

Multidisciplinary Management of Rectal Cancer: the OSTRICH

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Surgical Treatment of Rectal Cancer (OSTRiCh)

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Abstract

Background Disparity exists in outcomes for rectal cancer patients in the US. Similar problems in several European countries have been addressed by the creation of national networks of rectal cancer centers of excellence (CoEs) that follow evidence-based care pathways and specified protocols of care and process and are certified by regular external validation.

Aim This paper reviews the current status of rectal cancer care in the US and examines the evidence for multidisciplinary rectal cancer management. A US rectal cancer CoE system based on the existing UK model is proposed.

Methods A literature search was performed for publications related to US rectal cancer outcomes, multidisciplinary management of rectal cancer, and European rectal cancer programs.

Results US rectal cancer outcomes are highly variable. The majority of US rectal cancer patients are treated by generalists in low-volume hospitals. Current evidence supports five main principles of rectal cancer care that have been incorporated into European rectal cancer CoE programs. These programs have dramatically improved rectal cancer outcomes in Scandinavian countries and the UK.

Conclusions A similar CoE program should be established in the US to improve the outcomes of rectal cancer patients.

Keywords Rectal cancer · Centers of excellence · Multidisciplinary management · Multidisciplinary team · OSTRiCh · Total mesorectal excision

Introduction

Over 40,000 patients annually are diagnosed with carcinoma of the rectum each year in the USA, and approximately half will ultimately die as a consequence of the disease (<http://www.cancer.gov/cancertopics/types/colon-and-rectal>).^{1,1} Rectal cancer represents a significant healthcare problem in terms of incidence, lethality, and healthcare resource

consumption. The treatment of rectal cancer is also extremely complex. Surgical procedures are complicated by the challenges of operating in the narrow confines of the bony pelvis where surrounding structures are at risk for inadvertent injury and strict planes of dissection must be maintained in order to maximize chances of cure. Restoration of intestinal continuity can also be difficult with risk for significant complications related to anastomotic leak. In addition, healthcare providers are faced with complex treatment decisions regarding the risks and benefits of neoadjuvant and adjuvant therapy and these decisions rely heavily on the ability to perform high-quality preoperative imaging and postoperative pathology assessment of the primary tumor and lymph nodes. Due to the complexity of rectal cancer care, a huge variation has been described in the results of rectal cancer surgery worldwide, with statistically significant differences in curative resection rates, postoperative morbidity and mortality, and long-term oncologic outcomes among both surgeons and hospitals.² While national care delivery systems based on centers of excellence (CoE) model have been successfully established in several European countries over the past decade to address this disparity in care, no such effort has been undertaken in the USA.

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Current Status of Rectal Cancer Care in the USA

The quality of rectal cancer care in the USA is highly variable. While a small percentage of patients receive treatment at some of the busiest and most highly specialized rectal cancer centers in the world, the majority are treated in low-volume hospitals by surgeons and providers with no specialty training. A number of studies have been published which clearly illustrate the consequences of this variability in care, and the impact of the US generalist-centered model of rectal cancer care on oncologic outcomes, complications, and rates of permanent stoma. Variations in local recurrence rates between 0 and 13 % for colorectal surgeons and between 21 and 37 % for general surgeons have been demonstrated.^{3–5} Differences in mortality rates based on surgeon specialization have been found with rates of 1.4 % for colorectal surgeons and over 7 % for general surgeons being reported.⁵ The specialization of the surgeon has also been found to impact permanent stoma rates. A 2010 study of 20,000 proctectomies for rectal cancer using US county-level data found that 50 % of patients were left with a permanent stoma and the abdominoperineal rate (APR) exceeded 60 % in one fourth of the counties studied.^{5,6} The same authors have also found that 40 % of surgeons treating rectal cancer in the USA only perform non-restorative procedures (APR) for their patients and that these patients suffer higher mortality rates and longer lengths of stay as compared to those treated by specialists.^{7,8} Hospital volume has also been correlated with outcomes, as a recent US study found higher mortality, longer length of stay, and lower rates of sphincter preservation in low volume (<5 cases/year) hospitals compared to those caring for >10 cases annually. The real impact of this discrepancy, as well as the potential for improvement in patient care, is illustrated by the fact that of the 321 hospitals analyzed, nearly 75 % were classified as low volume.

OSTRiCh

OSTRiCh (Optimizing the Surgical Treatment of Rectal Cancer) is a consortium of 18 North American (17 USA and 1 Canadian) healthcare institutions that have come together with the purpose of transforming the delivery of rectal cancer care in the USA. The group was founded in 2011 at the inaugural meeting in Cleveland, Ohio, at which time the evidence for and causes of the existing disparities in US rectal cancer care were reviewed and broad plans to address the problem were created based on European endeavors of the past two decades. The group realizes the significant economic and political barriers that exist in the USA to raising the quality and uniformity of rectal cancer care, but is fully committed to achieving this goal. The OSTRiCh Consortium is a diverse group with no formal ties to any

particular society and individual representatives of the member institutions are active in all of the pertinent surgical societies (American College of Surgeons (ACS), Commission on Cancer, American Society of Colon and Rectal Surgeons (ASCRS), Society of Surgical Oncology, Society for Surgery of the Alimentary Tract, Society of Gastrointestinal and Endoscopic Surgeons). While OSTRiCh is clearly a surgeon-led initiative, the multidisciplinary nature of rectal cancer management demands that the group include representatives from pathology, radiology, and medical and radiation oncology. Members of the College of American Pathologist (CAP) and the American College of Radiology (ACR) have been added and the OSTRiCh plan has been presented at the annual meeting of the American Society of Clinical Oncology (ASCO). At the institutional level, OSTRiCh members represent most facets of the US healthcare delivery system; both large and small private clinics, university-affiliated hospitals, large healthcare systems, and smaller community hospitals.

One of the underlying principles of OSTRiCh is a spirit of inclusion rather than exclusion, as the ultimate goal is to provide access to high-quality rectal cancer care for all Americans, not just those living in proximity to existing expert centers. Achieving this goal will require the creation of new centers of excellence (CoEs) throughout the USA, each housing a highly trained multidisciplinary team administering a standard care pathway based on the five core principles of evidence-based rectal cancer care outlined below.

Evidence for the Multidisciplinary Management of Rectal Cancer

Current evidence supports the adoption of five main principles of rectal cancer care: (1) total mesorectal excision (TME); (2) measurement of quality of surgery by specific techniques of pathology assessment; (3) specialist imaging techniques identifying those patients at high risk of local recurrence; (4) the use of newer more effective neo-adjuvant and adjuvant therapies include radiotherapy and chemotherapy; and (5) a multidisciplinary team (MDT) approach that identifies, coordinates, delivers, and monitors the ideal treatment on an individual patient by patient basis.

Total Mesorectal Excision

Good surgical technique is vital to optimizing oncological outcome and minimizing morbidity in rectal cancer surgery. Proctectomy following the principles of TME maintains the integrity of the mesorectal fascial envelope by sharp, direct vision dissection of the plane between the mesorectal fascia and the presacral and endopelvic fascia. The ability of TME to lower local recurrence rates and increase survival has been

widely documented.^{9–11} Importantly, TME has also been demonstrated to be readily teachable. The training of surgeons and wide implementation of TME has been shown to reduce permanent stoma rates, decrease the incidence of local recurrence, and to improve 5-year survival in population-based studies.¹²

Pathology

Pathologic assessment of tumor stage (TNM) and margin status are widely known as the most important prognostic factors in rectal cancer. However, pathology grading of the TME specimen has also been shown to be an important indicator of surgical quality and resultant oncologic outcomes.^{13,14} Analysis of the plane of surgery and circumferential resection margin (CRM) status in patients enrolled in a large randomized controlled trial of preoperative radiotherapy provides evidence for the association between surgical quality and outcomes and the role of the pathologist in surgical quality assessment. The authors found the CRM to be involved with cancer in 11 % of cases and the plane of surgery achieved was classified as good (mesorectal plane) in 52 %, intermediate in 34 % and poor in 13 % of cases. At 3 years, the estimated local recurrence rates were 4 % for the group with a good plane of dissection compared to 13 % for the poor group and patients who had preoperative short-course radiotherapy and a resection in the mesorectal plane had a 3-year recurrence rate of only 1 %.¹⁵ It has been proposed that pathologists who are trained in specialized methods of rectal cancer specimen assessment would form an important component of the direct quality assurance of rectal cancer surgery.¹⁴

Imaging

Imaging of rectal cancer has evolved significantly in the last decade. In Europe, MRI has become the standard for the pre-treatment imaging of rectal cancer based on its accuracy in predicting the CRM, tumor invasion of adjacent pelvic structures, and, to a lesser degree, tumor (T)- and nodal(N)-stage.^{16,17} Routine use of MRI in the context of a multidisciplinary assessment of rectal cancer has been used to plan neoadjuvant therapy and surgery and has been shown to reduce the incidence of positive circumferential margins.^{18,19} MRI-based treatment planning may also allow for the more efficient use of neoadjuvant therapy, an important factor in potentially reducing both the costs and morbidity of rectal cancer care.²⁰

Adjuvant and Neoadjuvant Therapy

Preoperative chemoradiotherapy (CRT) is the current preferred treatment strategy for a significant proportion of US rectal cancer patients. The potential advantages for delivery

of chemotherapy and/or radiotherapy preoperatively include decreased tumor seeding at operation, less acute toxicity, and increased radio-sensitivity due to the higher oxygen content of tumor cells before surgery.²¹ The main disadvantage is the potential for overtreatment of patients with early stage tumors due to overstaging by preoperative imaging.²² Preoperative short-course radiotherapy (SCRT) has been shown to reduce local tumor recurrence and mortality compared with surgery alone and is superior to postoperative radiotherapy.²³ Compared to preoperative SCRT, preoperative CRT also results in tumor downsizing and has been shown to improve local control in resectable stages II and III rectal cancer and potentially improves sphincter preservation.²⁴ However, neoadjuvant therapy also carries risks. Preoperative radiotherapy can lead to increased sexual dysfunction and altered bowel function.^{25,26} Surgery in patients treated with neoadjuvant therapy is also more likely to include a temporary diverting ileostomy, which adds to the time and cost of treatment and may temporarily decrease quality of life. The potential for these adverse effects underscores the importance of accurate staging and offering neoadjuvant therapy only to appropriately selected patients. Adjuvant systemic chemotherapy reduces mortality compared with surgery alone in patients with stage III colon cancer and a similar benefit is felt to exist in stage II and III rectal cancer patients; however, the magnitude of this benefit is not clear. The addition of oxaliplatin and irinotecan may improve 5-year survival in rectal cancer patients but this is also associated with higher toxicity.²⁴ Another area of controversy is the need for adjuvant chemotherapy in patients achieving a complete pathologic response after preoperative CRT and TME. Therefore, the increasing complexity of adjuvant and neoadjuvant therapy lends itself very well to a multidisciplinary discussion of each rectal cancer patient in order to provide evidence-based and individualized treatment.

Multidisciplinary (MDT) Approach

Cancer-specific outcomes are better when patients are managed according to the principles of MDT care. There is increasing evidence that MDTs are associated with improved clinical decision making, clinical outcomes, and patient experience in several cancer types, including rectal.^{27–31} Accordingly, the American College of Surgeons Commission on Cancer has recognized the importance of the MDT in treatment planning for cancer patients and has included it as a key program requirement.³² The rectal cancer MDT consists of surgeons, radiation and medical oncologists, radiologists, pathologists, and key nursing professionals and its implementation in European countries several has resulted in lower rates of permanent stoma, reduced rates of local recurrence, greater delivery of evidence-based care, and improved overall survival.^{19,33}

Scandinavian and UK Experience

The present status of rectal cancer care in the USA is similar to what existed in both Scandinavia and the UK 20 years ago.³⁴ In response to this variability in quality of care, those countries established rectal cancer CoE's based on the core principles discussed above. That effort has resulted in a significant improvement in both short and long-term outcomes in rectal cancer patients on a population-wide basis. European experience revealed significant benefits when patients with rectal cancer were directed towards specialist centers. The philosophy was to have more patients treated by fewer centers thereby increasing overall quality of care. The mechanism used to alter the flow of patients in this way has varied from country to country based on their health care delivery system. For example, because of the their single-payer system, Norway, Sweden, and Denmark simply designated existing hospitals as rectal cancer CoEs and required that patients be treated only in these locations.³⁵⁻³⁸ In the UK, a different approach was taken whereby the designation of a CoE was based on the willingness and ability of the hospital to follow evidence-based care standards and to meet and demonstrate specific measures of care delivery. These standards covered various factors including volume of practice and volume and skills of workforce including minimum requirements for surgeons, oncologists, radiologists, and pathologists dedicated to rectal cancer care. In addition, patient care was delivered according to agreed protocols of care and process. Cancer units and cancer centers were set up with specified goals and remits.³⁹ A key component of the initiative was the Peer Review Program requiring a process of prospective data collection and monitoring, annual self-assessment, internal validation, and finally external verification. Stringent adherence to these standards resulted in a fundamental change in delivery of patient care and within a decade the overwhelming majority of patients with rectal cancer were being managed within CoEs verified as meeting these care standards.⁴⁰⁻⁴² This has subsequently translated into improvements in clinical outcome where, for example, permanent stoma rates have significantly fallen on a population basis.⁴³ Improvements are also evident in more appropriate preoperative treatment³³ and improved 5-year survival.¹⁹

Ostrich Proposal

The OSTRiCh consortium has proposed a plan whereby a system of rectal cancer CoEs would be established throughout the USA. The program would be closely modeled after that which is already in existence in the UK and would include the key components of standardized and evidence-based care

pathways, establishment and training of MDTs, internal collection and validation of data, and external verification of process adherence. An application was made in January 2012 to the Center for Medicare and Medicaid Services for funding of an OSTRiCh pilot program via the Healthcare Innovation Challenge Program. The grant was not funded; however, in the ensuing year the OSTRiCh group has continued to meet and to refine its proposal. Key stakeholders in the effort have been identified (ASCO, ACR) and others have been recruited and have participated in the meetings (ACS, CAP). The centerpiece of the proposal is a comprehensive education and training program that would require all members of a proposed CoE's MDT to attend a 2–3-day session where the evidence-based care pathways would be presented and the individual members of the team would undergo parallel expert level training in their particular functions (for example, training in rectal cancer MRI (radiologists), training in pathology assessment and reporting (pathologists), etc.). The ASCRS is currently developing a TME training module which will be incorporated into the program for the education and certification of surgeons in the proper technique of rectal cancer surgery. MDT members would also receive group training in team building, patient communication, data collection and reporting, internal validation, and program administration.

Conclusion

The quality of rectal cancer care in the USA is highly variable. The OSTRiCh group has been created in an attempt to transform the delivery of rectal cancer care in the USA through implementation of a CoE program based on five principles of rectal cancer care that have led to dramatic improvements in outcomes in several European countries. This model, based largely on that already in existence in the UK, would improve access of US patients to uniform and high-quality rectal cancer treatment. By following evidence-based care pathways and specified protocols of care and process, it is hypothesized that oncologic outcomes would be improved, costs would be reduced, and patient satisfaction would be increased on a national level.

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CME/MOC Questions

1. Regarding rectal cancer care in the United States, which of the following statements is true?

- a. The majority of rectal cancer surgery is performed by specialist surgeons in high-volume hospitals.
- b. Less than 20 % of patients with rectal cancer are left with a permanent stoma.
- c. Surgeon specialization has been shown to impact the risk for local recurrence, permanent stoma rates, and postoperative mortality.
- d. Hospital volume has not been found to impact rectal cancer outcomes.

Answer: c

2. Current evidence supports the adoption of each of the following principles of rectal cancer care EXCEPT:

- a. Rectal resection using the technique of “total mesorectal excision”.
- b. Abdominoperineal resection for all tumors with 10 centimeters of the anal verge.
- c. A multidisciplinary team approach for individualized treatment planning.
- d. Measurement of quality of surgery by specific techniques of pathology assessment.

Answer: b

3. The technique of total mesorectal excision is:

- a. based on blunt pelvic dissection.
- b. unlikely to significantly improve oncologic outcomes.
- c. responsible for increasing permanent stoma rates.
- d. readily teachable to interested surgeons.

Answer: d

4. Which of the following statements regarding pathology reporting after rectal cancer resection is true?

- a. Circumferential resection margin is a weak predictor of risk for local recurrence
- b. Tumor (T) stage is the strongest predictor of risk for local recurrence
- c. Specialized methods of rectal cancer specimen assessment are of limited value in surgical quality assessment and should be abandoned
- d. Mesorectal grading is an important indicator of the quality of surgery

Answer: d

5. MRI-based imaging of rectal cancer can be used to predict each of the following EXCEPT:

- a. Tumor (T) stage
- b. Nodal (N) stage
- c. Mesorectal grade
- d. Circumferential resection margin

Answer: c

6. Potential advantages of neoadjuvant radiation therapy in patients with rectal cancer include all of the following EXCEPT:

- a. decreased tumor seeding at operation
- b. overtreatment of patients with early stage tumors
- c. less acute toxicity
- d. increased tumor radio-sensitivity

Answer: b

7. Potential disadvantages of neoadjuvant radiation therapy in patients with rectal cancer include:

- a. sexual dysfunction
- b. altered bowel function
- c. need for temporary ileostomy
- d. all of the above

Answer: d

8. Implementation of a multidisciplinary team approach to rectal cancer care in several European countries has resulted in each of the following EXCEPT:

- a. increased rates of permanent stoma
- b. reduced rates of local recurrence
- c. greater delivery of evidence based care
- d. improved overall survival

Answer: a