General Assembly Meeting
May 19, 2014

Consortium for Optimizing Surgical Treatment of Rectal Cancer

www.ostrichconsortium.org
Agenda

1. Welcome and History of OSTRiCh
2. Current Status of U.S. Rectal Cancer Care
3. Case Study: UK Rectal Cancer Model and OSTRiCh Proposal
4. OSTRiCh/ACS/CoC Centers of Excellence Partnership
5. Update from OSTRiCh Council Meeting
History of OSTRiCh

Feza Remzi, MD
OSTRiCH
Consortium for Optimizing Surgical Treatment of Rectal Cancer

- Established 2011
- Members represent all facets of U.S. healthcare delivery system
  - Private clinics, academic centers, community hospitals
  - Diverse in size and geography
- Independent consortium with broad representation of pertinent societies
  - ACS, CoC, ASCRS, SSO, SSAT, SAGES, CAP, ACR
Mission

- The Consortium for Optimizing the Treatment of Rectal Cancer (OSTRiCh) is a diverse group of healthcare institutions dedicated to improving the quality of rectal cancer care in the U.S. through advocacy, education, and research.

- 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.
August 2011

- Cleveland Clinic
- University of Rochester
- Mayo Clinic
- MD Anderson
- Memorial Sloan Kettering
- Washington University in St Louis
- University of Minnesota

- Boone Hospital Center
- Medical College of Wisconsin
- The Oregon Clinic
- Johns Hopkins
- Lahey Clinic
- University of Toronto
- Ochsner Clinic
May 2014

- Cleveland Clinic
- University of Rochester
- Mayo Clinic
- MD Anderson
- Memorial Sloan Kettering
- Washington University St Louis
- University of Minnesota
- Boone Hospital Center
- Medical College of Wisconsin
- The Oregon Clinic
- Johns Hopkins
- Lahey Clinic
- University of Toronto
- Ochsner Clinic
- Kaiser Permanente
- Duke University Med Ctr
- University of Washington

- Baylor University Med Ctr
- University of North Carolina
- University of Michigan
- Geisinger Medical Center
- Summa Health System
- Jersey Shore University Med Ctr
- Inova Fairfax Med Campus
- Oregon Health and Sciences Univ
- Mayo Clinic Florida
- University Hospitals Case Med Ctr
- Dartmouth-Hitchcock Med Ctr
- Monmouth Med Ctr
- St. Clair Hospital

- ProMedica Health System
- Central Michigan University
- St Francis Hospital (TN)
- Fairview Southdale Hospital (MN)
- Hima Hospital Caguas (PR)
- Norwalk Hospital
- University of Maryland
- Parkview Health System (IN)
- Spectrum Health/Ferguson Clinic
- Bayfront Med Ctr (FL)
- Florida Hospital
- Mass. General Hospital
- John Muir Medical Center
- University of Nevada
- University of Virginia
Optimizing the Surgical Treatment of Rectal Cancer

We are a group of healthcare institutions that have come together with the purpose of improving the quality of rectal cancer care in the U.S.

Our Mission

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 Rectal Cancer Centers throughout the U.S., each housing a highly-trained multidisciplinary team administering a standard care pathway based on the five core principles of evidence-based rectal cancer care.

Become a Partner

If you are interested in participating in this important initiative to improve the care of our patients with rectal cancer, please fill out the form on our registration page.

Recent News

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Learn More

Resource Library

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Learn More

Upcoming Events

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Learn More
Need for Rectal Cancer Centers of Excellence Program

Multidisciplinary Management of Rectal Cancer: the OSTRICH

David W. Bates, on behalf of the Consortium for Optimizing Surgical Treatment of Rectal Cancer (OSTRICH)

Presentations at annual meetings of the American Society of Clinical Oncology, Society for Surgery of the Alimentary Tract, American College of Surgeons, American Surgical Association
Current Status of U.S. Rectal Cancer Care

John Monson, MD
Quality of Rectal Cancer Care in U.S. is **Highly** Variable

- Vast majority of surgery for rectal cancer performed by non-specialists in low-volume hospitals
- Rates for permanent colostomy variable and excessive
- Suboptimal adherence to evidence-based guidelines
- Oncologic outcomes?

“Cancer Lottery”
Who Performs Surgery for Rectal Cancer in the U.S.?

• Hospital discharge data from 11 states during 24 month period (2003-2004)
• >7500 proctectomies by 2600 surgeons

• 40% of surgeons performed **ONLY** non-restorative procedures (APR)!
• “Non-restorative” (APR) surgeons had higher mortality rates and longer lengths of stay
• “Restorative” (LAR) surgeons were **specialized** by virtue of more pelvic pouch and anorectal procedures

Ricciardi et al, Dis Colon Rectum 2011
Variability in Reconstructive Procedures Following Rectal Cancer Surgery in the U.S.

- 20,000 proctectomies (2002-2004)
- County-level data for 21 states

```
<table>
<thead>
<tr>
<th>Colostomy, %</th>
<th>County totals</th>
<th>All counties, %</th>
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</thead>
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<tr>
<td>0-20</td>
<td>11</td>
<td>2.2</td>
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<tr>
<td>21-40</td>
<td>87</td>
<td>17.8</td>
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<td>41-60</td>
<td>266</td>
<td>54.4</td>
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<td>61-80</td>
<td>107</td>
<td>21.9</td>
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<tr>
<td>81-100</td>
<td>18</td>
<td>3.7</td>
</tr>
<tr>
<td>All</td>
<td>489</td>
<td>100</td>
</tr>
</tbody>
</table>
```

- 50% of cases non-restorative (APR)!
- Only 20% of counties with colostomy rate <40%!

Ricciardi et al, Dis Colon Rectum 2010
## Hospital Volume and Rectal Cancer Surgery Outcomes

<table>
<thead>
<tr>
<th>Hospital Volume</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yearly case volume (avg)</td>
<td>1-5</td>
<td>6-10</td>
<td>11-24</td>
<td></td>
</tr>
<tr>
<td>Number of hospitals</td>
<td>232</td>
<td>65</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>2364</td>
<td>2686</td>
<td>2137</td>
<td></td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>2.1</td>
<td>1.1</td>
<td>0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Complications (%)</td>
<td>22</td>
<td>24</td>
<td>20</td>
<td>0.709</td>
</tr>
<tr>
<td>Sphincter preservation (%)</td>
<td>51</td>
<td>55</td>
<td>64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of stay (mean # days)</td>
<td>9.7</td>
<td>9.2</td>
<td>8.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

California Office of Statewide Health Planning and Development database (2000-2005)

Adherence to Evidence-Based Guidelines

- NCDB data 2006-2011
- Clinical stage II/III rectal cancer patients (n=32,171)

- Examined adherence to evidence-based guidelines for neoadjuvant therapy use based on center type and geographic location

- Significant variation found
  - Academic (79%) vs. Community (71%) (p<0.001)
  - Midwest (81%) vs. South (70.7%) (p<0.001)

How Well are the “Expert” U.S. Centers Performing?

Cleveland Clinic Colorectal Cancer MDT Conference
Practice Patterns at OSTRiCh Hospitals

- >2000 patients undergoing surgery for rectal cancer at 16 centers in 2010
  - ~ 130 patients/center
  - Range 39-350

**Good News**

- All surgeons either ASCRS/SSO/SSAT/SAGES members
- All surgeons performed TME
- All centers with MDT
- 94% held “regular” MDT conferences
OSTRiCh Practice Patterns

Bad News

- Frequency of MDT meetings varied
- All cases discussed at only 20% of centers
- Majority of centers discussed < 50% cases
- Little standardized pathology reporting
- MRI validated in only one-fourth of centers and standardized reports in less than half
Quality in Rectal Cancer Care

• Proper surgical technique
  • Total Mesorectal Excision (TME)

• Evidence-based treatment
  • Neoadjuvant and adjuvant therapy

• Multidisciplinary team approach by specialist providers
Multidisciplinary Team Management of Rectal Cancer

Radiology Specialist

Rad Oncology Specialist

Surgeon Specialist

Med Oncology Specialist

Pathology Specialist
Evidence for MDT Management

• Abundant evidence supports improved outcomes with MDT management in other cancers
  • Breast
  • Head and Neck
  • Esophagus
  • Lung

European Rectal Cancer Models and OSTRiCh Proposal

David Dietz, MD
Rectal Cancer Centers of Excellence
Swedish Experience

- Centralization of 4 hospitals into 1 CoE
- Local recurrence decreased from 8% to 3.5% (p=0.04)
- 5 year survival increased from 38% to 62% (p=0.003)
- Multivariate analysis: new colorectal unit independent predictor of long-term survival

Khani & Smedh. Colorectal Dis 2010
Rectal Cancer Standardization
Norwegian Experience

• Implementation of national standard surgical techniques and training, standardized TME techniques
• Increased proportion of patients undergoing TME (78% to 92%)
• Reduced local recurrence and improved survival in the TME group

Wibe et al. Dis Colon Rectum 2002
Rectal Cancer Centers of Excellence
Danish Experience

- Analysis of 10,632 rectal cancer patients
- National implementation of standards:
  - Total mesorectal excision
  - Improved staging
  - Centralization of care
- Increased 5-year survival from 37% to 51% after new standards

Bulow et al. Colorectal Dis 2010
Quality improvement initiatives have been successfully implemented on a national level in several European countries and ample outcomes data supports their efficacy.
Proof of Principle: The United Kingdom Experience

- Identified discrepancies in rectal cancer outcomes
  - between UK and mainland Europe (EUROCARE data)
  - within UK itself ("cancer lottery")

- Called for
  - Access to uniform and high-quality cancer care
  - Shift from generalist to cancer specialist-approach
The UK Rectal Cancer Model

Specialized Centers
(Regional MDTs)

Evidence-Based Protocols

External Audit
The Rectal Cancer MDT

- Surgeon
- Medical Oncologist
- Radiation Oncologist
- Pathologist
- Radiologist
- Patient Trackers

- All are **identifiable**

- Prescribes
- Coordinates
- Delivers
- Monitors

the *ideal treatment* on an individual patient-by-patient basis
UK Model: Process-driven

- Evidence-based care standards
- Defined protocols of patient care and process
- Peer Review Program
  - Prospective data collection
  - Annual self-assessment
  - Internal validation
  - External verification
- More patients now cared for in fewer centers
European Success Story

- Over two decades the implementation of TME and MDT-focused care has significantly altered rectal cancer outcomes:
  - Lower rates of local recurrence and permanent stoma
  - More patients receiving evidence-based care adhering to accepted guidelines
  - Better recruitment to clinical trials
  - Improved monitoring of standards and outcomes
  - Rectal cancer outcomes now exceed those for colon cancer
OSTRiCh Proposal

- *Create a CoE system in US based on already-successful international models:*
  - Train/establish MDT’s at interested/motivated hospitals
  - Follow defined protocols of patient care and process
  - Prospective data collection to track process compliance and outcomes
  - Peer-review/Accreditation program (ACS/CoC)
Need for Training

• Existing CoE programs did not have central training component

• Rectal Cancer is *different*

• Skill set is not universally present, but is teachable:
  • Total Mesorectal Excision
  • Pathology assessment
  • MRI protocol and reading
  • Administration and Teamwork
MDT Training

• 2-3 day training session at central location(s)

• Individual components created by relevant society
  • Surgery: ASCRS TME course (in development)
  • Pathology: CAP course for standard pathology specimen evaluation and reporting (in development)
  • Radiology: rectal cancer protocol MRI and standard reporting (ACR)
  • Medical/Radiation Oncology: neoadjuvant and adjuvant therapy (ASCO/ASTRO)

• Parallel sessions for all MDT members
• Group training for MDT functioning
• Training of program administrators and navigators
Proposed Standards

- Set of 20 Standards pertaining to program structure ("Structure Standards") and the process of patient care ("Process Standards")

- Accreditation based on achievement of series of Performance Indicators

- Quality improvement based on feedback related to Quality Indicators
OSTRiCh/ACS/CoC Centers of Excellence Partnership

Steven Wexner, MD
A U.S. Centers of Excellence (CoE) Program in Rectal Cancer
Proposal to the American College of Surgeons’ Commission on Cancer

Steven D Wexner, MD, PhD(Hon), FACS, FRCS, FRCS(Ed)
John Monson, MD, FRCS (Ire, Eng, Ed, Glas (Hon)), FASCRS, FACS;
David Dietz, MD, FACS, FASCRS;
Feza Remzi, MD, FACS, FASCRS, FTSS(Hon)
Mariana Berho, MD
Frederick Greene, MD, FACS
Proposed Standards

• Set of 20 Standards pertaining to program structure ("Structure Standards") and the process of patient care ("Process Standards")

• Accreditation based on achievement of series of Performance Indicators

• Quality improvement based on feedback related to Quality Indicators
“Structure Standards”

- **Standard 1.1**
  - The institution must have a defined multidisciplinary team (MDT) with a minimum of one named member from each of the following specialties: Surgery, Pathology, Radiology, Medical Oncology, Radiation Oncology, Patient Tracker

- **Standard 1.2**
  - The institution must have a named MDT Leader

- **Standard 1.3**
  - All members of the MDT must complete the prescribed OSTRiCh MDT Training Program
“Structure Standards” (continued)

Standard 1.4
- The institution must be a member of the American College of Surgeons Commission on Cancer (CoC)

- Standard 1.5
  - The institution’s pathology laboratory must be accredited by the College of American Pathologists (CAP)

- Standard 1.6
  - The institution’s MRI facility must be accredited by the American College of Radiology (ACR)

- Standard 1.7
  - The institution’s radiation oncology facility must be accredited by either the American College of Radiology (ACR), American Society of Clinical Oncology (ASCO), or American College of Radiation Oncology (ACRO)
“Process Standards”

- **Standard 2.1**
  - Diagnosis of rectal cancer confirmed by biopsy prior to treatment (Target rate: 95%)

- **Standard 2.2**
  - Patient must be registered into OSTRiCh database (Target rate: 100%)

- **Standard 2.3**
  - Both systemic and local staging must be performed prior to definitive treatment. Systemic staging should consist of CT scan of the chest, abdomen, and pelvis. Local tumor staging should consist of MRI +/- transrectal ultrasound (TRUS). Results of the staging MRI should be conveyed by a standardized synoptic report. (Target rate: 95%)

- **Standard 2.4**
  - CEA level should be obtained prior to definitive treatment (Target rate: 100%)

- **Standard 2.5**
  - Individualized treatment-planning discussion must occur at MDT Conference prior to definitive treatment. (Target rate: 100%)
“Process Standards” (continued)

- **Standard 2.6**
  - A Treatment Recommendation Summary (TRS) must be sent to the patient and referring or primary care physician prior to commencement of therapy (Target rate: 100%)

- **Standard 2.7**
  - Definitive treatment must begin within 30 days of patient’s initial clinical evaluation at the institution (Target rate: 90%)

- **Standard 2.8**
  - Standardized synoptic pathology report must be issued within 2 weeks of definitive surgical resection of the primary tumor. Tumor regression grade, budding, and growth border should be included in the report. (Target rate: 90%)

- **Standard 2.9**
  - Individualized treatment-outcome discussion must occur at MDT Conference (Target rate: 100%)
“Process Standards” (continued)

- **Standard 2.10**
  - Adjuvant treatment (if elected) must begin within 6 weeks of definitive surgical resection of the primary tumor in uncomplicated cases (Target rate: 75%)

- **Standard 2.11**
  - Pre-treatment staging, neoadjuvant therapy details, surgery details, pathology details, adjuvant therapy details should be entered into database with 6 months of surgery (Target rate: 100%)

- **Standard 2.12**
  - A Treatment Completion Summary (TCS) and follow up plan document must be sent to the patient and referring- or primary care-physician within 4 weeks of treatment completion (Target rate: 100%)

- **Standard 2.13**
  - The MDT must conduct an Annual Performance Review (APR) (Target rate: 100%)

- **Standard 2.14**
  - Molecular markers should be assessed when appropriate (Target rate: 90%)
Performance Indicators

• Adherence to the above standards at, or above, the target rate

• Initial Accreditation
  • Achievement of Structure Standards (1.1-1.7)

• Re-Accreditation
  • Achievement of Process Standards (2.1-2.13)
Quality Indicators

4.1 Abdominoperineal resection rate
4.2 Anastomotic leak rate
4.3 Reoperation rate
4.4 30-day mortality rate after surgery
4.5 Involved CRM rate
4.6 Involved distal resection margin rate
4.7 Mesorectal grade rate
4.8 Lymph node yield ≥ 12 rate
4.9 Local recurrence rate
4.10 3-year disease-free survival rate

Outliers identified and feedback provided to individual CoEs for quality improvement
Need for Skills Verification

• Existing CoE programs do not have central training or skills verification components

• Skills verification is mandatory:
  • Total Mesorectal Excision
  • Pathology assessment
  • MRI protocol and reading

• Requires administration and teamwork
“Transform the delivery of rectal cancer care in US by establishing a process-driven, evidence-based, and accountable centers of excellence program.”
Update from OSTRiCh Council Meeting (5/18/14)

- Attendees: Abbas, Berho, Chang, Dietz, Efron, Fleshman, Monson, Read, Remzi, Thorson, Wexner

- Update on OSTRiCh/CoC partnership to create U.S. Rectal Cancer CoE program
  - Database
  - Training Course
  - Committees
OSTRiCh Committees

- **Database**
  - Mission: work with CoC to establish separate database or incorporate into existing NCDB
  - Mechanism to audit CoE’s, track progress towards goal of improved care, powerful research tool

- **Education**
  - Mission: Design OSTRiCh MDT training course
  - Work with pertinent societies (ASCRS, CAP, ACR, ASCO, ASTRO)

- **Standards**
  - Mission: monitor literature and update standards as rectal cancer care continues to evolve
Consortium for Optimizing Surgical Treatment of Rectal Cancer

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