Multidisciplinary Care and Nonoperative Management For Rectal Cancer
Disclaimer

The information provided through this activity is for continuing education purposes only and is not meant to substitute for the independent medical judgment of a physician relative to diagnostic and treatment options of a specific patient’s medical condition.
Activity Overview
This presentation is to educate physicians and medical support staff on the milestones of rectal cancer management, the data on the watch and wait method, review of all treatment modalities and what is the future of rectal cancer management is.

Target Audience
This activity is intended for primary care physicians and oncologists.

Instructions to Receive Credit
To receive credit, read the introductory CME material, watch the webcast, and complete the evaluation, attestation, and post-test, answering at least 70% of the post-test questions correctly.
This disease is difficult to treat and the management around it is always evolving, tumor response to neoadjuvant therapies are variable and it’s unclear if all modalities are needed in aiding in appropriate treatment. Clinical trials are still needed along with research on aggressive multimodality approach to care.
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Associate Professor of Oncology
Department of Surgical Oncology
Roswell Park Comprehensive Cancer Center
Buffalo, NY
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<thead>
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<tbody>
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<td>Med-IQ</td>
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</table>
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Multidisciplinary Care and Nonoperative Management For Rectal Cancer

Steven Nurkin, MD, MS, FACS
Associate Professor of Oncology
Department of Surgical Oncology
Roswell Park Comprehensive Cancer Center
Upon completion, participants should be able to:

• Describe evidence-based approaches to the treatment of locally advanced rectal cancer, including referral to an expert center

• Recognize common side effects associated with treatment for rectal cancer and how they impact patient quality of life

• Identify patients who are likely to experience a complete clinical response with a watch-and-wait approach to treatment of their rectal cancer
Overview

• Background/Milestones of Rectal Cancer Management

• Are all the treatment modalities necessary?
  • Radiation, Surgery?

• The data on watch-and-wait

• What’s next and future directions?

Abbreviations:
CRT: chemoradiation
TNT: total neoadjuvant therapy
TME: total mesorectal excision
5-FU/LV: 5-fluorouracil/leucovorin
CapeOx: Capecitabine/Oxaliplatin
FOLFOX: 5-FU, folinic acid and Oxaliplatin
FOLFIRI: 5-FU, folinic acid and irinotecan

Abbreviations:
cCR: clinical complete response
pCR: pathologic complete response
NOM: nonoperative management
W&W or WW: watch & wait
Annual report to the nation on the status of Colorectal Cancer
Impact of interventions (risk factors, screening, and treatment) to reduce future rates

seer.cancer.gov
Colon Cancer's New Face: Getting Younger

If the trends continue, they report in the journal JAMA Surgery, the number of colon cancer cases in people aged 20 to 34 will spike by nearly ...

Colon cancer on the rise in young adults

Rate of colorectal cancer in young adults in the U.S. is rising, study ...

For Reasons Unknown, Colon And Rectal Cancer Rates Are Rising ...

Colon Cancer Rates Rising in Young Adults

Colon Cancer on the Rise for U.S. Adults Under 50
Figure 2. Annual Percentage Change–Based Predicted Incidence Rates of Colon Cancer by Age Compared With Incidence Rate in 2010
Deadliest Cancer Types for Ages 20-49, 2012 - 2016

MEN
1. COLORECTAL
2. LUNG
3. BRAIN

WOMEN
1. BREAST
2. LUNG
3. COLORECTAL
Milestones in the Management of Rectal Cancer

**1985**
- NSABP RO1 GITSG
  - Adjuvant Radiation Alone
- NCTTG
  - Adjuvant CRT
  - Systemic chemotherapy
- NIH Consensus Conference
  - TME
  - CRT
  - Chemo
- Swedish Rectal Cancer Trial
  - Preoperative short course radiation
- Dutch TME Trial
  - Preoperative radiation in the TME era
- German Rectal Cancer Trial
  - CAO/ARO/AIO3
  - Neoadjuvant CRT and adjuvant chemotherapy

2017-18
- MRI Stage
- CRT
- TME
- Adjuvant Chemo
- NSABP-R04 ACCORD-12 STAR-01 CAO/ARO/AIO4
  - No Oxaliplatin

Franke AJ et al. Clinical Colorectal Cancer 2017; 17:1-12
Smith Adapted
Challenges in Rectal Cancer Treatment

- Difficult surgery (low, male, obese)
- Patients still have local and distant rec
- Preservation of quality of life
  - Stoma, Genitourinary dysfunction
- Identifying responders and making treatment more individualized

“Poster child” for multidisciplinary care!!

The “Holy” Mesorectal Plane

Figure 4 Examples of rectal cancer excision specimens showing different surgical excision planes.
The Importance of Good TME Surgery

Total mesorectal excision reduces local recurrence rates

- 30-40% without TME, 3.7% with TME
- TME varies between surgeons (experience, training, techniques)

Consequences of radical surgery

**Total mesorectal excision (TME)**

Hospital *mortality*: 1-5%

Complications of CRT + TME
- Anastomotic *leak*: 28%
- Perineal wound *infection*: 37%
- *Readmission* 30 days: 20%

Bowel *obstruction/hernia*: 15%

Urinary *incontinence*: 39%

Sexual *dysfunction*
- women: 29%
- men: 45%

Defecatory problems: 38%

Permanent *stoma*: 30%

• Reduction in Local Recurrence
• Improved Sphincter Preservation
Dutch TME Trial - Pre Op RT/TME

Bowel Function 14 Years After Preoperative Short-Course Radiotherapy and Total Mesorectal Excision for Rectal Cancer: Report of a Multicenter Randomized Trial

Chen TY et al., Clinical Colorectal Cancer 2015; 14:106-114
# Adjuvant Rectal Cancer Trials: Poor Compliance

<table>
<thead>
<tr>
<th>Trial</th>
<th>N</th>
<th>Chemotherapy</th>
<th>Comments</th>
<th>DFS</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EORTC 22921</td>
<td>1011</td>
<td>2x2: Atypical 5-FU (Days 1-5)</td>
<td>37% underwent TME 27% did NOT initiate adjuvant CTX ONLY 43% received planned post-op CTX</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>LARC</td>
<td>655</td>
<td>Obs vs 5-FU/LV</td>
<td>28% did NOT initiate adjuvant CTX 58.4% received 3-6 of proposed 6 cycles</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>PROCTOR/SCRI</td>
<td>470 / 840</td>
<td>Obs vs. 5-FU/Cape CRT or 5x5</td>
<td>28% did NOT complete adjuvant CTX</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Chronicle</td>
<td>113 / 800</td>
<td>Obs. vs. XELOX x 6</td>
<td>52% did NOT complete planned CTX</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>ADORE</td>
<td>321</td>
<td>5-FU vs. FOLFOX x 8</td>
<td>Based on yp staging R0 resection 38m f/u 96% completion of CTX p=0.05 FOLFOX&gt;F (DFS)</td>
<td>NS (ITT)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Presented By Cathy Eng at 2018 ASCO Annual Meeting
Adapted by JJ Smith 16 June 2018
Existing Paradigm of Treatment for Locally Advanced Rectal Cancer

**Diagnosis**

2019: >44,000 new cases (US alone)¹

**Staging**

**NCRT**

5-FU based nCRT 6 weeks

**TME**

**Adjuvant Chemotherapy**

1st line: 5-FU or FOLFOX 16-18 weeks

2nd line: FOLFIRI

Targeted therapy: No clear role for locally advanced rectal cancer patients (e.g. Cetuximab)

**Targeted therapy 5-yr, RFS**

Incomplete response 55-75% 5-yr RFS

No remaining tumor in specimen = pCR

Remaining tumor in specimen = Non-pCR

4y: 75% 5y: ~60%


¹Organ Preservation in Rectal Cancer
<table>
<thead>
<tr>
<th>FOLFOX</th>
<th>Chemoradiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>Diarrhea</td>
</tr>
<tr>
<td>Anemia</td>
<td>Skin irritation at the site where radiation beams were aimed</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Bowel incontinence</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>Increased risk of infections</td>
</tr>
<tr>
<td>Nausea</td>
<td>Anemia</td>
</tr>
<tr>
<td>Stomatitis, diarrhea, vomiting</td>
<td>Hair thinning</td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
</tr>
</tbody>
</table>

Risk Information

- **FOLFOX**: Increased risk of serious or fatal adverse reactions in patients with low or absent dipyrimidine dehydrogenase activity; cardiotoxicity; hyperammonemic encephalopathy; neurologic toxicity; diarrhea, Palmar-plantar erythrodysesthesia, myelosuppression, mucositis, increased risk of elevated INR when administrated with warfarin; hypercalcemia, gastrointestinal toxicities, drug interactions with trimethoprim-sulfamethoxazole

- **Chemoradiation**: increased risk of serious or fatal adverse reactions in patients with low or absent dipyrimidine dehydrogenase activity (capecitabine or fluorouracil chemotherapy)

Recurrence-free survival by response

A

Recurrence-Free Survival

- Complete response
- Intermediate response
- Poor response

Time Since Surgery (months)

B

Disease-Free Survival (probability)

- TRG 0+1
- TRG 2+3
- TRG 4

Time (months)


Fokas E et al. J Clin Oncol 2014;32:1554-1562

Best response (TRG 4 or pCR)

Intermediate response (TRG 2-3)

Worst response (TRG 0-1)
Total Neoadjuvant Therapy (TNT)

1. Diagnosis
2. Staging
3. NCRT
4. TME
5. Adjuvant Chemotherapy

Induction → Consolidation
TNT is associated with higher pCR rates

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>All Patients, No.</th>
<th>All Patients, Sustained cCR, No. (%)</th>
<th>Surgery Within 12 Months, No.</th>
<th>Surgery Within 12 Months, pCR, No. (%)</th>
<th>Complete Response (pCR and Sustained cCR) at 12 Months, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ChemoRT with planned adjuvant chemotherapy</td>
<td>94</td>
<td>9 (9.6)</td>
<td>82</td>
<td>14 (17.1)</td>
<td>23 (24.5)</td>
</tr>
<tr>
<td>Stage II</td>
<td>226</td>
<td>10 (4.4)</td>
<td>214</td>
<td>35 (16.4)</td>
<td>45 (19.9)</td>
</tr>
<tr>
<td>Total</td>
<td>320</td>
<td>19 (5.9)</td>
<td>296</td>
<td>49 (16.6)</td>
<td><strong>68 (21.3)</strong></td>
</tr>
<tr>
<td>TNT</td>
<td>308</td>
<td>67 (21.8)</td>
<td>235</td>
<td>43 (18.3)</td>
<td><strong>110 (35.7)</strong></td>
</tr>
</tbody>
</table>
Effect of adding mFOLFOX6 after neoadjuvant chemoradiation in locally advanced rectal cancer: a multicentre, phase 2 trial

Systemic Chemotherapy Before Surgery
(Total Neoadjuvant Therapy – TNT)

**Potential Advantages**

- Earlier treatment of subclinical **micrometastasis**
- Improves treatment **compliance** and ensures efficacy
- Reduces the time to ileostomy closure
- **Enhances response** of the primary tumor
- Can be given before (induction) or after (consolidation) CRT
Do all rectal cancer patients require this aggressive multimodality approach?

Can we do the same or more with less?
“Pick Your Poison”

Chemotherapy

Radiation

Surgery
The Prospect Trial

**“Standard Arm”**

- Randomize 1:1
- Response ≥20%
  - FOLFOX x 6
  - Surgery
  - Chemo per primary MD
- Response <20%
  - XRT + 5FU
  - Surgery
  - Chemo per primary MD

**“Selective Arm”**

- XRT + 5FU
- Surgery
- Chemo per primary MD

---

Franke et al. *Clinical Colorectal Cancer* 2017; 17: 1-12
What if the tumor disappears after Neoadjuvant therapy?

Routine: CRT → TME

- **TME** has toxicity

- **pCR**
  - Occurs in 12-38% of patients
  - 85-95% 4-yr and 5-yr DFS

- **clinical complete response (cCR)**
  - pCR associated with cCR

Maas M et al. *Lancet Oncol* 2010 Sep;11(9):835-44
265 resectable LOW rectal cancer patients s/p CRT

- cCR → WW (n = 71)
- non-cCR → Resection (n = 194; 22 had pCR)

cCR = possible cure
Deferral of surgery = safe
Surgical salvage = effective
OS = no significant difference

International W&W Registry

- 880 patients entered in W&W protocols
- 47 centers
- 15 countries
- From 1991 to 2015
- Denominator unknown
- Most patients already published in other series

van der Valk et al, *The Lancet* 2018;391:2537-45
International W&W Registry: Results

Salvage Surgery
Missing data in 31%
TME in 54%

van der Valk et al, The Lancet 2018;391:2537-45
Recent MSK results with W&W

Smith JJ et al, *JAMA Oncology* 2019; 5:e185896
Organ Preservation in Rectal Cancer

W&W Outcomes

**Overall Survival**

- Watch & Wait: 73%

**Disease-specific survival**

- Watch & Wait: 90%

- >60% died of other causes

Smith JJ et al, *JAMA Oncology* 2019; 5:e185896
Rate of local regrowth in patients after apparent clinical complete response

21% local regrowth (95% CI 12–30)

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Metastasis</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local re-growths</td>
<td>22</td>
<td>8/22</td>
<td>36%</td>
</tr>
<tr>
<td>No Local re-growths</td>
<td>91</td>
<td>1/91</td>
<td>1%</td>
</tr>
</tbody>
</table>
• Use of a WW approach carries some risk—whether that risk would have been mitigated with upfront TME after neoadjuvant therapy is unknown

• Identification of those who will completely respond to neoadjuvant therapy and who are optimal candidates for WW approaches is as of yet unknown

• Use of a WW approach in the context of a cCR is likely best done in the context of a clinical trial (if possible)
Nonoperative management after neoadjuvant therapy for rectal cancer: A single institution experience over 5 years

Strode, M. Nurkin S. et. al Surgical Oncology Volume 28, March 2019
• Review from a prospectively collected database, of patients with rectal cancer at Roswell Park from 2012 – 2016.
• 29 patients experienced a cCR after neoadjuvant therapy
• 80% low tumors
• 45% N1,2+
• 65% TNT
## Tumor Response Assessment

<table>
<thead>
<tr>
<th></th>
<th><strong>Complete Response</strong></th>
<th><strong>Near Complete Response</strong></th>
<th><strong>Incomplete response</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endoscopy</strong></td>
<td>• Flat, white scar</td>
<td>• Small mucosal nodules or minor mucosal abnormality</td>
<td>• Visible tumor</td>
</tr>
<tr>
<td></td>
<td>• Telangiectasia</td>
<td>• Superficial ulceration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No ulcer</td>
<td>• Mild persisting erythema of the scar</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No nodularity</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Digital Rectal Exam</strong></td>
<td>• Normal</td>
<td>• Smooth induration or minor mucosal abnormalities</td>
<td>• Palpable tumor nodules</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MRI-T2W</strong></td>
<td>• Only dark T2 signal, no intermediate T2 signal</td>
<td>• Mostly dark T2 signal, some remaining intermediate signal</td>
<td>• More intermediate than dark T2 signal, no T2 scar</td>
</tr>
<tr>
<td></td>
<td>AND</td>
<td>AND/OR</td>
<td>AND/OR</td>
</tr>
<tr>
<td></td>
<td>• No visible lymph nodes</td>
<td>• Partial regression of lymph nodes</td>
<td>• No regression of lymph nodes</td>
</tr>
<tr>
<td><strong>MRI-DW</strong></td>
<td>• No visible tumor on B800-B1000 signal</td>
<td>• Significant regression of signal on B800-B1000</td>
<td>• Insignificant regression of signal on B800-B1000</td>
</tr>
<tr>
<td></td>
<td>AND/OR</td>
<td>AND/OR</td>
<td>AND/OR</td>
</tr>
<tr>
<td></td>
<td>• Lack of or low signal on ADC map</td>
<td>• Minimal or low residual signal on ADC map</td>
<td>• Obvious low signal on ADC map</td>
</tr>
<tr>
<td></td>
<td>• Uniform, linear signal in wall above tumor is ok</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Habr-Gama et al. DCR 53:12 (2010); 53: 1692-1698**

**Smith JJ et al., BMC Cancer, 2015; 15:767**
## Typical surveillance and intervals:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Yr1</th>
<th>Yr2</th>
<th>Yr3-5</th>
<th>&gt;Yr5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopy</td>
<td>q3m</td>
<td>q4m</td>
<td>q6m</td>
<td>q12m</td>
</tr>
<tr>
<td>DRE</td>
<td>q3m</td>
<td>q4m</td>
<td>q6m</td>
<td>q12m</td>
</tr>
<tr>
<td>Imaging (CT/MRI/EUS)</td>
<td>q6m</td>
<td>q6m</td>
<td>q6-12</td>
<td>-</td>
</tr>
</tbody>
</table>
2 patients with local recurrence, 5 distant recurrence

4 of 6 were salvaged with surgical management
• Median follow-up – 27.6 months

No mortalities

1-yr Rate (95% CI)  
LOCAL  0.95 (0.72, 0.99)  
DISTANT  0.89 (0.69, 0.96)  
Any Recurrence  0.89 (0.69, 0.96)

3-yr Rate (95% CI)  
LOCAL  0.87 (0.54, 0.97)  
DISTANT  0.76 (0.49, 0.90)  
Any Recurrence  0.68 (0.40, 0.85)

Strode, M. Nurkin S. et. al Surgical Oncology 2019; 28: 116-120
What we don’t know...

• How to **predict** response?
• How to **maximize** tumor response?
• When is the best time to **assess** response?
• How to **identify** true responders?
• How often to **survey** these patients?
• Will tumors **re-grow**? Will they be **salvageable**?
• Can **occult cancer cells** metastasize?

**Are we putting some patients at risk?**
Conclusions

• Neoadjuvant treatment strategies, like TNT, may facilitate durable rates of cCR.

• Continued responses after these treatments could possibly enable more patients to undergo nonoperative management.

• We believe nonoperative management can be offered to those seeking rectal preservation, but more research is required to select the appropriate patients.

• For those patients experiencing recurrence, the majority of patients can be salvaged surgically.
Optimal Design for a W&W Trial

Distal Rectal Cancer MRI staging

Neoadjuvant Treatment

Restaging
DRE – Endoscopy + Biopsy - MRI

- No Significant Clinical Response
  - TME

- Significant Clinical Response
  - TME
  - Randomize W & W
OPRA Trial - Protocol Schema

Distal Rectal Cancer
MRI staging

Randomization

Arm 1 (Induction)
INCT
FOLFOX / CapeOX
(16-18 weeks)
Interval Evaluation*
DRE - Endoscopy - MRI
CRT (5.5 weeks)
Restaging
DRE – Endoscopy + Biopsy - MRI
No Significant Clinical Response
TME

Arm 2 (Consolidation)
CNCT
CRT (5.5 weeks)
Interval Evaluation*
DRE - Endoscopy - MRI
FOLFOX / CapeOX
(16-18 weeks)

(*) Patients with tumor progression at the interval evaluation will be treated according to standard of care.

Target accrual: 221

Pre-operative TNT followed by selective W & W approach will not compromise DFS comparing to historical controls who received standard of care treatment

OPRA = Organ Preservation in Rectal Adenocarcinoma

Smith JJ et al, BMC Cancer. 2015; 15:767
RAPIDO Trial – Ongoing

R

SCRT

CRT

CAPOX

Surgery

Surgery

Chemo
Summary

- Rectal cancer is a difficult disease to treat, and its management is evolving.

- Tumor response to neoadjuvant therapies are variable, and it is unclear if all modalities are really needed.

- TME is effective but associated with significant morbidity.

- Like anal cancer, some patients can be CURED WITH CHEMOTHERAPY AND RADIATION!
  - But who are they?

- Nonoperative management may be feasible in a select group of patients, that achieve a complete clinical response.

- Clinical trials are still needed to address many of the unanswered questions.
2017
CrossRef View Record in ScopusGoogle Scholar

R.J. Heald, E.M. Husband, R.D. Ryall \textit{The mesorectum in rectal cancer surgery--the clue to pelvic recurrence?}
CrossRef View Record in ScopusGoogle Scholar

View Record in ScopusGoogle Scholar

CrossRef View Record in ScopusGoogle Scholar

A. Habr-Gama, R.O. Perez, W. Nadalin, et al. \textit{Operative versus nonoperative treatment for stage 0 distal rectal cancer following chemoradiation therapy: long-term results}
discussion 717-718
View Record in ScopusGoogle Scholar


References


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To receive credit, read the introductory CME material, watch the webcast, and complete the evaluation, attestation, and post-test, answering at least 70% of the post-test questions correctly.

Contact Information

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