectal cancer. Most studies have reported that patients treated by high-volume surgeons with colorectal fellowship training have lower rates of local recurrence and higher rates of disease specific survival compared patients treated by low volume surgeons or surgeons without specialty training[13-15]. However, there is little agreement as to threshold that defines high volume and it has been suggested that sub-specialty training in colorectal surgery may have a more significant impact on patient outcomes than procedure volume[14]. There are conflicting data regarding the impact of surgeon procedure volume and training on peri-operative mortality, disease-specific and overall survival[16].

It is unclear why treatment by high volume surgeons or those with specialty training leads to improve patient outcomes. It is possible that these variables are surrogate markers for aspects of rectal cancer care known to be associated with oncologic outcomes. These variables may include iatrogenic perforation of the bowel at the time of surgery[17-19], anastomotic leak[20,21], adequate of lymph node harvest[22] and appropriate administration of neo-adjuvant and adjuvant therapies[23]. Alternatively, patients treated by high volume surgeons may be more likely to be reviewed by multidisciplinary tumor boards or receive care in an environment with an emphasis on quality assurance.

Impact of Surgical technique on oncologic outcomes

Through the 1980s and 1990s, local recurrence after rectal cancer surgery was reported in more than 20 percent of patients[24-26]. TME was first described in 1982 and is now considered the gold standard of surgical dissection for mid and low rectal cancer. This technique involves resection of the tumor *en bloc* with its blood supply and lymphatic drainage (mesorectum). Historically high rates of local recurrence have likely resulted from blunt pelvic dissection that violates the fascia propria of the rectum. This may have led to tumor seeding of the pelvis. European studies have demonstrated that education and training of surgeons in the dissection technique total meso-rectal excision (TME) can lead to a significant decrease in the rate of local recurrence after surgery for rectal cancer. Quirke developed criteria for assessment of the TME specimen that was used in the Dutch TME trial [27]. These criteria grade the quality and completeness of a TME based on the mesorectum, defects in the specimen, the presence of coning and the appearance of the circumferential resection margin. Patients who undergo an incomplete TME are more likely to have a local recurrence and have shorter disease specific survival compared to patients who undergo a complete TME. Mesorectal grade is an independent factor associated with both local recurrence and disease specific survival[28]. With TME, local recurrence rates of 10 percent and lower have been reported after surgery without radiation treatment[29,30].

Iatrogenic perforation of the bowel at the time of surgery has also been identified as a risk factor for local recurrence[17-19] and worse disease-specific survival[18,19]. Perforation of the rectum may occur if the tumor is friable or because of poor surgical technique. It is unclear if the increased local recurrence and reduced disease specific survival occurs secondary to tumor spillage with re-implantation of tumor cells onto another surface or if iatrogenic perforation of the bowel is a surrogate marker for inferior operative technique, specifically inferior radial margins.

Anastomotic leak is an inherent risk in colorectal surgery and leak rate varies based on the location of the anastomosis. Colonic anatsomoses have leak rates of approximately 2% where as rectal anastomoses have leak rates of 6-10%[31,32]. Anastomotic leak after rectal cancer surgery can have deleterious effects on functional outcome, local recurrence and overall survival. Anastomotic leak has been independently associated with local recurrence and a worse cancer free survival[31]. Previous research has reported that patients with rectal cancer who have an anastomotic leak are 2.55 times more likely to develop local recurrence than patients who do not have an anastomotic leak [31].

Impact of pathologic assessment of lymph nodes on oncologic outcomes

The pathologist plays an important role in the care of rectal cancer patients. They are responsible for the identification of lymph nodes, determining the status of the margins and for quality assurance of surgical technique (TME). Accurate pathology reporting requires both an adequate resection by the surgeon and a satisfactory analysis of the specimen by the pathologist. The number of lymph nodes sampled at the time of surgery is believed to be an important predictor of patient outcome and decisions regarding the need for adjuvant chemotherapy are often based on the lymph node status. A recent systematic review has shown an association between increased lymph node assessment and increased survival among patients with stage II and III colorectal cancer[33].

Examining a greater number of lymph nodes increases the likelihood of proper staging. The current recommendation is that at least 12 lymph nodes should be assessed to provide accurate staging information[22]. A North American population-based analysis of patients with colorectal cancer found that only 37% of patients have adequate lymph node evaluation [34]. Reasons for this are likely multi-factorial and include patient, tumor, surgeon and pathologist factors. The use of neo-adjuvant therapy in patients with rectal cancer is an important factor in lymph node retrieval[35,36] because radiation therapy makes the lymph nodes more difficult to identify (and therefore retrieve) for both the surgeon and the pathologist. Thus the appropriate number of lymph nodes needed for assessment in these patients is uncertain.

Impact of chemo-radiation therapy on oncologic outcomes

Historically, radiation therapy only was given to patients with rectal cancer to reduce local recurrence. However in the late 1980's and early 1990's it became apparent that the use of chemotherapy combined with radiation therapy in patients with regional lymph node involvement could reduce local recurrence, improve disease-specific survival and improve overall survival[37]. Patients with stage II and III rectal cancer who receive adjuvant chemotherapy and radiation have a 10-15% absolute overall survival benefit compared to patients who don't adjuvant therapy[37].

Recently research in this area has focused on the impact of pre-operative vs post operative delivery of chemoradiation[38, 39] and the dosage regimen of radiation therapy[40]. Studies suggest that neo-adjuvant chemoradiation is associated with lower rates of local recurrence in patients with rectal compared to adjuvant therapy. There appears to be no difference in disease-specific or overall survival[39,40] regardless of whether treatments are given pre-operatively or post-operatively. Other benefits of neo-adjuvant chemotherapy and radiation include better tolerated in patients and facilitation the use of sphincter-preserving surgery in some patients[39,40]. Given the important impact neo-adjuvant and adjuvant therapy in patients with rectal cancer, appropriate use of these therapies has been suggested as an indicator of quality in rectal cancer care[41].

Sphincter Preservation

The treatment of rectal cancer may involve the creation of a permanent colostomy (ie. abdominal perineal resection, APR). This may be necessary for patients with rectal cancer who have tumor invasion of the anal sphincter, bulky tumors, incontinence or advanced age. Research has suggested that permanent colostomies are associated with decreased quality of life and most patients would choose to avoid a permanent colostomy if given a choice[42]. With advances in surgical technique, improved stapling devices and better knowledge of required oncologic margins, the role of abdominoperineal resection in the management of rectal cancer has substantially decreased. However, despite these advances significant variation in the permanent colostomy rate after treatment of rectal cancer persists. Population-based studies of rectal cancer have reported that the permanent colostomy rate in North America ranges from 50-60%[8,43-45]. In contrast, only 23-33%[46-48] of patients in Europe and Australia receive a permanent colostomy. The reason for this discrepancy is unclear. The need for a permanent colostomy should be primarily based on tumor factors and patient characteristics. However, variation in colostomy rates according to surgeon[46,49] and hospital[8,50,51] procedure volume has been reported suggesting that some patients may receive a permanent stoma unnecessarily.

CHAPTER 3: HYPOTHESES AND RESEARCH OBJECTIVES

Hypotheses: Treatment variation exists among the 10 hospitals in Nova Scotia that provide rectal cancer care and this variation results in differences in surgical and oncologic outcomes.

Research Objectives:

1. To describe patient and tumor characteristics at presentation in patients with rectal cancer and compare these factors among all hospitals providing rectal cancer care in a Canadian province.

2. To describe oncologic outcomes (local recurrence, disease-specific survival, overall survival) after radical resection for rectal and to determine if there were hospital or surgeon associated differences in treatment.

3. To provide a population-based assessment of permanent colostomy rates after rectal cancer surgery using patient level data and to determine factors associated with surgery resulting in a permanent colostomy.

4. To evaluate the relationship between surgeon knowledge of rectal cancer care and patient outcomes as measured by the permanent colostomy rate, use of total mesorectal excision (TME), lymph node harvest, local recurrence rate, disease specific survival and overall survival.

CHAPTER 4:

A POPULATION-BASED ASSESSMENT OF PATIENT AND TUMOR CHARACTERISTICS AMONG PATIENTS PRESENTING WITH RECTAL CANCER IN A CANADIAN PROVINCE

Running header: Presentation of rectal cancer

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Abstract

Introduction: Variation in outcomes after radical treatment for rectal cancer based on hospital setting has been identified. While differences in treatment have been proposed as the explanation for this variation, little research has explicitly examined the potential impact of patient and tumor factors. The purpose of this study was to describe patient and tumor characteristics at presentation in patients with rectal cancer who underwent radical surgery with curative intent and compare these factors among all hospitals providing rectal cancer care in a Canadian province.

Methods: The provincial cancer registry was used to identify all patients with a new diagnosis of rectal cancer from 7/1/2002 to 6/30/2006 in Nova Scotia, Canada. Data were collected through a standardized comprehensive review of inpatient and outpatient medical records and cancer center charts

Results: During the study period 466 patients (65% male) received potentially curative elective radical surgery for rectal cancer. Care was provided by 51 surgeons in 10 hospitals including one academic tertiary care referral center, two urban non-teaching hospitals and seven community hospitals. The annual hospital procedure volume ranged from 4 to 43 cases. At presentation, the mean age was 66 years (range 27-94), patients had an average BMI of 28 kg/m^2 (range 15-49) and a mean Charlson co-morbidity score of 1.6 (Range 0-13). Thirty eight percent of patients had low rectal cancers, 40% had mid rectal cancers and 22% had high tumors. The stage distribution at presentation was; 31% stage I, 27% stage II , 35% stage III and 7% stage IV. Patient and tumor characteristics were similar among the 10 hospitals providing radical rectal cancer surgery with the exception of patient age. Patients treated in community hospitals were older than those treated in the academic tertiary care referral center (67.5 vs. 64.1 years respectively, p=0.002).

Conclusions: Patient gender, co-morbidities, BMI, tumor height and stage were similar among hospitals providing rectal cancer care regardless of hospital type (tertiary care referral center vs. community hospital) or hospital procedure volume. It is unlikely that variation in rectal cancer outcomes is attributable to hospital-based differences in patient characteristics or tumor factors.

Introduction

Colorectal cancer (CRC) is the third most common cancer in men and women and the second leading cause of cancer-related mortality in North America. Of all CRC, rectal cancer accounts for approximately 25-30 percent of cases. Previous research has demonstrated variability in a variety of outcomes after treatment for rectal cancer such as cancer-specific survival[1,2], local recurrence[2,3], the use of permanent colostomy [4-6] and surgical complications[7]. This variation has been observed across different hospital types (high volume vs. low volume [1,6,8-10], specialized treatment center vs. other [11-13]) and geographic areas[3-5]. While differences in treatment have been proposed to account for the observed variation in outcomes[1,2,7,9-13], this variation could be due to differences in patient characteristics and tumor factors[2,8-10,14-19]. However, little research has explicitly examined the potential impact of such factors at a population level using detailed patient-level data. The purpose of this study was to describe patient and tumor characteristics at presentation in patients with rectal cancer who underwent radical surgery with curative intent and compare these factors among all hospitals providing rectal cancer care in a Canadian province. A comprehensive assessment and comparison of staging investigations was also performed.

Methods

This retrospective cohort study included all patients > 18 years of age in the province of Nova Scotia, Canada with a new diagnosis of rectal cancer between July 1, 2002 to June 30, 2006. Patients were excluded if they underwent primary treatment for rectal cancer outside of the province. Patients were identified from the Nova Scotia

Cancer Registry, which has been in existence since 1964. In Nova Scotia, it is a legal requirement that all new confirmed cancer cases in Nova Scotia be reported to the Registry.

Information regarding patient demographics, co-morbidities, presenting symptoms, location of presentation, staging investigations, treatment and outcomes was obtained through a comprehensive, standardized review of hospital inpatient and outpatient medical records, cancer centre charts and surgeon office charts. Patient co-morbidities were compared using the Charlson co-morbidity index[20]. Body mass index (BMI) was calculated as weight (kg) divided by height $(m)^2$. The location of first presentation to a physician with symptoms of rectal cancer was classified as family physician, emergency room or specialist clinic. Presentation to a specialist clinic refers to a non-gastroenterology or general surgery specialist (ie. Urology clinic). The primary symptom at presentation was collected for each patient. Postal codes were collected for each patient and this information was used to determine referral patterns for rectal cancer care. The TNM classification for staging rectal cancer was used. Rectal tumor height was determined using information from clinical findings on rectal examination, rigid and/or flexible endoscopic examinations and dictated operative reports. A low rectal tumor was defined as being <6 cm of the anal verge on endoscopy or involving the anal sphincter complex. A mid rectal tumor was defined as 6-12 cm from the anal verge and a high rectal tumor was defined as >12 cm from the anal verge. Patients with rectosigmoid cancers were excluded.

Information was collected regarding pre-operative staging investigations for each patient. Adequate pre-operative staging was defined as full evaluation of the colon and rectum (colonoscopy or barium enema + rigid or flexible sigmoidoscopy) imaging of the chest (chest x-ray or CT scan) imaging of the liver (ultrasound, CT scan or MRI) and imaging of the pelvis (CT scan or MRI) based on NCCN guidelines[21].

Data were entered into a computerized database. Three separate comparisons of patient and tumor characteristics were performed. The first comparison was across all hospitals providing rectal cancer care. The second comparison was between patients treated in the academic tertiary care referral hospital and those treated in community hospitals. The third comparison was between patients treated in cancer-center hospitals and those treated in non-cancer center hospitals. A cancer center was defined as a hospital that provided both medical oncology and radiation oncology services.

T-tests were used to test the means between two groups and ANOVA analysis was used to test the means between multiple groups. Chi-square tests were used to test differences between proportions. If a 2 X 2 table contained a cell count of <5, Fisher's exact test was used. Analyses were performed using SAS software version 9.2 (SAS Institute Carey, NC). Statistical significance was set at p=0.05

Approval for this study was obtained from the research ethics board in each hospital where rectal cancer care was provided in the province.

Results

During the four-year study period, 677 patients were diagnosed with rectal cancer (Table 1). Care was provided in 10 hospitals that included one academic tertiary care referral center and nine community hospitals (Table 2). Two of the 10 hospitals were associated with a cancer centre. Of the 677 patients, the initial treatment included radical surgery with curative intent in 472 patients (70%), transanal excision in 22 (3%) patients, endoscopic removal of a malignant polyp in 27 (4%) patients and 156 (23%) patients received palliative treatment only. Among the 472 patients who received radical surgery with curative intent six underwent emergency surgery leaving 466 patients who underwent elective radical excision. The mean age at presentation for these 466 patients was 66 (range 27-94) and 65% of patients were male. The average BMI and Charlson co-morbidity score was 28 (range 15-49) and 1.6 (range 0-13), respectively. Thirty-eight percent of patients had a low rectal tumor, 40% had a mid rectal tumor and 22% had a high rectal tumor. The stage distribution among patients treated with radical surgery was: 31% stage I, 27% stage II, 35% stage III and 7% stage IV. No significant variation was identified in patient and tumor characteristics among the 10 hospitals providing radical rectal cancer surgery with the exception of patient age and location of presentation (Table 3). Patients who were treated in the community hospitals were to be older than those treated in the academic tertiary care referral center and more likely to present to the emergency department.

Thirty seven percent (168/466) of patients were treated in the single academic tertiary care referral center and 63% were treated in community hospitals. Patients who were treated in the academic tertiary care center were younger than patients treated in community hospitals (64.1 years vs. 67.5 years, p=0.002). No other differences in patient or tumor factors were observed between these two treatment settings (Table 4). Of the 168 patients who were treated at the tertiary care academic center 136 (81%) lived in the catchment area for that hospital and 32 (19%) were referred from other regions of the province. Patients who were referred to the academic teaching tertiary care center were younger (64 vs. 69, p<0.01) and had fewer co-morbidities (Charlson comorbidity score 1.6 vs. 1.9, p=0.03) than patients who were treated in the community hospitals. There were no differences in sex, BMI, tumor height or stage distribution between these two patient groups. Of the 466 patients treated with radical surgery 246 (53%) were treated in hospitals associated with a cancer center and 220 (47%) received care at non-cancer center hospitals. Patients treated at the cancer center hospital were younger than those treated at the non-cancer center hospitals but there were no other differences in patient or tumor characteristics between these two groups (Table 5).

Pre-operative staging investigations were examined for the 466 patients with rectal cancer who received radical surgery with curative intent. Eighty one percent of patients had complete evaluation of their colon, 56% had chest imaging, 70% had imaging of the pelvis and 74% had liver imaging. However, only 45% of these patients had complete staging including evaluation of the colon and imaging of the pelvis, liver and chest. There were significant differences in the proportion of patients who received pre-operative staging investigations according to hospital type (tertiary care academic center versus community hospital, (Table 6) and cancer center hospital versus non-cancer center (Table 7)).

Discussion

Rectal cancer is a common disease that is treated in various hospital settings across North America including specialized cancer centers, academic teaching hospitals and community hospitals. As such, population-based assessments of rectal cancer care and outcomes are important to ensure that patients receive a high standard of care regardless of where they are treated. Previous population based-studies of rectal cancer care in North America have reported variation in rates of sphincter preserving surgery[4], local recurrence[3] and overall survival[1]. Similar results have been observed in multicenter studies of rectal cancer care[1-6]. It has been proposed that differences in treatment account for these variable outcomes[1,2,7,9-13] . However differences in patient characteristics and tumor factors across different treatment settings could also account for variation in outcomes. Previous research has demonstrated that younger patients are more likely to undergo sphincter-preserving surgery[8,14,15], have fewer post-operative complications[16] and have better overall and disease-specific survival[17] compared to older patients. Male patients are more likely to receive a permanent colostomy[15], have post-operative complications and have a local recurrence[18] compared to female patients. Patients with a high BMI are more likely to have a local recurrence[19,14] and less likely to receive sphincter-preserving surgery[14] compared to patients with a normal BMI. Patients with low rectal tumors are less likely to undergo sphincter-sparing procedures [9,15] and may be more likely to have a local recurrence [2,10] compared to patients with mid or upper rectal cancers. Patients with stage II or III tumors are more likely to have a recurrence [2,9,10] compared to patients with stage I disease.

Previous population-based studies of rectal cancer outcomes in North America have utilized administrative databases which lack the patient-level data needed to adequately assess and compare patient and tumor characteristics[1,4,5,8]. Studies using cancer registries from Europe have included assessments of patient and tumor characteristics but these have been incomplete and may not be applicable to patients in the North American setting[7,9,10]. In contrast, the present study was a comprehensive, population-based description of patient and tumor characteristics using patient-level data that was collected in a standardized manner from medical records. Data were collected for 466 patients who were treated with radical surgery at 10 hospitals over the four year study period. This included high and low volume hospitals as well as cancer center and non cancer center hospitals.

There were no differences in gender, BMI, co-morbidities, stage distribution or tumor height among patients treated at the 10 hospitals. There was variation in the mean age at presentation among the hospitals ranging from 64.1-71.9 with overall mean age of 66. It is unclear if these statistical differences in age are clinically relevant to patient outcomes. Variation was also observed in the location of first presentation with symptoms of rectal cancer. Significantly more patients presented to the emergency department in some hospitals compared to others. The reason for this is unclear but it could result from poor access to healthcare in some areas of the Province due to insufficient numbers of family physicians. It is recognized that emergency treatment of colon cancer is associated with worse outcomes compared to elective treatment[22]. However emergency surgery for rectal cancer in the present study was very uncommon (6/472 patients) and it is unlikely that the variation observed in the location of initial presentation across hospitals would impact treatment outcomes on a population level. Furthermore, despite the high numbers of patients presenting to the emergency department in some areas of the province, there was no difference in the stage distribution of rectal cancer at presentation among the 10 hospitals.

Patient characteristics and tumor factors were also compared according to hospital setting (cancer center vs. non cancer center and academic tertiary referral hospital vs.

community hospital). Patients who were treated in the cancer center hospitals were slightly younger than those who were treated elsewhere, however there were no differences in any of the other patient characteristics or tumor factors between these two groups. Identical findings were observed with the comparison of patients treated in the tertiary care academic center to those treated in community hospitals. These comparisons taken together with the comparison across all 10 hospitals, suggest that differences in outcomes after rectal cancer care are unlikely to be attributable to hospital-based differences in patient characteristics or tumor factors.

Treatment location and referral patterns for rectal care in North America are not well described. In the present study, the majority of patients (63%) were treated in community hospitals. Thirty seven percent of patients received care in the academic tertiary care referral hospital where all of the colorectal surgeons and surgical onologists in the Province practice. Only 19% of the patients treated at the academic tertiary care referral center were referred from other hospitals in the Province. Compared to patients treated in the community, patients who were referred to the academic tertiary care hospital were younger and had lower Charlson co-morbidity scores. Any perception that the most complex patients (ie. patients with multiple co-morbidities, higher BMI, more advanced tumors, etc.) are treated in academic tertiary care referral centers is not supported by the present study.

The stage distribution at presentation for the entire cohort of 677 patients was similar among all 10 hospitals as was the percentage of patients who were treated with curative intent at each hospital. It is concerning that 21% of all patients presenting with rectal cancer during the study period had stage IV disease. Furthermore, only 77% of all patients were offered treatment with curative intent. Identification of patients with earlier stage disease could lead to significant improvements in rectal cancer outcomes on a population level. These findings emphasize the need for population based screening for colorectal cancer.

Another concerning finding of this study is that only 43% of patients who were treated with radical surgery with curative intent underwent pre-operative evaluation of the colon, imaging of the chest, imaging of the pelvis and imaging of the liver. Current recommendations for the management of patients with rectal cancer suggest that pre-operative staging should include complete evaluation of the colon along with imaging of the chest, abdomen and pelvis[23,24]. The inclusion of pre-operative staging in the management of patients with rectal cancer has also been listed as a quality of care indicator[25]. Patients who were treated in the academic center or in a cancer center hospital were significantly more likely to undergo pre-operative evaluation of the colon and imaging of the chest, abdomen and pelvis compared to patients treated in community or non-cancer center hospitals. These findings could be related to unequal access to diagnostic imaging services or differences in surgeon practices. Incomplete pre-operative investigations could have lead to understaging of patients. The extent to which this occurred and its impact on comparisons of stage distribution among hospitals is unknown.

There are limitations associated with the present study that should be considered. Data were collected retrospectively which relied on the availability and accuracy of medical records. The availability of chest and liver imaging reports for procedures performed before 2003 was poor. However, this only affected 1/8th of the data collection period and it is unlikely that missing data alone accounted for all of the variation observed regarding pre-operative investigations among hospitals. Data capture for the other data elements was excellent with less than 10% of data missing.

Conclusions

Regardless of where rectal cancer care was provided (specialized treatment centers vs. community hospitals, high volume hospitals vs. low volume hospitals) patients were similar in terms of gender, co-morbidities, BMI, tumor height and stage. It is unlikely variation in rectal cancer outcomes is attributable to hospital-based differences in patient characteristics or tumor factors.

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Table 1. Patient characteristics, presentation patterns and tumor factors among all patients in Nova Scotia who were diagnosed with rectal cancer from 01/07/2002-30/06/2006

Variable		
Age (years)		67 (27-96)
Sex (% Male)		65%
Charlson Comorbidity		1.8 (0-14)
BMI		28 (15-49)
Primary symptom at presentation	Bleeding	75%
	Change in bowel habit	35%
	Pain	16%
	Screening colonoscopy	7%
	Obstruction/Perforation	4%
Location of presentation	Family Physician	69%
	Specialty Clinic	22%
	Emergency Dept	9%
Tumor Height	Low	39%
	Mid	39%
	High	22%
Stage	I	26%
	II	23%
	III	30%
	IV	21%

Table 2. Characteristics of hospitals providing rectal cancer care in Nova Scotia, Canada from 01/07/2002-30/06/2006

Hospital	Hospital type	Cancer center	Catchment Population	Number of surgeons	Number of patients with rectal cancer	Percentage of patients undergoing radical surgery with curative intent (p=0.08)
1	Academic	Yes	275,000	12	242	76%
2	Community	No	120,000	4	64	86%
3	Community	No	85,000	7	48	88%
4	Community	No	62,000	3	46	80%
5	Community	No	60,000	4	53	72%
6	Community	No	73,000	3	28	77%
7	Community	No	48,000	4	28	61%
8	Community	No	47,000	3	25	68%
9	Community	Yes	130,000	7	118	68%
10	Community	No	33,000	4	25	67%

Table 3. Patient characteristics and tumor factors among all hospitals that provided rectal cancer care in Nova Scotia from from 01/07/2002-30/06/2006

Hospital	1 n=172	2 n=48	3 n=44	4 n=35	5 n=33	6 n=17	7 n=14	8 n=17	9 n=78	10 n=14	P value
Annual Hospital Volume (cases/year)	43	12	11	9	8	4	3	4	19	3	
Age (years)	64.1 (30.6-92.8)	64.6 (43.8-86.7)	66.2 (44.6-94.4)	70.0 (47.5-89.5)	70.0 (40.5-87.4)	66.9 (45.8-89.4)	65.1 (40.6-82.3)	69.0 (57.3-82.5)	67.6 (27.4-88.7)	71.9 (54.1-93.3)	P=0.04
Sex (% Male)	59.9%	68.7%	72.7%	60.0%	72.7%	52.9%	78.6%	76.5%	69.2%	57.1%	P=0.45
Charlson Comorbidity	1.4 (0-8)	1.6 (0-7)	1.4 (0-7)	2.6 (0-9)	1.61 (0-7)	1.4 (0-10)	1.9 (0-7)	2.8 (0-13)	1.7 (0-9)	1.3 (0-3)	P=0.11
BMI	27.7 (14.9-49.3)	27.9 (19.9-48.0)	29.2 (21.1-46.6)	28.0 (16.1-46.4)	27.7 (18.1-35.4)	29.2 (22.9-36.0)	26.6 (18.5-40.8)	30.6 (19.4-37.7)	28.9 (16.6-48.3)	28.3 (24.7-36.9)	P=0.47
Site of presentation (FD/Clinic/Emerg)	78/8/14	81/11/8	71/12/17	67/7/26	87/0/13	100/0/0	45/0/54	87/0/13	62/10/28	92/8/0	P=0.01
Tumor Height (Low/Mid/High)	40/43/17	27/40/33	50/41/9	40/40/20	33/42/24	24/35/41	50/43/7	41/41/18	36/34/30	54/23/23	P=0.57
Stage (I/II/III/IV)	29/29/35/7	31/29/29/10	39/19/35/7	32/31/31/6	19/23/55/3	12/35/47/6	50/29/21/0	38/19/37/6	27/28/36/9	77/23/0/0	P=0.21

Table 4. Comparison of patient characteristics and tumor factors among patients who received radical surgery with curative intent in academic vs community hospitals.

		Tertiary care academic center (n=1)	Community hospital (n=9)	p value
Number of patients		168	298	
Age		64.1 (30.6-92.8)	67.5 (27.4-94.4)	0.002
Sex (% Male)		60%	68%	0.06
Co-morbidity score		1.4 (0-8)	1.8 (0-13)	0.12
BMI		27.7 (14.9-49.3)	28.6 (16.1-48.3)	0.13
Location of presentation	Family physician	78%	76%	0.44
	Specialty clinic	8%	8%	
	Emergency Dept	14%	16%	
Tumor Height	Low	40%	37%	0.25
	Mid	42%	38%	
	High	18%	25%	
Stage (%)	I	29%	32%	0.89
	II	29%	26%	
	III	35%	35%	
	IV	7%	7%	

Table 5. Comparison of patient characteristics and tumor factors among patients who received elective radical surgery with curative intent in cancer center vs. non cancer center hospitals.

		Cancer Center (n=2)	Non Cancer Center (n=8)	p Value
Number of patients		246	220	
Age		65.1 (27.4-92.8)	67.5 (40.5-94.4)	0.03
Sex (% Male)		63%	68%	0.25
Charlson		1.5 (0-9)	1.8 (0-13)	0.21
BMI		28.1 (14.9-49.3)	28.4 (16.1-48.0)	0.48
Location of Presentation	Family Physician	75%	79%	0.53
	Specialty clinic	9%	6%	
	Emergency Dept	16%	15%	
Tumor Height	Low	38%	38%	0.46
	Mid	39%	39%	
	High	22%	22%	
Stage	I	29%	34%	0.61
	II	29%	26%	
	III	35%	34%	
	IV	75	6%	

Table 6. Comparison of pre-operative staging investigations among patients treated in academic vs community hospitals.

	Patients treated in an academic center (n=168)	Patients treated in a community hospital (n=298)	P value
Complete evaluation of the colon	84%	79%	p>0.05
Chest imaging	77%	50%	p<0.01
Liver/Pelvis Imaging	85%	75%	p=0.01
All three	62%	36%	p<0.01

Table 7. Comparison of pre-operative staging investigations among patients treated in cancer center vs. non cancer center hospitals

	Patients treated in a cancer center hospital (n=246)	Patients treated in a non-cancer center hospital (n=220)	P value
Complete evaluation of the colon	84%	77%	p>0.05
Chest imaging	68%	51%	p<0.01
Liver/Pelvis Imaging	83%	74%	p=0.02
All three	56%	33%	p<0.01

CHAPTER 5

A POPULATION-BASED ASSESSMENT OF RECTAL CANCER TREATMENT AND ONCOLOGIC OUTCOMES

Running header: Rectal cancer treatment and outcomes

Key words: Rectal cancer, Surgery, Recurrence, Survival

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Abstract

Purpose: Although evidence suggests that patients with rectal cancer who are treated in specialized hospitals or by high volume surgeons experience improved oncologic outcomes, it is less clear *how* treatment by these surgeons or in these hospitals leads to better outcomes. The goal of this study was, using population-based patient-level data, to describe oncologic outcomes after radical surgery for rectal cancer and examine hospital- or surgeon-associated differences in treatment. **Methods:** All patients with a new diagnosis of rectal cancer from 7/1/2002 to 6/30/2006 in Nova Scotia, Canada were included. Data were collected through a comprehensive, standardized review of hospital inpatient and outpatient medical records and cancer center charts and used *a priori* definitions of potential operative factors (TME, perforation, radial margins). Hospitals providing both medical oncology and radiation oncology services were defined as cancer centers (CC). **Results:** During the study period 466 patients with rectal cancer underwent radical surgery with curative intent (median follow-up 4.2 years). Care was provided in 10 hospitals by 51 surgeons; the only 2 CC hospitals treated 53% of patients. All high volume surgeons (median 12 cases/yr) worked in the CC hospitals whereas low volume surgeons worked in both the CC hospitals (median 1 case/yr) and non-cancer center (NCC) hospitals (median 1.5 cases/yr). Patients treated in NCC hospitals were significantly less likely to receive total mesorectal excision (TME), although no differences in other aspects of rectal cancer treatment were identified. After controlling for stage, use of TME and iatrogenic perforation at surgery, there was an increased risk of local recurrence among patients of NCC surgeons (HR 2.05, 95% CI 1.02-4.1), but not low volume CC surgeons (HR 1.68, 95% CI 0.73-3.85), compared to treatment by high volume CC surgeons. There was no association between hospital setting/surgeon volume and disease specific survival or overall survival. **Conclusion:** The improved outcomes associated with treatment of rectal cancer by high volume surgeons or specialized centers may be attributable, at least in part, to differences in surgical technique.

Introduction

The treatment of rectal cancer is technically demanding and is associated with higher rates of local recurrence and functional disturbances compared to the treatment of colon cancer. Previous studies have reported that surgeon and hospital factors are associated with variation in local recurrence rates,[1-6] disease specific[1,7] and overall survival.[1,3,7-10] Patients treated by high volume surgeons or in high volume hospitals experience lower local recurrence rates[1-6] and better disease-specific[1] and overall survival[1,3,8] compared to patients treated by low volume surgeons or in low volume hospitals. In addition, patients treated in hospitals designated as cancer centers have improved disease-specific[7] and overall survival[7,9,10] compared to patients treated in non-cancer center hospitals. While differences in treatment have been proposed to account for this variation in outcomes,[2,9,10] exactly *how* treatment by high volume surgeons, in high volume hospitals or in cancer center hospitals leads to improved outcomes in unclear. The purpose of this study was to describe oncologic outcomes after radical resection for rectal cancer using a population-based retrospective cohort and to determine if there were hospital or surgeon associated differences in treatment.

Methods

This was a retrospective cohort study of all patients in Nova Scotia, Canada with a newly diagnosed adenocarcinoma of the rectum from July 1, 2002 to June 30, 2006 who underwent radical surgery with curative intent. Patients were excluded if they were <18 years of age or if they underwent primary treatment for rectal cancer outside of the province. Patients were identified from the Nova Scotia Cancer Registry. This Registry has been in existence since 1964 and it is a legal requirement that all new confirmed cancer cases in Nova Scotia be reported to the registry. A comprehensive standardized review of hospital inpatient and outpatient medical records, cancer center charts and surgeon office charts was performed. Data were collected regarding patient demographics, co-morbidities, tumor height, stage, surgical treatment, pathology, post-operative complications, use of neoadjuvant and adjuvant therapies, surveillance investigations and long term outcomes.

Patient age was calculated as the age at the time of first presentation. Patient co-morbidities were compared using the Charlson co-morbidity index[11]. The TNM classification for staging rectal cancer was used (6th edition). Rectal tumor height was determined using documented findings of digital rectal examination, rigid and/or flexible endoscopy reports, operative reports and pathology reports. A low rectal tumor was defined as <6cm from the anal verge on endoscopy or involving the anal sphincter complex. A mid rectal tumor was defined as 6-12 cm from the anal verge, and a high rectal tumor was defined as >12 cm from the anal verge. Patients with rectosigmoid tumors were excluded. Locally invasive tumors were defined as T4 tumors on the pathology report or tumors that were noted to be adherent to adjacent structures by the surgeon at the time of surgery. Receipt of neo-adjuvant therapy was defined as administration of chemotherapy, radiation therapy or both prior to surgical resection for any duration.

Treatment outcomes included local recurrence, disease-specific survival and overall survival. Local recurrence was defined as histologically proven recurrence at the anastomosis, in the pelvis or on the perineum or clear radiologic evidence of recurrence.

Disease-specific survival involved the absence of death attributable to rectal cancer. Outcomes were analyzed across all hospitals providing rectal cancer care and according to surgeon volume (high volume vs. low volume) and hospital type (cancer center vs. non-cancer center). A cancer center (CC) was defined as a hospital that provided both medical oncology and radiation oncology services. Patients were divided into three groups based on surgeon volume and location of care; 1. treatment by high volume surgeons (median 12 cases/yr, range 9-14.5) who worked in a cancer center 2. treatment by low volume surgeons (median 1 case/yr, 0.25-4.25) who worked in a cancer center and 3. treatment by low volume surgeons (median 1.5 cases/yr 0.25-4.5) who worked in a non-cancer center. This categorization was based on the analysis of the data which demonstrated that there was a small group of high volume surgeons who all worked in cancer center hospitals.

To determine if there were differences in treatment among the hospitals providing rectal cancer care five factors were examined; the use of total mesorectal excision (TME), iatrogenic perforation of the rectum at surgery, positive radial margins, the rate of anastomotic leak and the use of adjuvant chemotherapy and radiation. The use of TME was determined from operative reports and based on dictated use of "TME" or "total mesorectal excision". Iatrogenic perforation of the rectum was defined as an inadvertent perforation of the bowel at the time of surgery that was documented either by the surgeon in the operative note or in the pathology report. Radial margin status was ascertained from the pathology report and a positive radial margin was defined as tumor <1 mm from the circumferential margin. Anastomotic leak was defined as any clinical finding consistent with a leak (pain, fever, ileus or leukocytosis) in association with a CT-confirmed abscess, extravasation at the time of contrast enema or confirmed leak at laparotomy. Receipt of adjuvant therapy was defined as post-operative chemotherapy, post-operative radiation therapy or both for any duration. These five treatment factors were compared among all hospitals that provided rectal cancer care and according to surgeon volume/ hospital setting.

Data were entered into a computerized database. Patient age and co-morbidities were transformed into categorical variables based on tertile distributions. T-tests were used to test the means between two groups and ANOVA analysis was used to test the means between multiple groups. Chi-square tests were used to test differences between proportions. If a 2 X 2 table contained a cell count of <5, Fisher's exact test was used. Kaplan-Meier survival curves were constructed using local recurrence, death from rectal cancer and death from all causes as end points. The log rank test was used to compare Kaplan-Meier curves for patients treated by the three different surgeon volume/hospital type groups. Univariate and multivariate Cox proportional hazards regression analysis was performed to determine which factors were associated with local recurrence, disease specific survival and overall survival. The explanatory variables were chosen *a priori* and included surgeon volume/hospital type, TNM stage, patient age, Charlson co-morbidity score, use of TME, iatrogenic perforation, local invasion, radial margin status, anastomotic leak, tumor height and use of sphincter preserving surgery. Separate multivariate models for local recurrence, disease-specific survival and overall survival were created using a forward selection approach with all explanatory variables, with entry into the model set at $p<0.10$. Given that Surgeon volume/ hospital type was the variable of interest, it was forced into all three models. The final model was chosen based on the set of variables that produced the best AIC score. The proportional hazards assumption was assessed by including time dependent covariates for each variable in the model. There were no models in which a time dependent covariate was significant. No significant interaction terms were identified. Statistical significance was set at $p<0.05$. Analyses were performed using SAS version 9.2 (SAS Institute Carey, NC).

Approval for this study was obtained from each hospital where rectal cancer care was provided in Nova Scotia.

Results

During the four-year study period 466 patients were diagnosed with rectal cancer and underwent elective radical surgery with curative intent (Table 1). The median duration of follow up was 4.2 years (range 0.008-7.63 years). There were no follow up data for three patients and 6% (27/466) were lost to follow-up within three years after surgery. Care was provided by 51 surgeons in 10 hospitals that included 2 cancer center hospitals (Table 2). The median annual surgeon case volume was 2, (range 0.25-14.5) and the median annual hospital volume was 8 (range 3-43). There were no differences in gender, BMI, co-morbidities, tumor height, stage distribution or duration of follow-up among the 10 hospitals that provided rectal cancer care (data not shown). There were differences in mean patient age among the 10 hospitals (range 64-72, $p=0.04$). Patients treated community hospitals were older compared to patients treated in the academic tertiary care referral hospital.

<u>Local Recurrence</u>

The five-year local recurrence rate among the entire cohort was 16%. There was significant variation in the local recurrence rate among the 10 hospitals providing rectal cancer care (Table 2). Patients treated by high volume surgeons in cancer center hospitals had a lower local recurrence rate compared to patients treated by low volume surgeons in non-cancer center hospitals (Figure 1). Factors found to be significantly associated with local recurrence on univariate analysis included treatment in a non cancer center hospital, stage, TME, iatrogenic perforation of bowel at the time of surgery, local invasion and positive radial margin (Table 3). On multivariate analysis, independent risk factors for local recurrence included treatment by a low volume surgeon in non cancer center hospital, increasing tumor stage and iatrogenic perforation of the bowel during surgery (Table 4).

Disease Specific Survival

The five-year disease specific survival among the entire cohort was 75%. There was no difference in disease specific survival among the 10 hospitals that provided rectal cancer care (Table 1) or according to surgeon volume/ hospital setting (Figure 2). Factors found to be significantly associated with disease specific survival on univariate analysis included stage, iatrogenic perforation of bowel at the time of surgery, local invasion and positive radial margin (Table 3). On multivariate analysis surgeon volume hospital setting/ was not an independent predictor of disease specific survival (Table 5).

Overall Survival

The five-year overall survival among the entire cohort was 64%. There was no difference in overall survival among the 10 hospitals that provided rectal cancer care (Table 2) or according to surgeon volume/ hospital setting (Figure 3). Factors found to be significantly associated with overall survival on univariate analysis included age, charlson co-morbidity score, stage, iatrogenic perforation of bowel at the time of surgery, local invasion and sphincter preserving surgery (Table 3). There was not an independent association between overall survival and hospital setting/surgeon volume (Table 6).

Treatment factors were examined for all patients who received rectal cancer care (Table 7). Fifty two percent of patients underwent a restorative procedure and 10% experienced an anastomotic leak. Only 17% (79/466) of patients received neo-adjuvant treatment. After excluding these patients, 84% (272/323) of patients treated with curative intent with Stage II/III/IV disease on pathology were referred for adjuvant therapy and 65% (210/323) of patients actually received adjuvant therapy. There were significant differences in the use of TME and the rate of anastomotic leak among the 10 hospitals where rectal cancer care was provided (Table 2).

Fifty-three percent of patients (247/466) were treated in a hospital associated with a cancer center and 47% (219/466) of patients were treated in non-cancer hospitals. There were no differences in patient age, co-morbidities, BMI, tumor height, tumor stage or duration of follow-up regardless of surgeon volume/ hospital type (Table 8). Patients who were treated by low volume surgeons in non-cancer center hospitals were significantly less likely to receive TME. There were no differences in iatrogenic perforation of the rectum, positive radial margins, anastomotic leak or use of adjuvant therapy according to surgeon volume hospital type (Table 9). Patients who were treated at a cancer center hospital were significantly more likely to have neo-adjuvant treatment than patients treated elsewhere 72/174 vs. 7/213 ($p<0.01$).

Discussion

Numerous studies have reported that patients with rectal cancer experience better oncologic outcomes if they are treated by high volume surgeons, in high volume hospitals or in specialized cancer centers[1-10]. These factors may be surrogate markers for better pre-operative, intra-operative or post-operative treatment including meticulous surgical technique, appropriate use if neoadjuvant/ adjuvant therapies, case review by multidisciplinary tumor boards, emphasis on quality assurance or some other aspect of rectal cancer care. Determining which aspects of care are responsible for the observed variation in outcomes may help guide quality improvement and quality assurance initiatives.

The present study was a comprehensive population-based assessment of rectal cancer treatment using patient level data in a Canadian Province The overall 5-year local recurrence rate in the cohort was 16%. This is high compared to previous population-based studies from Europe that have reported rates of 5-10%[6,12,13] but is in keeping with a contemporary population- based study from another Canadian province which found a 5 year local recurrence rate of 17%[4]. The Dutch TME study demonstrated that with standardized surgical technique, 5-year local recurrence rates of 11% with surgery alone and 4.6% with surgery and adjuvant therapy could be acheived[14]. Only 1/10 hospitals that provided rectal cancer care in the present study achieved a local recurrence rate of <10% and half of the hospitals had local recurrence rates >20%.

The variation observed in local recurrence did not appear to be due to differences in patient or tumor characteristics among patients treated at the 10 hospitals. The ability to assess and control for these factors on a population level was a strength of this study. To determine if differences in treatment explained the variation in local recurrence rates, five separate treatment factors were compared among the 10 hospitals including: the use of TME at surgery, perforation of the rectum during surgery, positive radial margins, anastomotic leak and the use of adjuvant therapy. These factors have been associated with local recurrence, disease specific and overall survival after treatment of rectal cancer[1,3,5,6,13,15-17]. There were significant differences in the reported use of TME at surgery (18-91%) and anastomotic leak (0-50%) across the 10 hospitals that provided rectal cancer care. Although the variation in iatrogenic perforation of the rectum during surgery (0-18%) and positive radial margins (0-20%) across the 10 hospitals did not reach statistical significance, differences in these factors may be important. Taken together these data suggest that differences in surgical technique may account for the some of the variation observed in local recurrence rates.

A comparison of local recurrence rates and treatment factors was also performed according to surgeon volume and hospital type (cancer center vs. non cancer center). Patient and tumor characteristics were similar among these treatment groups. Patients who were treated by high volume surgeons in cancer center hospitals had a lower local recurrence rate (9%) compared to patients who were treated by low volume surgeons in non cancer center hospitals (20%). It should be noted that all of the high volume surgeons worked in the cancer center hospitals which were also the high volume hospitals. The local recurrence rate was 16% in patients who were treated by low volume surgeons in the cancer center hospitals suggesting that surgeon volume may be more important than hospital volume or hospital type in predicting local recurrence. This has been suggested by others[3]. Surgeon volume may be a surrogate marker for good surgical technique. The use of TME was reported by 87% of the high volume surgeons who worked in the cancer center hospitals compared to 67% and 48% for the low volume surgeons who worked in the cancer centers and non-cancer center hospitals respectively.

The importance of TME in the management of rectal cancer has been well established for more than a decade[18]. Despite this, the present study suggests that many patients with rectal cancer still do not receive a TME. Improving access to appropriate surgical care may improve patient outcomes. A program in British Columbia, Canada to standardize surgical technique with TME reported an improvement in 2-year local recurrence rates from 18% to 9% among patients with stage III rectal cancer[19]. In contrast, a cluster-randomized trial in Ontario, Canada which randomized hospitals to an intervention that integrated the use of workshops, opinion leaders, intra-operative demonstrations, postoperative questionnaires, audit and feedback[20] failed to show an improvement in local recurrence rates. However, the hospitals that participated in the trial were relatively high volume and the effect of this type of intervention on low volume hospitals is unknown

The rates of referral and receipt of adjuvant therapy for patients with stage II, III and IV disease was similar across the 10 hospitals that provided rectal cancer care. Compared to previous studies, the proportion of patients who received neoadjuvant therapy in the present study was relatively low (17%). This likely reflects the study time period and current use of neoadjuvant therapy is much more widespread throughout the province. Not surprisingly, patients who were treated in cancer center hospitals were more likely to receive neoadjuvant therapy than those patients who were treated in non cancer center hospitals. Neoadjuvant therapy has been associated with a decrease in local recurrence after treatment of rectal cancer[21]. The extent to which local recurrence rates in the cancer center hospitals were influenced by the use of neoadjuvant therapy is unclear.

Multivariate analysis was used to examine which factors were associated with local recurrence, disease specific and overall survival. In keeping with previous studies there was an association between poor oncologic outcomes and treatment by low volume surgeons and non cancer center hospitals. The use of TME trended towards being an independent predictor of local recurrence but it did not reach statistical significance. The impact of TME on rectal cancer outcomes is well established[6,16] and the lack of association observed in the present study likely reflects the sample size and limitations associated with retrospective methodology. Iatrogenic perforation of the rectum at surgery was associated with local recurrence, disease specific and overall survival. In keeping with previous studies[1,5,6,13], this is an intra-operative event that carries a very poor prognosis.

In the present study many patients received rectal cancer care by very low volume surgeons and hospitals. The median annual surgeon procedure volume was 2 cases. It may not be appropriate for surgeons to care patients with rectal cancer if they only treat one or two patients or fewer each year. However, some of these low volume surgeons and hospitals delivered care with acceptable outcomes equivalent to or better than the high volume surgeons and high volume hospitals. These issues need to be considered in the context of strategies to improve rectal cancer care. Any hospital that provides rectal cancer care should be able to meet a minimum standard of care and monitor outcomes on a prospective basis for quality assurance. One option is to limit who can perform rectal cancer surgery and regionalize services as has been done in many European countries[22,23]. Such decisions have implications for patients who may end up traveling considerable distances to receive care particularly in North America where geography may be more of a challenge. Alternatively, rectal cancer care could be provided in low volume centers by having one or two surgeons designated to provide rectal cancer care to establish expertise and maintain volume as opposed to having four or five surgeons performing infrequent operations. Ultimately, decisions regarding the delivery of rectal cancer care should be based on objective assessments of surgical technique and oncologic outcomes as opposed to surgeon or hospital procedure volume.

There are several limitations associated with this research. This was a retrospective study that relied on the availability and accuracy of medical records. Missing data are an inherent limitation of this type of research. Data quality and capture was excellent for most data fields. However, surgeons may have performed TME during surgery but did not record this in the operative note. Furthermore there were no data available regarding the quality of the TME specimen. Only 50% of pathology reports commented on radial margins. Thus the true rate of positive radial margins may have been different. Some patients were lost to follow up and therefore local recurrence, disease-specific survival and overall survival may not be accurate. For the purposes of statistical analysis the unit of measurement was the patient, however clustering naturally occurred in the dataset. Despite this, each patient was treated as an independent observation for statistical simplicity. Among the 51 surgeons, four clearly stood apart based on their procedure volume (median 12 cases/yr, range 9-14.5) and were defined as high volume surgeons. While this was an arbitrary decision it was consistent with all of the volume-outcome studies in the literature which use different volume thresholds. There is no consensus on what defines a high volume surgeon or a high volume hospital. Most previous studies have based volume thresholds on statistical considerations to create equivalent groups for comparison. The definition of a cancer center used in the present study is consistent with the Canadian model of care in which medical and radiation oncology services are not available in all hospitals. This may limit the generalizability of these findings to other areas.

Conclusions

In this population based study of rectal cancer, there was significant variation in the use of TME and rate of local recurrence among all hospitals that provided surgical care and according to surgeon volume / hospital type. Patients who were treated by high volume surgeons in cancer center hospitals were more likely to undergo a TME and less likely to experience a local recurrence compared to patients treated by low volume surgeons in non cancer center hospitals. The improved outcomes associated with treatment of rectal cancer by high volume surgeons or specialized centers may be attributable, at least in part, to differences in surgical technique.

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Table 1. Patient characterictics and tumor factors among all patients with rectal cancer who underwent radical surgery with curative intent in Nova Scotia from 07/01/2002 to 06/30/2006.

Variable		
Mean Age (range)		66 (27-94)
Sex (% male)		65%
Mean BMI (range)		28 (15-49)
Mean Charlson Comorbidity Score (range)		1.6 (0-13)
Tumor Height	Low	39%
	Mid	39%
	High	22%
Stage	I	31%
	II	27%
	III	35%
	IV	7%

Table 2. Comparison of treatment factors for rectal cancer care and oncologic outcomes among patients with rectal cancer who underwent elective radical surgery with curative intent across the ten hospitals that provided rectal cancer care in Nova Scotia.

Hospital	1	2	3	4	5	6	7	8	9	10	P value
Total number of patients	168	44	34	14	17	14	17	78	48	32	
Annual procedure volume	42	11	8	3	4	3	4	19	12	8	
Cancer center	Y	N	N	N	N	N	N	Y	N	N	
% of patients who received a TME	91%	59%	57%	64%	18%	29%	18%	55%	50%	58%	P<0.01
Positive radial margin	6%	2%	3%	0%	6%	7%	20%	4%	0%	9%	P=0.16
Anastomotic leak	8%	27%	0%	0%	0%	0%	50%	3%	29%	13%	P<0.01
Iatrogenic perforation	10%	7%	9%	0%	18%	0%	18%	12%	2%	3%	P=0.25
% stage II/II/IV patients referred for adjuvant therapy	83%	81%	74%	50%	100%	100%	82%	82%	94%	85%	P=0.20
% stage II/III/IV patients who received adjuvant therapy	67%	56%	48%	0%	80%	86%	82%	67%	64%	67%	P=0.07
5 year Local recurrence	12%	15%	23%	7%	23%	31%	29%	12%	15%	33%	P=0.02
5 year disease-specific survival	72%	76%	76%	84%	74%	92%	79%	75%	74%	74%	P=0.91
5 year overall survival	64%	66%	61%	84%	68%	69%	59%	58%	70%	61%	P=0.46

TME = total mesorectal dissection

Table 3. Univariate associations for local recurrence, disease specific survival and overall survival using Cox proportional hazards

Variable		Local Recurrence HR (95% CI)	Disease Specific Survival HR (95% CI)	Overall Survival HR (95% CI)
Surgeon volume/hospital setting	HVCC	1.0	1.0	1.0
	LVCC	1.82 (0.79-4.22)	1.38 (0.78-2.45)	1.24 (0.77-2.00)
	NCC	2.31 (1.20-4.45)	1.17 (0.73-1.88)	1.12 (0.76-1.64)
Stage	I	1.0	1.0	1.0
	II	1.89 (0.82-4.37)	4.30 (1.57-11.67)	1.81 (1.04-3.16)
	III	3.16 (1.50-6.65)	9.48 (3.76-23.88)	2.90 (1.76-4.76)
	IV	2.87 (0.89-9.35)	35.67 (13.43-94.74)	8.64 (4.81-15.50)
Age	<62	1.0	1.0	1.0
	62-71	0.57 (0.27-1.24)	1.00 (0.57-1.76)	1.19 (0.72-1.95)
	>71	1.30 (0.74-2.29)	1.84 (1.15-2.94)	2.93 (1.97-4.36)
Charlson co-morbidity Score	0-1	1.0	1.0	1.0
	2	1.55 (0.84-2.85)	1.08 (0.63-1.84)	1.33 (0.85-2.10)
	3	1.01 (0.48-2.11)	1.37 (0.80-2.33)	2.74 (1.88-3.98)
TME	Yes	1.0	1.0	1.0
	Not Stated	2.19 (1.30-3.68)	1.11 (0.73-1.68)	1.16 (0.83-1.63)
Iatrogenic Perforation	No	1.0	1.0	1.0
	Yes	2.71 (1.32-5.53)	2.83 (1.63-4.94)	2.79 (1.77-4.14)
Local Invasion of tumor	No	1.0	1.0	1.0
	Yes	2.71 (1.16-6.32)	3.13 (1.62-6.05)	2.43 (1.34-4.39)
Radial Margin	Negative	1.0	1.0	1.0
	Positive	2.43 (1.00-5.94)	2.34 (1.15-4.73)	1.81 (0.95-3.47)
	Not stated	0.93 (0.54-1.62)	0.94 (0.61-1.45)	0.96 (0.68-1.37)
Anastomotic Leak	N	1.0	1.0	1.0
	Y	0.94 (0.28-3.10)	1.06 (0.45-2.49)	0.89 (0.43-1.85)
Tumor Height	High	1.0	1.0	1.0
	Low	0.94 (0.46-1.93)	0.82 (0.48-1.40)	1.05 (0.67-1.63)
	Mid	1.08 (0.54-2.16)	0.85 (0.50-1.42)	0.90 (0.58-1.39)
Sphincter Preserving surgery	No	1.0	1.0	1.0
	Yes	1.00 (0.60-1.69)	0.70 (0.46-1.05)	0.64 (0.45-0.89)

TME = Total mesorectal excision

Table 4. Multivariate Cox Proportional hazards regression model for local recurrence

Variable		Hazard Ratio (95% CI)
Surgeon volume/ hospital setting	HVCC	1.0
	LVCC	1.68 (0.73-3.85)
	LVNon-CC	2.05 (1.02 – 4.12)
Stage	I	1.0
	II	1.88 (0.81-4.36)
	III	3.14 (1.48-6.67)
	IV	2.76 (0.84-9.02)
TME	Yes	1.0
	Not Stated	1.63 (0.94-2.83)
Iatrogenic perforation	No	1.0
	Yes	2.20 (1.06-4.59)

HVCC = high volume surgeon practicing in a cancer center; LVCC = low volume surgeons practicing in a cancer center; LVNon-CC = low volume surgeons practicing in a non-cancer center; TME = Total mesorectal excision

Table 5. Multivariate Cox proportional hazards regression model for disease specific survival

Variable		Hazard Ratio (95% CI)
Surgeon volume/hospital setting	HVCC	1.0
	LVCC	1.22 (0.68-2.19)
	LVNon-CC	1.38 (0.86-2.23)
Stage	I	1.0
	II	4.10 (1.67-14.84)
	III	10.79 (3.86-30.14))
	IV	43.04 (14.67-126.27)
Iatrogenic perforation	No	1.0
	Yes	2.10 (1.15-3.81)
Local Invasion of tumor	No	1.0
	Yes	2.16 (1.05-4.43)

HVCC = high volume surgeon practicing in a cancer center; LVCC = low volume surgeons practicing in a cancer center; LVNon-CC = low volume surgeons practicing in a non-cancer center;TME = Total mesorectal excision

Table 6. Multivariate Cox proportional hazards regression model for overall survival

Variable		Hazard Ratio (95% CI)
Surgeon volume/hospital setting	HVCC	1.0
	LVCC	1.15 (0.71-1.87)
	LVNon-CC	1.08 (0.73-1.60)
Stage	I	1.0
	II	2.00 (1.13-3.54)
	III	2.83 (1.69-4.73)
	IV	11.18 (6.08-20.52)
Age	<62	1.0
	62-71	1.11 (0.69-1.78)
	>71	2.66 (1.79-3.94)
Charlson	0-1	1.0
Co-morbidity	2	1.10 (0.69-1.77)
Score	3	2.59 (1.75-3.83)
Iatrogenic Perforation	No	1.0
	Yes	2.61 (1.60-4.26)

HVCC = high volume surgeon practicing in a cancer center; LVCC = low volume surgeons practicing in a cancer center; LVNon-CC = low volume surgeons practicing in a non-cancer center;TME = Total mesorectal excision

Table 7. Treatment factors and oncologic outcomes among patients with rectal cancer who underwent radical surgery with curative intent.

Treatment factor and Outcomes	
% of patients who received a TME	65%
Positive Radial Margin	5%
Anastomotic Leak	10%
Iatrogenic Perforation during surgery	9%
% stage II/III/IV patients referred for adjuvant therapy	84%
% stage II/III/IV patients who received adjuvant therapy	65%
5 year local recurrence	16%
5 year disease specific survival	75%
5 year overall survival	64%

TME = Total mesorectal excision

Table 8. Comparison of patient and tumor characteristics across surgeon volume/hospital type.

		High volume surgeons cancer center	Low volume surgeon cancer center	Low volume surgeon Non cancer center	p value
Number of patients		167	80	219	
Mean age (range)		65.0 (27-91)	65.0 (41-93)	67 (40-94)	P=0.07
Sex (% male)		66%	56%	68%	P=0.18
BMI		27.9 (16-49)	28.3 (15-48)	28.4 (16-48)	P=0.76
Charlson Co-morbidity Score		1.7 (0-9)	1.3 (0-8)	1.8 (0-13)	P=0.21
Tumor height	Low	39%	37%	39%	
	Mid	42%	37%	39%	P=0.18
	High	19%	26%	22%	
Stage	I	29%	28%	34%	
	II	29%	28%	26%	P=0.76
	III	35%	34%	35%	
	IV	7%	10%	5%	

Table 9. Comparison of treatment factors for rectal cancer care and oncologic outcomes across hospital setting/surgeon volume

	High volume surgeon cancer center	Low volume surgeon cancer center	Low volume surgeon Non cancer center	p value
Anastomotic Leak	8%	0%	14%	p=0.07
TME	87%	67%	48%	p<0.01
Iatrogenic Perforation	10%	11%	6%	p=0.11
Positive radial Margin	5%	8%	5%	p=0.15
% stage II/III/IV Referred for Adjuvant therapy	86%	78%	86%	p=0.31
% stage II/III/IV who Received Adjuvant	71%	59%	62%	p=0.16
5 year Local Recurrence	9%	16%	20%	p=0.02
5 year Disease specific survival	75%	70%	77%	p=0.47
5 year Overall survival	65%	60%	66%	p=0.62

Figure 1. Kaplan-Meier survival curve for local recurrence by surgeon volume/hospital type

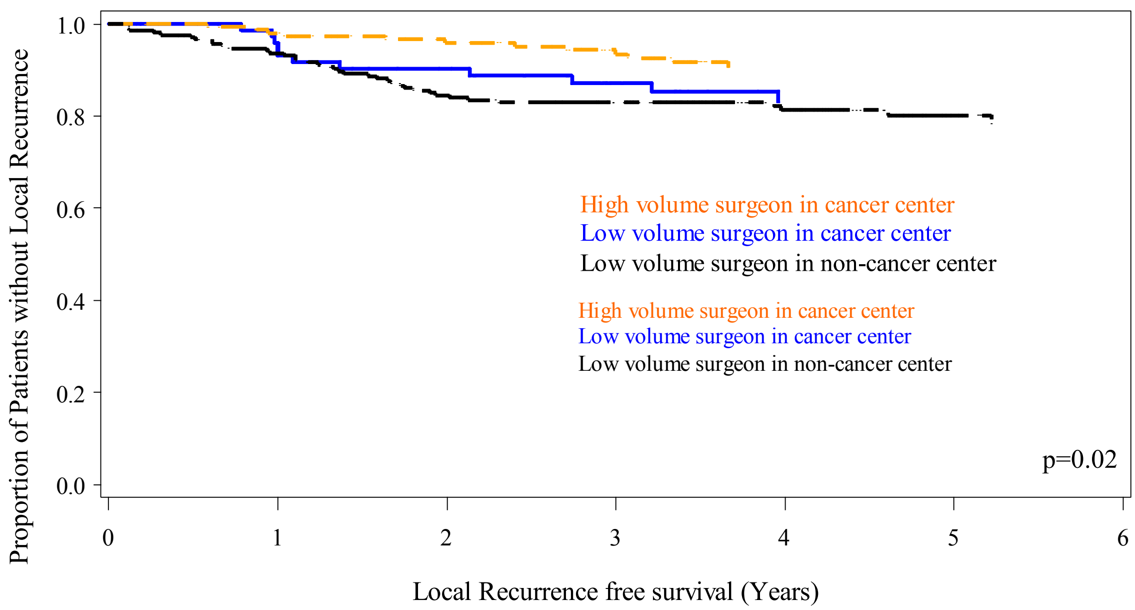


Figure 2. Kaplan-Meier survival curve for disease specific survival by surgeon volume/hospital type

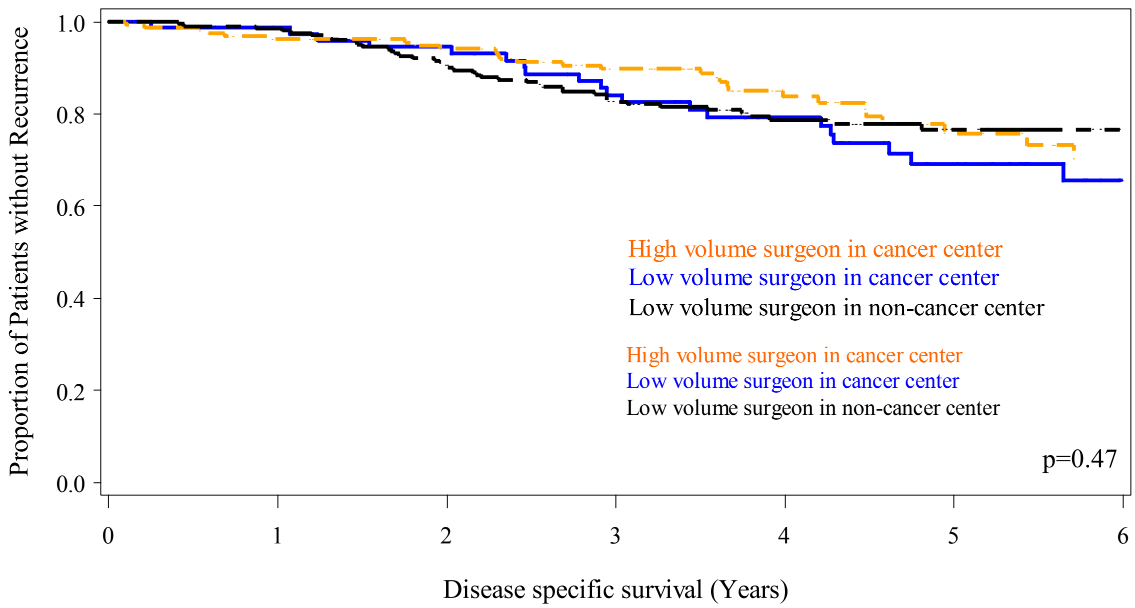
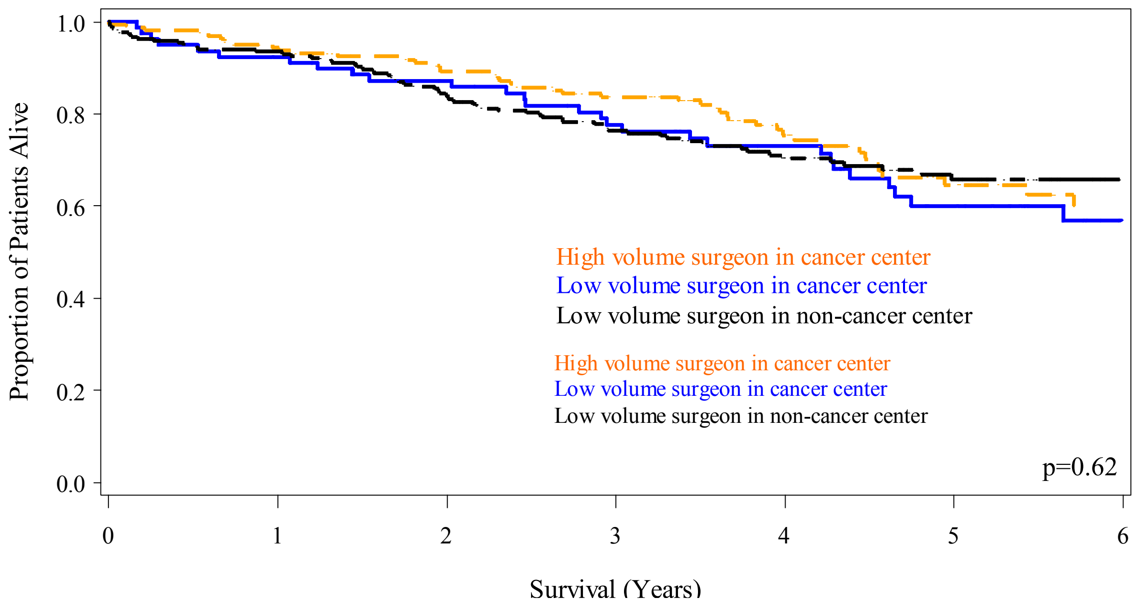


Figure 3. Kaplan-Meier curve for overall survival by surgeon volume/hospital type



CHAPTER 6

VARIATION IN THE RATE OF PERMANENT COLOSTOMY AMONG HOSPITALS PROVIDING RECTAL CANCER CARE IN A CANADIAN PROVINCE: HOW MUCH IMPROVEMENT IS POSSIBLE?

Running header: Permanent colostomy rates

Key words: Rectal cancer, surgery, colostomy

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This manuscript is in preparation for submission

Abstract

Purpose:. Variation in the rates of permanent colostomy use in patients with rectal cancer has been reported. It is not clear if this variation is due to differences in patient and tumor factors or variation in surgical ability leading to unnecessary colostomy use in some patients. The objectives of this study, using population level data, were to determine if there was variation in permanent colostomy rates among all hospitals providing rectal cancer care, identify the factors associated with creation of a permanent colostomy and quantify potential for decreasing the use of permanent stomas.

Methods**:** All patients with a new diagnosis of rectal cancer from 7/1/2002 to 6/30/2006 in Nova Scotia, Canada who underwent curative radical surgery were included. Data were collected through a comprehensive, standardized review of hospital inpatient and outpatient medical records and cancer center charts. Patients who underwent an abdominoperineal resection or an anterior resection with end colostomy were defined as having a permanent colostomy. Patients were categorized as having an appropriate or inappropriate colostomy based on patient, tumor, operative and pathologic criteria. Colostomy rates, patient characteristics and tumors factors were compared among hospitals providing rectal cancer care. Logistic regression analysis was used to identify factors associated with receiving a permanent colostomy.

Results: During the study period 466 patients with rectal cancer underwent radical surgery with curative intent (median follow-up 4.2 years). Care was provided in 10 hospitals and the overall permanent colostomy rate was 48%. There was significant variation in the permanent colostomy rate among the 10 hospitals (27-88%). Factors associated with a permanent colostomy on multivariate analysis included sex, tumor height, stage, treatment in a low or medium volume hospital, treatment by a low volume surgeon and treatment in a cancer center. Twenty nine percent of patients who received a permanent colostomy were defined as having an inappropriate stoma.

Conclusions: There was significant variation in the rate of permanent colostomy use among hospitals providing rectal cancer care. These data suggest that creation of a colostomy was not always appropriate and that there may be potential to decrease the rate of permanent colostomy use by 29%.

Introduction

The treatment of rectal cancer may involve the creation of a permanent colostomy and this can have a significant impact on patient quality of life[1]. There is variation reported in the permanent colostomy rate among hospitals providing rectal cancer care in North America[2-4]. A recent study reported that 60% of patients with rectal cancer in the United States receive a permanent colostomy[4]. Overall, the permanent colostomy rates in North America are higher compared to those reported by investigators on other continents[5-7]. The reason for this discrepancy is unclear. The need for a permanent colostomy should be primarily based on tumor factors and patient characteristics. However, variation in colostomy rates according to surgeon[2,5] and hospital[3,8,9] procedure volume has been reported suggesting that some patients may receive a permanent stoma unnecessarily. The primary objective of this study was to examine the variation in permanent colostomy rates among all hospitals providing rectal cancer care in a Canadian province and to determine if the observed variation was due to patient, tumor or treatment factors. The secondary objective was to perform a comprehensive assessment of indications for creation of a permanent colostomy among patients with rectal cancer and determine the extent of inappropriate stoma use.

Methods

All patients with a new diagnosis of adenocarcinoma of the rectum from July 1, 2002 to June 30, 2006 in Nova Scotia, Canada were identified. Patients who underwent elective radical surgery with curative intent were included in this retrospective cohort study. Patients were excluded if they were <18 years of age or if they underwent primary treatment for rectal cancer outside of the province. Patients were identified from the Nova Scotia Cancer Registry. This Registry has been in existence since 1964 and it is a legal requirement that all new confirmed cancer cases in Nova Scotia be reported to the registry. A comprehensive standardized review of hospital inpatient and outpatient medical records, cancer centre charts and surgeon office charts was performed. Data were collected regarding patient demographics, co-morbidities, tumor height, stage, surgical treatment, post-operative complications, use of neoadjuvant and adjuvant therapies, surveillance investigations and long term outcomes.

Patient age was calculated based on the date of presentation. Patient co-morbidities were compared using the Charlson co-morbidity index[10]. The TNM classification for staging rectal cancer was used (6th edition). Rectal tumor height was determined using documented findings of digital rectal examination, rigid and/or flexible endoscopy reports, operative reports and pathology reports. A low rectal tumor was defined as being <6cm from the anal verge on endoscopy or involving the anal sphincter complex. A mid rectal tumor was defined as 6-12 cm from the anal verge, and a high rectal tumor was defined as >12 cm from the anal verge. Patients with rectosigmoid tumors were excluded. Patients who underwent an abdominoerineal resection (APR) or an anterior resection with end colostomy (Hartmann procedure) were defined as having a permanent colostomy. Patients who underwent a low anterior resection (+/- loop ileostomy) were defined as having a sphincter preserving surgery.

Patients who received a permanent colostomy were separated into two groups according to whether or not the creation of a permanent colostomy was appropriate. A colostomy was defined as appropriate if (1) there was documentation that the tumor invaded the anal sphincter based on rectal examination, or pathology report ; or (2) the tumor was <6cm of the anal skin on the pathology report. Patients who received a colostomy due to technical problems during surgery according to the operative note (inability to get below the tumor, stapler malfunction or inability to obtain a tension free anastomosis), pre-existing incontinence, patient immobility, patient preference or advanced age (as defined by the operating surgeon, regardless of tumor height) were also included in the appropriate colostomy group. A colostomy was defined as inappropriate if (1) the tumor did not invade the anal sphincter based on rectal examination or the pathology report, (2) the tumor was >6cm from the anal skin on the pathology report or (3) there was no documented reason in the medical record or operative note for creating a colostomy.

Patient demographics, tumor characteristics and permanent colostomy rates were compared across all hospitals that provided rectal cancer care. The rate of permanent colostomy and appropriate/ inappropriate use of permanent colostomy was analyzed according to surgeon volume, hospital volume and hospital type (cancer center vs. non-cancer center). A cancer center was defined as a hospital that provided both medical oncology and radiation oncology services. Hospital volume was defined as high (mean 42 cases/year), medium (mean 15 cases/year, range 12-19) or low (mean 6 cases/year, range 2-11) based on the tercile distribution. Surgeon volume was defined as high volume (mean 12 cases/year, range 9-14.5) and low volume (mean 1.5 cases/year, range0.25-4.5). Based on analysis of the data, a small group of surgeons who performed ≥9 procedures/ year were arbitrarily defined as high volume surgeons their procedure volume was well above the median surgeon procedures volume of 2 cases/year.

Data were entered into a computerized database. Patient age and co-morbidities were transformed into categorical variables based on terciles. Body mass index was classified as normal (<25), overweight (25-30) or obese (>30). T-tests were used to test the means between two groups and ANOVA analysis was used to test the means between multiple groups. Chi-square tests were used to test differences between proportions. If a 2 X 2 table contained a cell count of <5, Fisher's exact test was used. Univariate and multivariate logistic regression was performed to determine which factors were associated with receiving a permanent colostomy. The explanatory variables were selected *a priori* and included hospital volume, surgeon volume, cancer center designation, age, co-morbidities, BMI, sex, tumor height, stage and receipt of neo-adjuvant therapy. Separate models for surgeon volume, hospital volume and cancer center designation were created using a forward selection approach with all explanatory variables, with entry into the model set at p<0.10. No significant interaction terms were identified. Univariate and multivariate regression were also used to determine which factors were associated with receiving an inappropriate permanent colostomy. The explanatory variables were selected *a priori* and included hospital volume, surgeon volume, cancer center designation, age, co-morbidities, BMI, sex, stage and receipt of neo-adjuvant therapy. Tumor height was not included as a potential variable because it was used to assign patients to the appropriate/ inappropriate colostomy groups. Separate models for surgeon volume, hospital volume and cancer center designation were created using a forward selection approach with all explanatory variables, with entry into the model set at p<0.10. No significant interaction terms were identified.

Statistical significance was set at p<0.05. Analyses were performed using SAS version 9.2 (SAS Institute Carey, NC). Approval for this study was obtained from each hospital where rectal cancer care was provided in Nova Scotia.

Results

During the four-year study period 466 patients underwent elective radical surgery with curative intent (Table 1). Treatment was provided in 10 hospitals by 51 surgeons. The average age of patients in the cohort was 66 (range 27-94) and 65% of patients were male. The mean BMI and Charlson co-morbidity index were 28 (range 15-49) and 1.6 (0-13), respectively. Twenty-two percent of patients had a high rectal tumor, 39% had a mid rectal tumor and 39% had a low rectal tumor. The stage distribution of patients in the cohort was: 31% Stage I, 27% Stage II, 35% Stage III, 7% Stage IV. There were no differences in co-morbidities, BMI, tumor height or tumor stage among patients treated in each of the 10 hospitals (Table 2). There was significant variation in mean patient age across the 10 hospitals (range 64-72 years).

The overall permanent colostomy rate was 48% (224/466). There was significant variation in the permanent colostomy rate among the 10 hospitals providing rectal cancer care ranging from 27% to 88% (Table 2.). Forty nine percent of patients had a clear reason for creation of a permanent colostomy documented by the surgeon in the medical record. There was no recorded reason for creation of a permanent colostomy in 51% of cases. The rates of permanent colostomy use were similar between high and low volume surgeons, cancer center and non-cancer center hospitals and among high, medium and low volume hospitals (Table 3). However, on multivariate analysis, after controlling for sex, tumor height and stage, patients were more likely to receive a permanent colostomy if they were treated in a low or medium volume hospital, by a low volume surgeon or in a non-cancer center hospital (Table 4).

Based on the study criteria defining appropriate and inappropriate creation of a colostomy, 71% (160/224) of the patients who received a stoma in this study had an appropriate colostomy. Invasion of the sphincter was present in 43% (68/160) of patients, 45% (72/160) of patients had a tumor <6cm from the anal skin without sphincter invasion and 12% (20/160) of patients had another appropriate indication for creation of a permanent colostomy. Patients who received appropriate and inappropriate permanent colostomies were similar in terms of age, co-morbidities and gender (Table 5).

There was significant variation in the proportion of patients who received an appropriate/ inappropriate colostomy according to annual hospital procedure volume , surgeon procedure volume and hospital type (cancer center vs. non cancer center) (Table 6). Univariate and multivariate analysis were performed to determine which factors were associated with receiving an inappropriate colostomy (Table 7). After controlling for sex, patients were more likely to receive an inappropriate colostomy if they were treated in a low or medium volume hospital, by a low volume surgeon or in a non-cancer center hospital.

Discussion

With advances in surgical technique, improved stapling devices and better knowledge of required oncologic margins, the role of abdominoperineal resection in the management of rectal cancer has substantially decreased. However, despite these advances, significant variation in the permanent colostomy rate after treatment of rectal cancer persists. Population-based studies of rectal cancer have reported that the permanent colostomy rate in North America ranges from 50-60%[3,4,11,12]. In contrast, only 23-33%[5-7] of patients in Europe and Australia received a permanent colostomy. It is not clear if this variation reflects differences in patient, tumor or treatment factors among patients in these different setting. If differences in treatment are responsible, then there may be an opportunity to decrease the permanent colostomy rate among rectal cancer patients in North America. Variation in treatment could result from differences in surgical skill. Surgeon volume[2,5], hospital volume[3,8,9] and surgeon training[6,13] have all been associated with colostomy rates suggesting that there may be differences in surgeon technical ability to perform a sphincter preserving operation. Decisions to create or avoid a permanent colostomy may also reflect differences in surgeon acceptance of short distal margins or opinions regarding functional outcomes after ultra-low anastomosis[14].

The permanent colostomy rate in the present population-based study was 48%, in keeping with previous North American population-based research[3,4,11,12]. While there was significant variation in the rate of permanent colostomy across the 10 hospitals that provided rectal cancer care this did not appear to be due to differences in patient sex, BMI, co-morbidities, tumor height or stage. The ability to assess and control for these factors is a strength of this study. There was variation in mean patient age among hospitals providing rectal cancer care. The extent to which this contributed to differences in colostomy rates is unclear. On multivariate analysis patient sex, tumor height and stage were found to be independent predictors for a permanent colostomy consistent with previous findings[3-5,7,14]. Treatment factors including surgeon volume, hospital volume and hospital type (cancer center vs. non cancer center) were also associated with the creation of a permanent colostomy. Although the association between creation of permanent colostomy and surgical subspecialty training was not examined in the current study, ¾ of the high volume surgeons had colorectal/surgical oncology subspecialty training compared to 2/47 of the low volume surgeons. . The results of this study suggest that variation in treatment, as opposed to variation in patient or tumor factors, was responsible for the discrepancy observed in the rate of permanent colostomy use.

The indications for a permanent colostomy were examined for each patient. Patients were categorized into two groups according to whether or not the colostomy was appropriate or inappropriate. This differentiation was largely based on the recorded distal resection margin in the pathology report. Sigmoid and rectum specimens have previously been studied to determine the amount of organ shrinkage that occurs after surgical removal and fixation in formalin[15]. On average the specimens shrank 57%[15] and the authors concluded that a correction factor of 2x should be applied when interpreting margin length. Therefore it was felt that a resection margin of 6cm on pathology may have represented a 12cm margin from the tumor to the anal skin prior to resection and that this distal margin should be amenable to a restorative procedure. In addition to this conservative anatomic definition of an appropriate colostomy, other legitimate reasons for a permanent colostomy were recognized and included technical factors during surgery, incontinence, immobility, patient preference and age. The ability to assess for factors unrelated to the pathology report on a population level is a strength of this study The age at which a restorative procedure is no longer appropriate is uncertain. Therefore, this indication for a colostomy was based on surgeon recommendation documented in the medical record as opposed to a defined age. Overall, creation of a permanent colostomy was appropriate in 71% of patients.

An inappropriate colostomy was created in 29% of patients with rectal cancer who received a permanent colostomy. This determination was based on distal margin alone. Some of these patients likely had legitimate reasons for creation of a permanent colostomy but these could not be identified given the retrospective nature of this study. However patients who received appropriate and inappropriate colostomies were similar in terms of age, co-morbidities and gender. There was a statistically significant difference in BMI between the two groups (27 vs 29) but it unlikely that this was clinically important. Given that all of the patients with an inappropriate colostomy had a minimum distal resection margin of approximately 12cm and some as long as 23cm it is likely that most patients were given a colostomy for one of the following reasons: 1. the surgeon lacked the technical ability to perform sphincter-preserving surgery, 2. the surgeon didn't understand that a sphincter preserving surgery was oncologically feasible or 3. the surgeon didn't appreciate the negative impact a colostomy has on quality of life.

These data suggest that there may be potential to improve patient quality of life after rectal cancer care through greater use of sphincter preserving surgery. If all of the patients who were given an inappropriate colostomy in the present study were, in fact, eligible for a restorative procedure then the permanent colostomy rate in this cohort would decrease from 48% to 35%. This is in line with favorable rates reported in the literature. Strategies to expand the use of sphincter preserving surgery will need to address surgical technique and knowledge related to oncologic principles and patient quality of life. Whether or not improved outcomes can be achieved in system where rectal caner care is delivered in many low volume hospitals is unclear. Regionalization of care may be required.

There are a number of limitations to the current study that should be addressed. These data were collected retrospectively and therefore some data may have been missing, including indications for permanent colostomy. Hospital inpatient and outpatient charts as well as surgeon office letters were examined to determine if a legitimate reason existed for permanent colostomy. It is possible that in some cases a legitimate reason for a permanent colostomy existed but was not documented in the medical charts. The current study compared patients treated in cancer center hospitals with those treated in non-cancer center hospitals. The definition of a cancer center hospital is applicable to the Canadian healthcare system, but may not be generalizable to other areas where medical oncology and radiation oncology services may be more widely available. The threshold that determined whether surgeons or hospitals were high volume was made arbitrarily. The distal margin length that defined whether a permanent colostomy was appropriate or inappropriate was based on limited scientific literature and the exact amount of organ shrinkage that occurred is unknown. For the purposes of statistical analysis the unit of measurement was the patient, however clustering naturally occurred in the dataset. Despite this, each patient was treated as an independent observation for statistical simplicity.

Conclusions

In this population-based study there was significant variation in the permanent colostomy rates among all hospitals providing rectal cancer care. While this variation did not appear to be related to patient or tumor characteristics, treatment factors including hospital and surgeon volume were associated with use of a permanent colostomy. Among patients who were given a colostomy, only 70% has an appropriate indication to receive one. These data suggest that there is potential for expanded use of sphincter preserving surgery in the management of rectal cancer.

Table 1. Patient characterictics and tumor factors among all patients with rectal cancer who underwent radical surgery with curative intent in Nova Scotia from 07/01/2002 to 06/30/2006.

Mean Age (range)		66 (27-94)
Sex (% male)		65%
Mean BMI (range)		28 (15-49)
Mean Charlson Comorbidity Score (range)		1.6 (0-13)
Tumor Height	Low	39%
	Mid	39%
	High	22%
Stage	I	31%
	II	27%
	III	35%
	IV	7%

Table 2. Comparison of patient factors, tumor factors and permanent colostomy rates among patients who underwent elective radical resection with curative intent across 10 hospitals in Nova Scotia providing rectal cancer care

Hospital	1 n=168	2 n=47	3 n=44	4 n=34	5 n=33	6 n=17	7 n=14	8 n=17	9 n=78	10 n=14	P value
Age	64.1 (30.6-92.8)	64.6 (43.8-86.7)	66.2 (44.6-94.4)	70.0 (47.5-89.5)	70.0 (40.5-87.4)	66.9 (45.8-89.4)	65.1 (40.6-82.3)	69.0 (57.3-82.5)	67.6 (27.4-88.7)	71.9 (54.1-93.3)	P=0.04
Sex (% Male)	59.9%	68.7%	72.7%	60.0%	72.7%	52.9%	78.6%	76.5%	69.2%	57.1%	P=0.45
Charlson	1.4 (0-8)	1.6 (0-7)	1.4 (0-7)	2.6 (0-9)	1.61 (0-7)	1.4 (0-10)	1.9 (0-7)	2.8 (0-13)	1.7 (0-9)	1.3 (0-3)	P=0.11
BMI	27.7 (14.9-49.3)	27.9 (19.9-48.0)	29.2 (21.1-46.6)	28.0 (16.1-46.4)	27.7 (18.1-35.4)	29.2 (22.9-36.0)	26.6 (18.5-40.8)	30.6 (19.4-37.7)	28.9 (16.6-48.3)	28.3 (24.7-36.9)	P=0.47
Tumor Height (Low/Mid/High)	40/43/17	27/40/33	50/41/9	40/40/20	33/42/24	24/35/41	50/43/7	41/41/18	36/34/30	54/23/23	P=0.57
Stage (I/II/III/IV)	29/29/35/7	31/29/29/10	39/19/35/7	32/31/31/6	19/23/55/3	12/35/47/6	50/29/21/0	38/19/37/6	27/28/36/9	77/23/0/0	P=0.21
Permanent Colostomy rate	42%	31%	61%	43%	27%	41%	71%	88%	58%	64%	P<0.01

Table 3. Comparison of permanent colostomy rates among patients with rectal cancer who underwent elective radical surgery with curative intent based on surgeon volume, hospital volume and cancer center designation.

	Median annual procedure volume (range)	Permanent colostomy rate	P value
High volume surgeon (n=4)	12 (9-14.5)	46% (77/167)	0.20
Low volume surgeon (n=47)	1.5 (0.25-4.5)	50% (150/299)	
High volume hospital (n=1)	42	42% (71/168)	0.1
Medium volume hospital (n=2)	15 (12-19)	48% (60/125)	
Low volume hospital (n=7)	6 (3-11)	53% (92/173)	
Cancer center hospital (n=2)	31 (19-42)	47% (116/247)	0.68
Non-cancer center hospital (n=8)	6 (3-12)	49% (107/219)	

Table 4. Univariate and Multivariate analysis of factors associated with creation of a permanent colostomy among patients with rectal cancer undergoing elective radical surgery with curative intent.

Variable		Univariate	Multivariate analysis by hospital volume	Multivariate analysis by surgeon volume	Multivariate analysis by cancer center
Hospital Volume	High	1.0	1.0		
	Mid	1.30 (0.81-2.07)	2.02 (1.05-3.87)		
	Low	1.66 (1.08-2.56)	2.17 (1.16-4.03)		
Surgeon Volume	High	1.0		1.0	
	Low	1.28 (0.87-1.88)		1.77 (1.03-3.03)	
Cancer center	Yes	1.0			1.0
	No	1.11 (0.77-1.60)			1.26 (0.75-2.10)
Age	<62	1.0			
	62-71	1.01 (0.63-1.61)			
	>71	1.52 (0.99-2.33)			
Comorbidities	0-1	1.0			
	2	1.33 (0.82-2.17)			
	>3	1.18 (0.74-1.90)			
BMI	Normal (<25)	1.0			
	Overweight (25-30)	0.67 (0.44-1.03)			
	Obese (>30)	0.82 (0.51-1.31)			
Sex	Female	1.0	1.0	1.0	1.0
	Male	1.60 (1.09-2.36)	2.07 (1.18-3.64)	2.18 (1.24-3.81)	2.112 (1.22-3.71)

Variable		Univariate	Multivariate analysis by hospital volume	Multivariate analysis by surgeon volume	Multivariate analysis by cancer center
Tumor Height	High	1.0	1.0	1.0	1.0
	Mid	2.63 (1.37-5.05)	2.74 (1.39-5.43)	2.74 (1.39-5.41)	2.66 (1.35-5.23)
	Low	44.72 (23.06-86.73)	61.31 (29.67-126.70)	59.51 (29.04-121.98)	55.98 (27.61-113.52)
Stage	I	1.0	1.0	1.0	1.0
	II	1.44 (0.89-2.32)	2.29 (1.16-4.53)	2.26 (1.15-4.43)	2.22 (1.13-4.35)
	III	1.11 (0.70-1.75)	1.18 (0.63-2.23)	1.19 (0.63-2.23)	1.19 (0.63-2.24)
	IV	2.07 (0.93-4.58)	4.34 (1.46-12.83)	2.23 (1.45-12.34)	4.10 (1.41-11.89)
Neoadjuvant	No	1.0			
	Yes	2.07 (1.26-3.43)			

Table 5. Comparison for patient characteristics and distal resection margin between patients with a clear indication of permanent colostomy and unclear indication for permanent colostomy.

	Permanent colostomy appropriate (n=160)	Permanent colostomy inappropriate (n=64)	p value
Mean Age	66	68	p=0.3
Co-morbidities	1.6	1.8	p=0.6
Sex (% Male)	67%	76%	p=0.1
BMI	27	29	p=0.01
Mean distal resection margin	3.3 (0.2-11.5)	7.4 (6-11)	p<0.01

Table 6. Comparison of appropriate and inappropriate use of permanent colostomy based on hospital volume, surgeon volume and cancer center designation.

		Permanent colostomy appropriate (n=160)	Permanent colostomy inappropriate (n=64)	
Hospital volume	High	90%	10%	
	Med	70%	30%	P<0.01
	Low	58%	42%	
Surgeon Volume	High	86%	14%	
	Low	64%	36%	P<0.01
Cancer Center	Yes	80%	20%	
	No	62%	38%	P<0.01

Table 7. Univariate and multivariate analysis of factors associated with receiving an inappropriate colostomy among patients with rectal cancer who underwent elective radical surgery with curative intent.

Variable		Univariate	Multivariate analysis by hospital volume	Multivariate analysis by surgeon volume	Multivariate analysis by cancer center
Hospital Volume	High	1.0	1.0		
	Mid	3.80 (1.46-9.88)	4.75 (1.78-12.64)		
	Low	6.64 (2.74-16.09)	7.16 (2.92-17.56)		
Surgeon Volume	High	1.0		1.0	
	Low	3.66 (1.73-7.72)		4.02 (1.88-8.58)	
Cancer Center	Yes	1.0			1.0
	No	2.50 (1.37-4.55)			2.67 (1.44-4.93)
Age	<62	1.0			
	62-71	1.33 (0.63-2.82)			
	>71	0.91 (0.46-1.79)			
Comorbidities	0-1	1.0			
	2	1.23 (0.58-2.57)			
	>3	1.36 (0.65-2.82)			
BMI	Normal (<25)	1.0			
	Overweight (25-30)	1.39 (0.69-2.79)			
	Obese (>30)	1.97 (0.95-4.09)			

Variable		Univariate	Multivariate analysis by hospital volume	Multivariate analysis by surgeon volume	Multivariate analysis by cancer center
Sex	Female	1.	1.0	1.0	1.0
	Male	2.23 (1.09-4.53)	2.54 (1.21-5.32)	2.56 (1.88-8.58)	2.45 (1.18-5.07)
Stage	I	1.0			
	II	1.14 (0.54-2.42)			
	III	0.92 (0.43-1.96)			
	IV	0.87 (0.27-2.78)			
Neoadjuvant	No	1.0			
	Yes	0.40 (0.18-0.91)			

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Chapter 7

Surgeon knowledge is associated with clinical and oncologic outcomes in patients with rectal cancer

Running header: Surgeon knowledge and patient outcomes

Key words: Rectal cancer, local recurrence, disease specific survival, overall survival, surgical quality

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Abstract

Introduction: Much of the variation in rectal cancer outcomes has been attributed to surgeon factors. In addition to performing the technical aspects of surgery, surgeons are often responsible for making pre-operative and post-operative treatment decisions related to rectal cancer care. The purpose of this study was to examine the relationship between surgeon knowledge of rectal cancer care and quality of care, as measured by permanent colostomy rate, use of total mesorectal excision (TME), lymph node harvest, local recurrence (LR) and overall survival (OS). **Methods:** A mail survey with 8 questions pertaining to staging, surgical decision-making in low rectal cancer, surgical margins, lymph node harvest and surveillance was sent to all general and subspecialty general surgeons in Nova Scotia, Canada. Each surgeon received a score based on the number of correct responses (max score=8). Surgeons were dichotomized into high and low score groups based on the median score. The provincial cancer registry was used to identify new rectal cancer patients from 7/1/2002-6/30/2006 in Nova Scotia. A comprehensive review of inpatient, outpatient and cancer center medical records was used to assemble this population-based cohort. **Results:** Of 521 patients who underwent treatment with curative intent, 377 (72%) were treated by 25 surgeons who responded to the survey (median survey score 6, range 1-8). The median follow-up after surgery was 4.2 years. On multivariate logistic regression analysis controlling for patient and tumor factors, patients treated by surgeons with a high survey score were more likely to receive a TME (OR 2.52, 95%CI 1.59-4.00) and have an adequate lymph node harvest (OR 2.31 95%CI 1.45-3.67) and less likely to have a permanent colostomy (OR 0.48 95%CI 0.28-0.81). On multivariate Cox proportional hazards regression, patients treated by surgeons with a high survey score had a 33% improvement in OS (HR 0.67, 95%CI 0.46-0.98) and were 46% less likely to develop LR (HR 0.54, 95%CI 0.30-0.96) compared to patients treated by surgeons with a low survey score. **Conclusion:** There was a clear association between surgeon knowledge and quality of care as measured by clinical and oncologic outcomes in rectal cancer. These results suggest that rectal cancer may be well-suited to knowledge-based quality initiatives.

Introduction

Surgeons play a central role in the management of patients with rectal cancer. In addition to performing the technical aspects of surgery, surgeons make decisions about pre-operative staging investigations, the type of surgical procedure to be performed, the management of post-operative complications, referral for neo-adjuvant and adjuvant therapies and post-operative surveillance investigations. Hence, the treatment of rectal cancer requires more than just technical skills; knowledge of all aspects of rectal cancer care is necessary. Surgeon-related factors such as type of training, procedure volume and surgical technique have been associated with patient outcomes including local recurrence[1], cancer specific survival[2,3], permanent colostomy rate[3-5] and complications[6,7]. However, it is unknown to what extent surgeon knowledge of rectal cancer care vs technical ability contributes to patient outcomes. The purpose of this study was to evaluate the relationship between surgeon knowledge of rectal cancer care and patient outcomes as measured by the use of permanent colostomy, use of total mesorectal excision (TME), lymph node harvest, local recurrence rate, disease specific survival and overall survival.

Methods

Surgeon knowledge was assessed by a mail questionnaire (Appendix 1) that was sent to all practicing general surgeons in Nova Scotia Canada in January, 2009. A second questionnaire was mailed to non-responders after six weeks. The survey was developed by the study investigators and reviewed by two colorectal surgeons who were not affiliated with the study for content validity. The survey collected information regarding surgical training and years in clinical practice. There were eight questions pertaining to pre-operative staging investigations, surgical management of low rectal cancer, surgical margins, lymph node harvest and post-operative surveillance. The response to each survey question was scored as 'appropriate' or 'inappropriate'. Surgeons obtained one point for each appropriate response, with a maximum possible score of 8. For analysis, an *a priori* decision was made to dichotomize survey scores into 2 groups (high score and low score) based on the median score.

Correct responses to the survey questions were defined *a priori*. Appropriate pre-operative staging investigations were defined as complete assessment of the colon (colonoscopy or sigmoidoscopy + barium enema), imaging of the chest (CT scan or chest x-ray) and imaging of the liver and pelvis (abdominal and pelvic CT scan or MRI) based on NCCN guidelines[8]. An adequate lymph node harvest was defined as 12 nodes[9]. An adequate distal resection margin for upper rectal cancer was defined as 5cm[10]. Utilization of adjuvant therapy was defined as appropriate if surgeons indicated that they would refer patients with stage II and III rectal cancer for chemotherapy and radiation. Two clinical scenarios regarding the management of low rectal cancer were presented. Appropriate management of a healthy 55 year old woman with normal continence and a mid-rectal cancer with T3N1 staging on pre-operative imaging was defined as a low anterior resection (+/- loop ileostomy) and either neo-adjuvant chemotherapy and radiation or adjuvant therapy based on the pathology. Referral to a specialized treatment center was also considered an acceptable response. Appropriate treatment for a healthy 55 year old female patient with normal continence and a mid rectal cancer that was 3cm in diameter and encompassed 20% of the lumen staged as T2N0 was defined as a low anterior resection (+/- loop ileostomy) followed by adjuvant therapy if indicated by pathology or referral of the patient for surgical treatment at a specialized center. Appropriate follow-up after treatment for stage II and III rectal cancer was defined as chest, abdominal and pelvic CT scans annually for 3-5 years and colonoscopy one year after surgery and then three or five years later based on NCCN guidelines[8].

To determine if there was an association between surgeon knowledge and patient outcomes, patients who were treated by survey respondents were identified through a retrospective review. All patients with a new diagnosis of adenocarcinoma of the rectum between July 1, 2002 and June 30, 2006, who were residents of Nova Scotia, Canada and underwent resection with curative intent were identified. Patients were excluded if they were <18 years of age or if they underwent primary treatment for rectal cancer outside of the Province. Patients were identified from the Nova Scotia Cancer Registry. This Registry has been in existence since 1964 and it is a legal requirement that all new confirmed cancer cases in Nova Scotia be reported to the registry. A comprehensive, standardized review of hospital inpatient and outpatient medical records, cancer centre charts and surgeon office charts was performed. Data were collected regarding patient demographics, co-morbidities, tumor height, stage, surgical treatment, post-operative complications and long term outcomes. Patient age was calculated as their age at the time of first presentation. Patient co-morbidities were compared using the Charlson co-morbidity index. Body mass index was calculated as patient weight (kg) divided by patient height^2 (m^2). The TNM classification for staging rectal cancer was used. Rectal tumor height was determined using documented findings of digital rectal examination, rigid and/or flexible endoscopy reports, operative reports and pathology reports. A low rectal tumor was defined as being <6cm from the anal verge on endoscopy or involving the anal sphincter complex. A mid rectal tumor was defined as 6-12 cm from the anal verge, and a high rectal tumor was defined as >12 cm from the anal verge. Patients with rectosigmoid cancer were excluded. Receipt of neo-adjuvant therapy was defined as administration of chemotherapy, radiation therapy or both prior to surgical resection for any duration.

The relationship between surgeon knowledge and six different outcomes of rectal cancer care was examined; the use of a permanent colostomy, the use of TME, lymph node harvest, local recurrence, disease-specific survival and overall survival. These outcomes were selected *a priori*. Patients who underwent an abdominal perineal resection or an anterior resection with end colostomy (Hartmann procedure) were defined as having a permanent colostomy. Patients who underwent a low anterior resection (+/- loop ileostomy) were defined a having a restorative procedure. Use of total mesorectal excision (TME) was determined from dictated operative reports that described "TME" or "total mesorectal dissection" as part of the procedure. Lymph node harvest was defined as adequate if 12 or more lymph nodes were examined based on the pathology report. Local recurrence was defined as histologically-proven recurrence at the anastomosis, in the pelvis or on the perineum or clear radiographic evidence of recurrence. Disease-specific survival involved the absence of death attributable to rectal cancer. Patients were followed for a minimum of 3 years after surgery.

Each of the six clinical and oncologic outcomes was compared between patients who were treated by surgeons with high survey scores and those treated by surgeons with low survey scores. T-tests were used to test the difference between the means of two groups. Chi-square tests were used to test the difference between categorical variables. If a 2 X 2 table contained a cell count of <5, Fisher's exact test was used. Logistic regression analysis was used to determine the univariate and multivariate associations between surgeon survey scores and dichotomous patient outcomes (permanent colostomy rate, use of TME and adequate lymph node harvest). Kaplan Meier survival curves were used to examine the relationship between surgeon survey scores and local recurrence, disease specific survival and overall survival. Patients were censored at the time of last contact for those lost to follow-up or at the end of the study date (March 15, 2010). For all univariate analyses of recurrence and survival, the log-rank test was used to compare patients treated by surgeons with high and low survey scores. For all multivariate analysis co-variates were determined *a priori* and included: age, sex, BMI, charlson co-morbidity score, tumor height, use of neo-adjuvant therapy and TNM stage. However, because of the low number of events the multivariate local recurrence model included fewer covariates. The covariates in the multivariate local recurrence model were determined *a priori* and included: use of neo-adjuvant therapy, tumor height and TNM stage. All potential two-way interaction terms were assessed for significance in each model. The proportional hazards assumption was assessed for the local recurrence, disease specific survival and overall survival models using time-dependant covariates. Analyses were performed using SAS version 9.2 (SAS Institute Carey, NC). Statistical significance was set at p=0.05.

Results

The mail survey was sent to 55 general surgeons in Nova Scotia and the response rate was 89% (49/55). Twenty-five survey respondents treated 377 patients who were diagnosed with rectal cancer between July 1, 2002 and June 30, 2006 in Nova Scotia.

These 377 patients represent 72% of the 521 patients who were treated with rectal cancer during the study period. The remaining 144 patients were treated by surgeons who had retired from clinical practice or had moved out of the province by the time the mail survey was sent in 2009. There were 15 patients treated by 2 surgeons who did not complete the mail survey. The median survey score for the 25 surgeons with patient outcomes for comparison was 6 (range 1- 8) Based on the median score 56% (14/25) of surgeons had a high survey score (score=6-8) and 44% (11/25) had a low survey score score (score 1-5). The surgeons with a high score included four surgeons with colorectal /surgical oncology training and 10 non subspecialty-trained general surgeons. None of the general surgeons with a low score had colorectal or surgical oncology fellowship training. There was no difference in years in clinical practice between surgeons with high scores and surgeons with low scores (17 vs. 19 years respectively, p=0.64). Surgeons with low survey scores treated fewer patients with rectal cancer per year compared to surgeons with high survey scores (mean 1.8 [range 0.25-2.75] vs. 4.8 [range 0.5-14.25] cases/ year, p=0.03).

Surgeons with a high survey score treated 285 patients during the study period and surgeons with a low survey score treated 92 patients. There were no differences in patient age, BMI, co-morbidities, tumor height, stage or surgical procedures between patients treated by surgeons with high and low survey scores (Table 1). Clinical and oncologic outcomes were compared between patients according to surgeon survey score (Table 2). Patients who were treated by a surgeon with a high survey score were more likely to undergo a TME and have >12 lymph nodes assessed and less likely to receive a permanent colostomy compared to patients treated by surgeons with a low survey score.

Local recurrence was more common in patients who were treated by a surgeon with a low survey score. There were no differences in DSS and OS between patients treated by surgeons with high and low survey scores.

On multivariate analysis, after controlling for age, co-morbidities, stage, tumor height, BMI and use of neo-adjuvant therapy, treatment by a surgeon with a high survey score was associated with lower rate of permanent colostomy, a lower risk of local recurrence improved DSS and OS compared to treatment by surgeons with a low survey score (Table 3). Patients treated by surgeons with a high survey score were also more likely to undergo a TME at surgery and have an adequate lymph node harvest compared to patients treated by surgeons with a low survey score.

Discussion

Rectal cancer is a complex disease and surgeons play a primary role in patient management. Surgeons are responsible for decisions relating to preoperative, intra-operative and post-operative care. While many of these decisions will be made exclusively by the surgeon, others will be made by the patient based on information or recommendations provided by the surgeon. Treatment decisions made by surgeons can impact patient outcomes in many ways. For example, patients with stage II and III rectal cancer should be referred for consideration of neoadjuvant or adjuvant chemotherapy and radiation as these treatments are associated with a survival benefit[11-13]. Treatment of a T1 rectal cancer with transanal excision will be associated with worse survival compared to radical excision[14]. Appropriate selection of patients for neoadjuvant chemotherapy and radiation may facilitate sphincter preserving surgery by decreasing tumor bulk[13,15]. Ensuring a 5cm distal resection margin in the management of upper rectal cancer may decrease the rate of local recurrence after anterior resection[10,16]. Intensive surveillance investigations have been associated with earlier detection of recurrence and improved survival[17]. In order make proper treatment decisions, surgeons need to have accurate knowledge of rectal cancer, the available treatments and expected outcomes. If surgeons make appropriate decisions based on sound knowledge, patients should have good outcomes. However, this association has not been previously established.

In the present study there was a clear relationship between surgeon knowledge of rectal care and patient outcomes; this is the first study to establish this relationship. The mail survey was used to assess surgeon knowledge and focused on core aspects of rectal cancer care including staging investigations, management of low rectal cancer, surgical margins, lymph node harvest, appropriate use of adjuvant therapy and surveillance investigations. These issues would need to be considered in patients who would be seen in community hospitals by general surgeons and are not specific to subspecialty surgeons or tertiary care settings. This is relevant because the majority of patients with rectal cancer in Canada are treated by general surgeons in community hospitals. It is likely that rectal cancer care is provided in a similar manner across North America.

The relationship between surgeon knowledge and outcomes was assessed by examining six different outcomes that have an important impact on patients. The use of TME is associated with low rates of local recurrence[1]. An adequate lymph node harvest has been associated with accurate staging and prognosis[9]. The use of a permanent colostomy may be required for adequate treatment of rectal cancer but is associated with a decreased quality of life compared to a restorative procedure[18]. Therefore a colostomy should be avoided unless clearly indicated; contemporary studies suggest that permanent colostomy rates of 20-30% are achievable[19,20]. Local recurrence of rectal cancer is associated with decreased survival and may require radical surgery for treatment[21]. Disease-specific and overall-survival represent the central goals of cancer treatment.

Little has been previously published regarding the relationship between physician or surgeon knowledge, treatment decisions and patient outcomes. In primary care physician knowledge has been found to be associated with healthcare resource utilization and quality of care. Tamblyn et al. examined the relationship between the licensing exam scores of 614 family physicians and treatment provided to patients during the first 18 months of clinical practice[22]. Patients who were treated by physicians with higher licensing scores were less likely to receive inappropriate prescriptions and had higher rates of screening mammography and higher referral rates for consultations. They were also more likely to be prescribed disease-specific medications as opposed to drugs for symptom relief. A follow-up study by the same authors reported that there was a long term-relationship between physician licensing exams and healthcare utilization and quality of care based on patient care provided four to seven years after starting clinical practice[23]. While these two studies have demonstrated an association between physician knowledge and decision making, they did not examine the relationship between knowledge and patient outcomes.

The results from the present study suggest that knowledge based initiatives may play a role in strategies aimed at improving rectal cancer outcomes. However, how such knowledge is obtained may be important. Two provinces in Canada have designed surgeon-directed quality improvement strategies aimed at improving outcomes for patients with rectal cancer. In Ontario a cluster-randomized trial was performed which randomized hospitals to an intervention that integrated the use of workshops, opinion leaders, intra-operative demonstrations, postoperative questionnaires, audit and feedback[24]. Although there were no significant improvements in permanent colostomy rates or local recurrence of rectal cancer in this study, the hospitals that participated in the trial were relatively high volume, and therefore the effect of this type of intervention on low volume hospitals is unknown. In British Columbia, the Surgical Oncology Network and the BC Cancer Agency recommended that all stage II and III rectal cancers be treated with neo-adjuvant therapy and receive a TME. To implement the recommended standard of care, TME and rectal cancer management education workshops were held and it was estimated that 80% of surgeons in the province participated[25]. A significant decrease in local recurrence after treatment of stage III cancer was observed following the educational workshops. It is unknown to what extent standardization of surgical technique vs. improvement in surgeon knowledge contributed to the decrease in local recurrence.

The results of the present study may also have implications for maintenance of certification and credentialing. While successful completion of licensing and fellowship examinations is required to obtain a license to practice medicine, license renewal is not based on objective assessments of medical knowledge. Maintenance of certification by the American Board of Surgery requires intermittent examinations in the United States. Re-certification examinations are not required by the Royal College of Physicians and Surgeons of Canada. Instead, surgeons are required to participate in continuing medical education activities. However, recertification by these organizations is not required to practice surgery or maintain a medical license. Furthermore, there is no evidence that these programs are associated with surgeon knowledge, surgeon practice patterns or patient outcomes. Recognizing the importance of quality assurance, volume-based credentialing has been introduced in some areas of medicine to limit who may perform procedures such as colonoscopy[26]. There may be a potential role for knowledge assessment in the process of obtaining and maintaining privileges and further research in this area is needed.

Numerous studies have reported a relationship between surgeon procedure volume and patient outcomes[2-4,7,20]. Procedure volume could be a confounding variable in the present study as the surgeons with high survey scores had higher procedure volumes compared to surgeons with low survey scores. However there is no consensus as to the threshold that defines high volume. Furthermore, Martling et al. have reported that surgeon training (colorectal) is a more important predictor of patient outcomes than surgeon procedure volume[27].

There are several limitations of this study that should be addressed. The survey used to assess surgeon knowledge has not been validated. Each of the survey items was given equal weighting in the scoring system and it is unknown if this was appropriate. The correct responses to the survey were based on consensus decisions of the colorectal surgeons and surgical oncologists at the author's institution. Although the questions were designed to have clear correct responses, there may be controversy surrounding some of the topics that were addressed and alternative answers to the questions may have been considered reasonable by some. The use of the median score to differentiate surgeons with high and low scores was arbitrary. However, exploratory analysis was performed using the current data set and it was determined that as surgeon score increased by one point patient survival improved by 18%, after controlling for patient age, comorbidities and tumor stage. Patient outcomes were assessed through a retrospective chart review which is limited by the availability and accuracy of medical records. Missing data are an inherent limitation of this type of research. Data quality and capture was excellent for most data fields. However, surgeons may have performed TME during surgery but did not record this in the operative note. Furthermore there were no data available regarding the quality of the TME specimen. Some patients were lost to follow up and therefore local recurrence, disease-specific survival and overall survival may not be accurate. For the purposes of statistical analysis the unit of measurement was the patient, however clustering naturally occurred in the dataset. Despite this, each patient was treated as an independent observation for statistical simplicity. Finally, given that surgeon knowledge was assessed several years after patient care was provided by the surveyed surgeon, it is possible that that surgeon knowledge was different at the time of actual patient care.

Conclusions

There was a clear association between surgeon knowledge and patient outcomes in rectal cancer; this relationship may, at least in part, explain reported volume and training-associated differences in rectal cancer outcomes. The results of this study suggest that rectal cancer may be well-suited to knowledge-based quality initiatives and that knowledge assessment may be important component of quality assurance.

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Table 1. A comparison of patient and tumor factors and type of surgical procedures between patients treated by surgeons with high survey scores and patients treated by surgeons with low survey scores.

		Patients treated by surgeons with high survey scores (n=285)	Patients treated by surgeons with low survey scores (n=92)	p Value
Age		66.2 (27.4-93.0)	67.5 (40.5-96.3)	p=0.22
Sex (% Male)		62%	67%	p=0.19
BMI		27.9 (15.7-49.3)	28.5 (14.9-48.3)	p=0.29
Charlson		1.72 (0-13)	1.65 (0-10)	p=0.68
Tumor Height	Low	42%	44%	
	Mid	29%	27%	p=0.84
	High	29%	29%	
Stage	I	29%	34%	
	II	28%	27%	p=0.58
	III	37%	32%	
	IV	6%	7%	
Surgical procedures	Radical excision	89%	90%	P=0.23
	Transanal excision	7%	4%	
	Endoscopic excision	4%	6%	

Table 2. A comparison of clinical and oncologic outcomes between patients treated by a surgeon with a high survey score and patients treated by surgeons with a low survey score.

	All patients (n=377)	Treatment by a surgeon with a high survey Score (n=285 patients)	Treatment by a surgeon with a low survey score (n=92 patients)	p Value
Permanent colostomy	48%	43%	54%	p=0.02
TME	65%	75%	53%	p<0.01
>12 Nodes	33%	39%	25%	p<0.01
5-year local recurrence	16%	13%	18%	p=0.04
5-year disease specific survival	75%	76%	74%	p=0.38
5-year overall survival	61%	65%	64%	p=0.35

Table 3. Multivariate analyses of clinical and oncologic outcomes

Variable		Permanent Colostomy (Y)	TME (Y)	>12 nodes (Y)	Local Recurrence	Disease Specific Survival	Overall Survival
Score	High	0.48 (0.28-0.81)	2.48 (1.61-3.79)	2.00 (1.30-3.08)	0.54 (0.30-0.96)	0.66 (0.42-0.97)	0.68 (0.48-0.97)
	Low	1.0	1.0	1.0	1.0	1.0	1.0
Age	<62	1.0	1.0	1.0		1.0	1.0
	62-71	0.62 (0.31-1.24)	0.92 (0.53-1.60)	0.52 (0.31-0.89)		1.31 (0.72-2.36)	1.25 (0.74-2.13)
	>71	0.51 (0.26-0.98)	0.88 (0.52-1.50)	0.49 (0.29-0.82)		2.56 (1.49-4.41)	3.22 (2.04-5.08)
Charlson	0-1	1.0	1.0	1.0		1.0	1.0
	2-3	0.56 (0.26-1.19)	2.01 (1.09-3.73)	0.92 (0.51-1.67)		0.75 (0.40-1.40)	0.95 (0.57-1.58)
	>3	0.76 (0.38-1.52)	1.23 (0.69-2.15)	0.59 (0.33-1.07)		1.25 (0.70-2.25)	2.57 (1.71-3.87)
Stage	I	1.0	1.0	1.0	1.0	1.0	1.0
	II	0.56 (0.28-1.13)	0.80 (0.45-1.42)	1.18 (0.66-2.10)	1.87 (0.79-4.39)	4.17 (1.49-11.65)	2.19 (1.21-3.95)
	III	0.81 (0.42-1.56)	0.87 (0.52-1.47)	1.52 (0.90-2.58)	2.94 (1.37-6.30)	9.80 (3.84-24.99)	3.34 (2.00-5.56)
	IV	0.21 (0.07-0.67)	0.92 (0.37-2.30)	1.70 (0.70-4.10)	2.81 (0.86-9.22)	41.59 (15.14-114.22)	13.15 (7.01-25.68)
Tumor Height	Low	0.01 (0.004-0.02)	0.89 (0.50-1.58)	0.49 (0.27-0.87)	0.75 (0.36-1.56)	0.62 (0.33-1.14)	0.81 (0.50-1.33)
	Mid	0.24 (0.11-0.53)	0.91 (0.52-1.60)	0.79 (0.46-1.37)	0.89 (0.45-1.79)	0.83 (0.47-1.46)	0.81 (0.51-1.30)
	High	1.0	1.0	1.0	1.0	1.0	1.0
BMI	<25	1.0	1.0	1.0		1.0	1.0
	25-27	0.93 (0.42-2.03)	1.25 (0.65-2.39)	0.67 (0.35-1.27)		0.71 (0.36-1.37)	0.70 (0.42-1.19)
	27-31	1,16 (0.60-2.26)	1.33 (0.76-2.32)	1.13 (0.67-1.93)		0.65 (0.35-1.18)	0.55 (0.33-0.90)
	>31	1,21 (0.56-2.6)	0.78 (0.42-1.42)	0.89 (0.48-1.63)		0.90 (0.49-1.65)	0.86 (0.53-1.41)
Neoadjuvant	Yes	0.79 (0.37-1.68)	7.63 (3.21-18.68)	2.67 (1.51-4.71)	1.16 (0.55-2.46)	2.15 (1.20-3.84)	1.64 (1.00-2.69)
	No	1.0	1.0	1.0	1.0	1.0	1.0

Chapter 8: Conclusion

The management of rectal cancer is complex. The nature of treatment, post-operative complications and disease recurrence are associated with functional disturbances and significant patient suffering. Providing high quality care is important to minimize adverse outcomes. Although there are specialized centers across North America where rectal cancer care is provided, many patients receive their care outside of these facilities. Therefore an evaluation of the delivery of rectal cancer care and treatment outcomes at a population level will add to the current body of knowledge and was necessary to identify the unique circumstances and problems faced by surgeons and patients in a variety of clinical environments.

The current research was a comprehensive population-based evaluation of rectal cancer care and outcomes using patient-level data. All aspects of care including pre-operative staging, surgery, pathology, peri-operative complications, the use adjuvant therapies and surveillance were examined. The current research has determined that patient gender, co-morbidities, BMI, tumor height and stage were similar between hospitals providing rectal cancer care regardless of hospital type (tertiary care referral center vs. community hospital) or hospital procedure volume . It is unlikely that variation in rectal cancer outcomes is attributable to hospital-based differences in patient characteristics or tumor factors. Improvements in 5 year local recurrence rates were observed in patients treated by high volume surgeons who worked in cancer center hospitals. The improved outcomes associated with treatment of rectal cancer by high volume surgeons or specialized centers may be attributable, at least in part, to differences in surgical technique. There is variation in the permanent colostomy rate in the Province. Patients treated by a low volume surgeon, in a low volume hospital, or in a non-cancer center hospital may be more likely to receive a permanent colostomy. Furthermore many of the permanent colostomies performed by low volume surgeons, in medium/low volume hospitals or in non-cancer centers may be unnecessary. The opportunity to improve the permanent colostomy rate at a population level exists. There was a clear association between surgeon knowledge and quality of care as measured by clinical and oncologic outcomes in rectal cancer. These results suggest that rectal cancer may be well-suited to knowledge-based quality initiatives.

This research project has helped to identify areas of rectal cancer care in Nova Scotia that require improvement.

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Appendix

Dear Colleague,

We are conducting a study of rectal cancer care in Atlantic Canada. We are interested in the current practices of general surgeons across the region. Attached is a brief questionnaire that will take **Approximately 7 minutes to complete**.

The survey will be returned to a 3rd party research assistant who will remove the study ID number on your survey before returning it to the study investigators. This will ensure that your responses are completely anonymous.

We appreciate that you are busy and that you time is valuable. Please have a coffee on us with the enclosed $5 TimCard (perhaps while you complete the questionnaire!) as a small token of thanks for your participation.

Please return the survey in the enclosed envelope. Once we have received your completed survey we will mail you an "answer sheet" providing correct responses for questions where clinical practice guidelines currently exist.

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Thank you

Sincerely,

Devon Richardson MD

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MSc Candidate
Dalhousie University
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Atlantic Rectal Cancer Care Survey

1. Since you completed all training how long have you been in surgical practice? ________ years

2. Did you do a fellowship ☐ YES ☐ NO

   If yes, in what subspecialty:

   ☐ Colorectal surgery
   ☐ Surgical Oncology
   ☐ Other ______________________

3. In your current practice do you treat patients with rectal cancer, defined as cancer within 15cm of the anal sphincter? YES NO

   If YES, please complete the rest of the questionnaire

   If NO, please stop here and return the survey

4. Approximately how many resections do you perform annually for primary rectal cancer?

5. When you perform surgery for rectal cancer who typically assists you?

   Select **one** only

   ☐ Another general surgeon
   ☐ Another surgeon from a different discipline
   ☐ A family doctor
   ☐ A resident
   ☐ Other

6. You have just seen a 55 year old healthy patient in the clinic with rectal bleeding and you can easily palpate a rectal cancer at the fingertip on DRE. In your current practice which investigations would you **routinely** order for this patient for assessment of the primary tumor and metastatic disease? Please check **all** that apply.

☐ CT abdomen & pelvis ☐ CT chest ☐ CXR
☐ Colonoscopy ☐ MRI pelvis
☐ Rigid sigmoidoscopy
☐ Flexible sigmoidoscopy ☐ Barium Enema
☐ Endorectal ultrasound ☐ CEA

7. You are caring for a healthy 55 year old female (BMI=27 and normal continence) with a palpable rectal cancer 5cm above the anorectal ring. There is no evidence of metastases. The tumor is circumferential. CT scan shows stranding of the mesorectal fat adjacent to the tumor and a 1.2 cm node in the mesorectum. **Which of the following would you recommend for this patient?** Please select **one** only:

☐ pre-operative chemotherapy and radiation followed by low anterior resection (+/- loop ileostomy)

☐ Pre-operative chemotherapy and radiation followed by APR

☐ Low anterior resection (+/- loop ileostomy) and post-operative chemotherapy and radiation if indicated by the pathology
APR and post-operative chemotherapy and radiation if indicated by the pathology

☐ I would refer this patient for surgical treatment at a specialized centre

8. You are caring for a healthy 55 year old female (BMI=27 and normal continence) with a palpable rectal cancer 5cm above the anorectal ring. There is no evidence of metastases. The tumor is located posteriorly and it is mobile. At endoscopy the tumor encompasses 20% of the lumen of the bowel and is 3cm in diameter. Endorectal ultrasound is available and tumor is staged as T2N0. **Which of the following would you recommend for this patient?** Please select **one** only:

☐ Pre-operative chemotherapy and radiation followed by low anterior resection (+/- loop ileostomy)

- [ ] Pre-operative chemotherapy and radiation followed by APR
- [ ] Low anterior resection (+/- loop ileostomy) and post-operative chemotherapy and radiation if indicated by the pathology
- [ ] APR and post-operative chemotherapy and radiation if indicated by the pathology
- [ ] Transanal excision with possible post operative chemo-radiation
- [ ] Pre-operative chemo/ radiation followed by transanal excision
- [ ] I would refer this patient for surgical treatment at a specialized centre

9. How many lymph nodes in the pathology report are required to accurately stage
   rectal cancer? _______ Not Sure ☐

10. When performing curative resection for a cancer in the upper rectum how far distal to the tumor do you divide the rectum? (ie. How far from the tumor is your distal resection margin?)

    _______ cm

11. After potentially curative resection for rectal cancer, in a patient who did not have pre-operative chemotherapy and radiation, who would you refer for adjuvant chemotherapy and radiation given the following pathology reports? Please check **all** that apply.

- [ ] T2N0
- [ ] T2N1
- [ ] T3N0
- [ ] T3N1

12. After potentially curative treatment for stage II-III rectal cancer which best describes the recommended timing of post-operative surveillance abdominal and pelvic CT scans? Please select **one** only:

- ☐ Annually for 5 years
- ☐ One year after surgery and then 3 years later if normal
- ☐ One year after surgery and then 5 years later if normal
- ☐ Three years after surgery
- ☐ Five years after surgery
- ☐ Routine CT scans are not recommended

13. After potentially curative surgery for stage II-III rectal cancer which best describes the recommended timing of post-operative surveillance colonoscopy in a patient who had a complete pre-operative colonoscopy? Please select **one** only:

- ☐ Annually for 5 years, then every 3 years
- ☐ One year after surgery and then 3 years later if normal
- ☐ One year after surgery and then 5 years later if normal
- ☐ Three years after surgery
- ☐ Five years after surgery

14. After potentially curative surgery for rectal cancer which best describes how often you order surveillance CEA levels? Please select **one** only

- ☐ Every 3-6 months for 5 years
- ☐ Annually for 5 years
- ☐ I do not routinely order CEA levels
- ☐ Other:

15. Have there been any recent changes (in the last 1-2 years) in how you treat patients with rectal cancer? YES ☐ NO ☐

If yes please check **all** that apply:

- ☐ Increased use of pre-operative chemo/radiation treatment
- ☐ Increased use of post-operative chemo/radiation treatment
- ☐ Higher patient volume
- ☐ Lower patient volume
- ☐ Other:

16. Are there barriers in your current practice regarding how you treat rectal cancer? Please check **all** that apply:

- ☐ Availability of specific rectal imaging such as MRI or ERUS
- ☐ Availability of endoscopy resources for diagnosis and/or surveillance
- ☐ Availability of timely OR resources
- ☐ Availability of timely radiation/ medical oncology consultation and treatment
- ☐ Availability of education/support services for rectal cancer patients
- ☐ Uncertainty about adequate performance of total mesorectal excision (TME)
- ☐ Other: