



Rectal resection following neoadjuvant therapy in a Midwest community hospital setting: The case for standardization over centralization as the means to optimize rectal cancer outcomes in the United States

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ARTICLE INFO

Article history:

Received 9 July 2018

Received in revised form

31 August 2018

Accepted 3 September 2018

Keywords:

Adenocarcinoma of rectum

Rectal cancer resection

Neoadjuvant therapy

Neoadjuvant chemoradiotherapy

Outcomes

ABSTRACT

Background: Incomplete and flawed national databases reveal strikingly inferior outcomes for rectal cancer patients resected at “low” versus “high” volume hospitals, therefore, a study of outcomes of a “high” volume surgeon in a “low” volume Midwest community hospital setting examined this perception in comparison to contemporary studies.

Methods: Review of 109 consecutive patients who underwent open resection of rectal cancer following neoadjuvant therapy, 1999–2010.

Results: Despite the majority of tumors in the low rectum (54%), the rate of abdominoperineal resection was only 39% with R0 resection achieved in 94% and primary anastomosis in 61/109 patients (56%). Disease-free survival (DFS) 73%: stage 0 (complete response)- 100%, stage I- 88%, stage II- 68%, stage III- 50%, stage IV- 0% with recurrence rate of 11% (local recurrence (LR) - 3%, distant - 8%).

Conclusion: Outcomes of rectal cancer resection by a “high” volume surgeon in a “low” volume Midwest community hospital setting were comparable to contemporary studies from tertiary care institutions. Geographic location and hospital capacity matter less than access to multispecialty expertise providing neoadjuvant therapy and following standard principles of oncologic resection, in efforts to optimize rectal cancer outcomes.

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Introduction

There is significant variation in the management decisions, operations performed and outcomes of rectal cancer treatment both within the United States (US) and in comparison to Europe. In many European countries rectal cancer care has been centralized to high performing, so-called “centers of excellence”¹ touting high rates of sphincter preservation, improved overall survival and low rates of recurrence.² These improved outcomes have been attributed to the consolidation of patients to more central or regional multidisciplinary centers that boast the availability and use of neoadjuvant chemoradiotherapy and the increased proficiency of total mesorectal excision (TME) among their high volume rectal surgeons.^{1,2} To the contrary, published analyses of rectal cancer outcomes in national databases in the US reveal that rectal

resection was typically performed by low volume surgeons in low volume hospitals with higher rates of mortality and comparatively meager rates of sphincter preservation,³ culminating with a call to “standardize care for rectal cancer across the United States”.⁴ Others have gone a step further and advise developing and certifying rectal cancer “centers of excellence”, mirroring the European model.⁵

The overwhelming majority of published outcomes from single⁶ or multiple institution studies of rectal cancer resection⁷ are based at tertiary care institutions where multispecialty expertise is concentrated and integrated with research apparatus in place to both execute treatment algorithms and gather outcomes data. Similar teams of specialists may be cobbled together at smaller, less integrated “low” volume community hospitals, where the majority of rectal cancer operations in the US are performed, to provide essentially the same cooperative multidisciplinary management, however, outcomes data from these hospitals are seldom, if ever, gathered, published and made available for public consumption.

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The following data are presented in an attempt to fill the outcomes ‘void’ that exists outside of regional tertiary care institutions or designated cancer centers that dominate the outcomes literature. This information contributes to the ongoing debate between proposals to standardize versus centralize care, including calls to establish rectal cancer “centers of excellence” in the US, similar to the European model.

Methods

A retrospective review of 109 consecutive patients with a diagnosis of adenocarcinoma of the rectum, defined as < 15 cm from the anal verge (excluding patients with prior resection of rectal cancer) who underwent neoadjuvant therapy followed by open resection by a single “high” volume American Board of Colon and Rectal Surgery (ABCRS)- certified surgeon in 14 community hospitals (range 55–623 licensed beds, 5 hospitals with <159 licensed beds) in a bistate Midwest region between 1999 and 2010. Before the time period of this study, 5 of these 14 hospitals had never credentialed a colorectal surgeon. The study passed through the internal review board at Shawnee Mission Medical Center (Merriam, KS) where the majority of the operations were performed. The vast majority of these adenocarcinomas (94%) were located in the low (54%) or mid rectum (39%).

Neoadjuvant therapy was completed in its entirety by 103 of 109 patients (94%): 4 patients had RT alone (completed by all) and 88 of the remaining 105 patients (84%) had uninterrupted completion of CRT. Of the 17 patients (16%) who had an interrupted course of CRT, 11 patients eventually completed the full dose of RT after a break and the other 6 patients did not complete the full intended course of RT.

All patients underwent mechanical bowel preparation (MBP) followed by oral antibiotics, prophylactic intravenous antibiotics and deep venous thromboembolism prophylaxis. Operations were performed in dorsal lithotomy position following routine cystoscopy with placement of ureteral stents and rectal irrigation with povidone-iodine. Takedown of the splenic flexure was performed for all patients who underwent sphincter preservation (SP) with an anastomosis. High ligation of the inferior mesenteric artery (IMA) and sharp rectal dissection was performed with at least a 5 cm distal margin for upper rectal carcinomas and total mesorectal excision (TME) for mid and low rectal carcinomas to enable a 1–2 cm distal margin of resection. Stapling instruments were used for colorectal anastomoses with a coloanal anastomosis defined as a very distal resection that required a combined abdominal/transanal approach to achieve an adequate resection margin and included a handsewn anastomosis.

Following 3 anastomotic leaks without proximal fecal diversion in the first 12 months, routine diverting loop ileostomy was established for the subsequent 58 patients who had SP. Resection margin < 1 mm from the tumor was deemed a R1 resection. Postoperative mortality was defined as occurring in 30 days or less. Excluding those patients who did not survive the 30 day postoperative period, the median length of follow-up was 6.3 years (IQR: 5.51).

Results

Of the 109 patients included in the study, 104 patients (95%) were white and 5 patients (5%) were of non-white race (4 Black, 1 Asian) with patient demographics displayed in [Table 1a](#). The mean distance of the carcinoma from the dentate line was 5.2 cm (range 0–15 cm). Operations were performed a mean of 43 days following the last dose of RT (range 30–58 days). The mean time for operation included added time and EBL for the associated incidental

procedures listed in [Table 1a](#). R0 resection (resection margin > 1 mm) was achieved in 94% of patients. Of 5 patients with distal resection margin between 1 and 2 mm, 4 remain disease-free and 1 patient died of distant disease. Of the 6 patients with R1 resection (<1 mm resection margin), none underwent anastomosis (APR-5 patients, Hartmann's- 1 patient): 3 patients died in less than 6 months, a 4th patient died at 18 months and a 5th patient died at 34 months, the latter two patients with local recurrence (LR).

A total of 48 patients (44%) required a permanent stoma and 61 patients (56%) had SP with a temporary diverting loop ileostomy. The 3 patients with high rectal carcinomas without SP had advanced local or distant stage 4 disease so that distal anastomosis was not attempted. Of the 61 patients (56%) who had SP, there were 4 anastomotic leaks (6.6%), 3 patients in the 1st 12 months of the study prior to routine diverting loop ileostomy, who all had eventual successful takedown of the loop ileostomy.

The overall morbidity rate was 42%: surgery-specific complications in 17% (requiring return to the operating room) and non-surgery specific complications in 26%. The 30 day re-admission rate was 18%, 13 of these 20 readmitted patients (65%) underwent SP with a temporary diverting loop ileostomy explaining ‘dehydration’ as the top re-admission diagnosis.

The 30-day mortality rate was 5%, all between 10 and 22 days into the postoperative period (4 patients ASA 3, 1 patient ASA 4) with 4 of these 5 patients >70 years of age (87, 81, 78 and 71 years of age) and all expired from a cardiopulmonary event.

The overall survival was 78% and disease-free survival (DFS) was 73% for the entire study group. Overall survival and DFS by stage of carcinoma is depicted in [Table 1b](#) and by Kaplan-Meier analysis in [Fig. 1](#). Excluding patients with R1 resection, 2 patients developed LR, both after APR. Thus, the LR rate was 3% combined with an 8% rate of distant recurrence for a total rate of recurrence of 11%.

Five patients developed second cancers (1.5–9.5 years into the postoperative period): uterus (hysterectomy), left breast (local excision), right colon (colectomy), neck (right radical neck for squamous cell carcinoma) and anus (expired 10 months after APR for neuroendocrine carcinoma).

Discussion

The majority of rectal cancer cases in the US are managed in low volume community hospitals by low volume surgeons. The only published outcomes data available from this setting have been extrapolated from incomplete and flawed national/regional databases. These publications reveal inferior outcomes compared to high volume tertiary care institutions, and especially when compared to many small Western European countries with socialized healthcare allowing coordinated national efforts to implement so-called rectal cancer “centers of excellence”.^{1,2,5} At present, “most radical resections for rectal cancer in hospitals in the United States result in a colostomy”¹ as 40% of US surgeons performed ONLY non-restorative proctectomy for rectal cancer,³ associated with a “lack of standard use of neoadjuvant radiation”.¹

Neoadjuvant chemoradiotherapy combined with the precision of TME has had a significant impact on lowering the recurrence rate of rectal cancer, increasing sphincter preservation and improving mortality/survival statistics. Surgeon volume to achieve and maintain proficiency is believed to be > 10 rectal resections per surgeon per year and institution volume >25 cases per year.³ Given the ongoing debate regarding methods of improving rectal cancer outcomes in the US, some authors have proposed establishing rectal cancer “centers of excellence”,^{1,5} similar to the successful European approach.²

The current study reveals that standard oncologic techniques of rectal resection combined with access to neoadjuvant therapy may

Table 1a
Description of patient population.

Total number of Patients	109
Race (%)	104 White (95)/5 Non-White (5)
Age, mean (range)	60.7 years (28–88 years)
Sex, number (%)	
Male	68 (62)
Female	41 (38)
BMI, mean (range)	27.9 (16.1–46.6)
ASA Class, number (%)	
1	5 (4.5)
2	48 (44)
3	49 (45)
4	7 (6)
Tumor Location from Dentate Line, n (%)	
0–5 cm “Low rectum”	59 (54)
>5–10 cm “Middle rectum”	43 (39)
>10–15 cm “High rectum”	7 (6)
Operation, number (%)	
Hartmann’s Procedure	5 (4.5)
LAR + Loop Ileostomy (3 ‘delayed’ loop)	38 (35)
Coloanal (all with loop ileostomy)	23 (21)
APR (including 2 proctocolectomies)	43 (39)
Additional Organs Resected, number of patients	
Appendectomy	77
BSO/SO	15
TAHBSO	10
Cholecystectomy	6
Posterior Vaginal Wall (en bloc)	5
Meckel’s Diverticulum	4
Wedge Liver Resection/Biopsy	2
Ileal Resection (radiation damage)	1
Lymph Node Harvest, mean (range)	10.5 (0–38)
Time for Operation, mean minutes (range)	245.4 (139–392)
EBL, mean mL (range)	471.4 (50–2100)
Days to Tolerating 1st Diet, mean days (range)	7.2 (4–26)
Length of Stay, mean days (range)	9.2 (5–28)
TNM Stage, number (%)	
CR	22 (20)
1	32 (29)
2	28 (26)
3	22 (20)
4	5 (5)

provide rectal cancer outcomes that rival those of tertiary care centers. Table 1c provides a side-by-side comparison of outcomes of open resection in the current study to contemporary data of open resection from a tertiary care institution in the same state (Missouri)⁶ and from ACOSOG Z6051, a multi-institution study including only select specialist surgeons who demonstrated proficiency in rectal cancer resection by videotape of operations and graded rectal specimens before being accepted to participate in the study.⁷ The following outcomes from the current study were comparable to the contemporary studies in Table 1c including: R0 resection, lymph node (LN) harvest, anastomotic leak rate, complication rate, hospital LOS, readmission rate, LR rate and 5-year DFS.

The National Accreditation Program for Rectal Cancer (NAPRC) proposes evidence-based quality-of-care measures and standards centered around multidisciplinary care established under the

auspices of the American College of Surgeons Commission on Cancer.⁸ This is an attempt to alleviate volume differences and improve rectal cancer outcomes, including survival, by standardizing rectal cancer care through widespread adoption of NAPRC

Table 1b
Overall survival and disease-free survival (DFS) by stage of rectal cancer.

Pathologic Stage	Total # Patients	Overall Survival	Disease-Free Survival
Stage 0 (CR)	22 patients	22/22 (100%)	22/22 (100%)
Stage 1	32 patients	29/32 (91%)	28/32 (88%)
Stage 2	28 patients	20/28 (71%)	19/28 (68%)
Stage 3	22 patients	14/22 (64%)	11/22 (50%)
Stage 4	5 patients	0/5 (0%)	0/5 (0%)

= number.

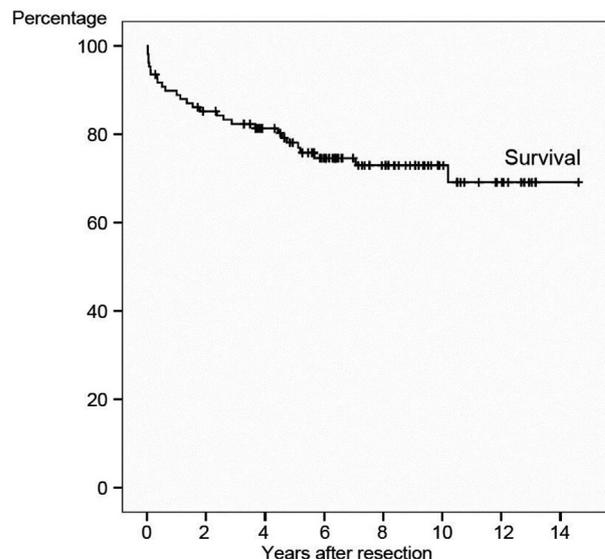


Fig. 1. Kaplan-Meier analysis of overall survival.

Table 1cComparison to contemporary studies from a tertiary care center in the state of Missouri⁶ and a multi-institutional trial (ACOSOG Z6051) of select specialist surgeons.⁷

	⁶ Washington U. St. Louis, MO	⁷ ACOSOG Z6051	Current Study
Years of Study	2001–2005	2008–2013	1999–2010
Patient Exclusions	T ₄ , ASA IV & V	^a	Hx rectal ca resection
Number of Patients	108	222	109
Race	–	87% White	95% White
Age, mean years (range)	61 ± 14 (21–94)	57	61 (28–88)
Sex, number (%)			
Male	62 (57)	158 (66)	68 (62)
Female	46 (43)	81 (34)	41 (38)
BMI, mean (range)	29 ± 5 (19–44)	27	28 (16–47)
ASA Class, number (%)			
1	5 (5)	–	5 (5)
2	70 (65)	–	48 (44)
3	33 (31)	–	49 (45)
4	→	–	7 (6)
Tumor Location			
“High” (8/10–12/15 cm)	29%	12%	6%
“Middle” (4/5–8/10 cm)	36%	40%	39%
“Low” (0–4/5 cm)	35%	49%	54%
Neoadjuvant Therapy	82%	100%	100%
Time for Operation, mean (range)	173 (68–360 min)	221	245 (139–392 min)
Estimated Blood Loss (range)	421 (75–1800 mL)	318	471 (50–2100 mL)
TNM Stage, number (%)			
Complete Response	10 (11)	43 (19)	22 (20)
1	33 (37)	68 (31)	32 (29)
2	19 (21)	50 (22)	28 (26)
3	27 (30)	65 (29)	22 (20)
4	–	3 (1)	5 (5)
No. Harvested LNs(mean)	11	17	11
Primary Anastomosis	73%	76%	56%
Method of Coloanal Anastomosis	Stapled	–	Hand-Sewn
Anastomotic Leak Rate	7%	2%	7%
Distal Resection Margin- Negative	–	98%	94%
CRM- Negative	93%	92%	–
Time to Tolerating 1st meal (mean)	4 days	–	7 days
Hospital Length of Stay (mean)	9 days	7 days	9 days
Complication Rate	44%	54%	42%
30 Day Mortality Rate	2%	1%	5%
Readmission Rate	26%	4%	18%
Median Follow-up Time	59 months	–	75 months
Local Recurrence Rate	4%	–	3%
5-Year Overall Survival	89%	–	78%
5-Year DFS	76%	–	73%

^a History of invasive pelvic malignancy within 5 years, psychiatric or addictive disorders, ASA IV & V, systemic disease (e.g. cardiovascular, renal, hepatic), multiple previous laparotomies or severe adhesions, BMI >34, T₄ or Stage IV rectal cancer and Eastern Cooperative Oncology Group performance score <3.

guidelines versus efforts to merely centralize care.^{8,9} Funneling all rectal cancer cases to a central institution may be successful in small western European countries or New England States the size of Rhode Island or Vermont, however, replicating this approach throughout the continental US is problematic. For example, the bariatric surgery experiment with Centers for Medicare and Medicaid Services (CMS) ONLY reimbursing for procedures performed in certified “centers of excellence” backfired and actually resulted in a DECREASE in access to qualified care, diminished outcomes and the subsequent abandonment of these certification and reimbursement policies by CMS.¹⁰

Similarly, centralizing rectal cancer care to select high-volume institutions may seem to be an “ideal model”, however, “full enactment of this model may not be realistic or practical in the United States” with travel distance and socioeconomic status major barriers.³ Aquina and associates note the “increased travel distances and cost of travel may impose substantial obstacles to certain patient populations, such as those who are living in rural areas, are elderly, or have limited financial resources ... or who have Medicaid insurance” and end up being treated at non-high volume hospitals by non-high volume surgeons.³ Etzioni and associates agree that while the concept of centers of excellence may seem “an

attractive option”, the “concept often becomes mired in pragmatic considerations regarding criteria for certification and the propensity of payers to restrict payment based on certification. Historically the approach has not worked well within the health care free market that currently exists in the United States”.¹¹ Xu and colleagues note, “targeting standardizing quality of care through widespread adoption of NAPRC standards, as opposed to centralization alone, could help mitigate volume differences and improve outcomes and survival in patients with rectal cancer”.⁹ Formal education outreach, including clinical practice guidelines and workshops established via ACS chapters has been successful in significantly increasing the use of neoadjuvant chemoradiotherapy (43%–86%) and the TME technique (35%–71%) over a 5-year time period, resulting in decreased rates of local recurrence of rectal cancer in the Canadian province of British Columbia.

High rectal cancer recurrence rates in the Canadian province of Manitoba could be directly attributed to the absence of access to radiotherapy, so that patients living outside of Winnipeg (the ONLY city offering radiotherapy in the entire province) and therefore without access to radiotherapy had higher rates of recurrence and diminished survival. Therefore, improvement in surgical technique alone would have limited impact outside of Winnipeg, given the

absence of access to neoadjuvant radiotherapy for patients in the rest of Manitoba.¹⁰ The combination of optimal surgical technique and access to radiotherapy is a must.

Outcomes of a high volume surgical specialist in a low volume community hospital setting in the current study were comparable to published outcomes from high volume surgeons in high volume tertiary care institutions across the US and Canada. Ricciardi and colleagues studied hospital discharge data following rectal cancer surgery from 21 states and found the “data reveal that availability of specialty surgeons is more important than any other variable in determining whether a patient undergoes a restorative vs non-restorative proctectomy for rectal cancer in the United States” with a call to “standardize care for rectal cancer across the country”.⁴

Combining the surgical expertise and experience in performing TME with increased access/use of neoadjuvant therapy results in improved outcomes, including improved rates of SP, LR and overall survival. Patients with access to multispecialty expertise in rectal cancer treatment, even in a hospital that might otherwise be described as “low” volume, may also have outcomes approaching those from established and recognized tertiary care centers. This may be particularly important given the finding that “patients were often inclined to receive complicated surgical care at a local center, even with the knowledge that their likelihood of mortality was distinctly lower with travel to a regional center”.¹¹ Besides the fact that patients may be unwilling to travel, in one study of 6938 patients who underwent major surgery at a tertiary-care center, patients who traveled farther for their care had outcomes that were WORSE than expected. This phenomenon, named “reverse distance bias”, may reflect the negative impact of long distance travel for surgical services or perhaps merely reflect the increased severity of the underlying disease state in those patients who travelled.¹¹

The obstacle of travel distance to surgical specialists in tertiary care centers may have contributed to the results of a Surveillance, Epidemiology, and End Results-Medicare program study which revealed that 26.6% of the time rectal resection was performed by ABCRS-certified surgeons during nonurgent hospitalization, however, this rate fell dramatically to 13.6% for urgent hospitalization.¹² Hence, emergency conditions, such as obstruction or hemorrhage, may not allow travel to surgical specialists. Considering the limitations of emergency surgery, low socioeconomic status, absence of insurance or patient preference to have their healthcare needs provided close to home, non-specialist surgeons at local community hospitals will continue to play an important role in the care of these patients.

Collaborative efforts to educate non-specialist surgeons on TME and the use of neoadjuvant therapy have been successful in both Canada (via chapters of the ACS) and Europe.¹⁰ Whichever way efforts to improve the outcomes of rectal cancer management are directed in the US, standardized care versus centralized care, we can all agree with the sentiments of Etzioni and colleagues, “What is the best means by which to tailor a ‘match’ between the needs of a patient and the available skills of the surgical community? As the fields of general surgery and its subspecialties evolve, these questions should be addressed in a way that maximizes quality of patient care.”¹²

Efforts to centralize or regionalize rectal cancer care to ‘centers of excellence’ with the goal to improve access to appropriate imaging, oncology services, neoadjuvant therapy, standard techniques of resection and pathologic examination/staging of specimens, patterned after the European experience, may be achievable in small states/countries or densely populated areas, however, the rural expanse of North America presents a significant obstacle to overcome. Therefore, given the challenges of travel, advanced age, frailty, and financial constraints of this patient population, it is

obvious that local community hospitals and their surgeons will continue to play a significant role in the care of these patients. In this context, efforts to patchwork local multidisciplinary teams of qualified specialists, including the acquisition of a surgical specialist, as in the current study, or enhancing the TME skills of general surgeons (education workshops, designation of a rectum specialist within a group to consolidate and increase caseload) has a better chance of advancing the ultimate goal of standardizing rectal cancer care and thus improving cancer outcomes across the continental US versus the inflexible, “one size fits all” European-style centralization model.

Summary sentence

Efforts to centralize rectal cancer care to ‘centers of excellence’ patterned after the European experience, may be achievable in small states/countries or densely populated areas, however, the rural expanse of North America presents a significant obstacle to overcome. Given the challenges of travel, advanced age, frailty, and financial constraints of this patient population, local community hospitals and their surgeons will continue to play a significant role in the care of these patients. In this context, efforts to patchwork local multidisciplinary teams of qualified specialists, including the acquisition of a surgical specialist, as in the current study, or enhancing the TME skills of general surgeons (education workshops, designation of a rectum specialist within a group to consolidate and increase caseload) has a better chance of advancing the ultimate goal of standardizing rectal cancer care and thus improving outcomes across the continental US versus the inflexible, “one size fits all” European-style centralization model.

Conflicts of interest

No conflicts of interest.

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