The National Accreditation Program for Rectal Cancer: Issues for the Pathology Team

Frederick L. Greene MD, FACS
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American College of Surgeons’ Quality Programs

Commission on Cancer’s Mission

The Commission on Cancer is a consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard-setting, prevention, research, education, and the monitoring of comprehensive quality care.
“that every hospital should follow every patient it treats, long enough to determine whether or not treatment has been successful, and then to inquire ‘if not why not?’ with a view to preventing similar failures in the future”

E. A. Codman
The Donabedian Model

- **Structure**: attributes of health care systems; availability of resources
- **Process**: what we do to and for patients
- **Outcome**: change in patient’s health status linked to the healthcare process

Quality of Rectal Cancer Care

**Structure**: 1) Hospital accreditation; 2) Annual case volume; 3) Availability of specialists; 4) MDT review

**Process**: 1) Effective imaging after nCRT; 2) Adequate TME (surgeon and pathologist)

**Outcome**: 1) 30-day mortality 2) LR rate 3) OS

Evolution of CoC Standards

- **Focus on Structure**
- **Focus on Process**
- **Focus on Outcomes**
The Principles of the COC and the National Accreditation Program for Rectal Cancer (NAPRC) are aimed at developing goals that allow for the best outcomes for our patients.

Types of Measures

**Accountability Measures** (i.e. BCSRT, HT, MASTRT)
Based on randomized clinical trials and considered standard of care. Compliance with these measures should be very high.

**Quality Improvement Measures** (i.e. nBX, 12RLN, LCT)
Usually based on retrospective data or consensus. Initial compliance may be low nationally but should improve over time as providers are educated about the measure.

**Surveillance Measures** (i.e. BCS)
For informational purposes and internal program quality improvement. CoC does not assign a compliance threshold for surveillance measures.

Specific Quality Benchmarks

**Pathology Reporting:**

- Synoptic format with defined elements
- 1) lymphatic/vascular and perineural invasion
- 2) nodal assessment
- 3) CRM completeness
- 4) regression “score” after nRCT
A Needed Quality Indicator:

Synoptic Reporting and Specified Clinical Indicators for Oncologic Imaging

MRI Reporting for pre/post Neoadjuvant Treatment for Rectal Cancer:

1) Tumor proximity to mesorectal fascia;
2) Tumor extension into mesorectum;
3) Invasion of structures, levator ani and pelvic sidewall; 4) Lower (relation to puborectalis), mid- or upper rectal location; 5) Mesorectal nodes

TUMOR DEPOSITS

• 1935-Described by Gabriel, Dukes, Bussey-result of vascular tumor dissemination (Br. J. Surg 1935;23:395-413)
• Focal aggregates of tumor located in pericolic or perirectal fat discontinuous with the primary tumor and unassociated with a lymph node
Incidence of Tumor Deposits in rectal cancer is not trivial and varies from 4.5% to 31%

CLASICC Trial—31.9%
Dalarna County, Sweden-35.4%

Need Better Definition of Tumor Deposits

• How many cells are required
• Distance of TD from primary tumor
• How many levels of tissue or tissue blocks should be cut before discontinuous extension is ruled out
• Need to fully rule out TD’s before calling response a CR

Total Mesorectal Excision (TME)
Rectal Anatomy

Classical pathology reports of rectal cancer specimens
- pTN
- Histopathological variables that affect prognosis
- Vascular and perineural invasion
- Grade of tumor differentiation
- Status of the resection margins

TME: Pathologic variables not reflected in the pTN staging
- PLANE OF SURGERY: Mesorectal integrity
- MARGINS OF RESECTION: CRM
- LYMPH NODE YIELD
Evaluation of the margins of resection

Distal and Proximal

Circumferential margin of resection

- Strong predictor of local and overall recurrence $^{1,2}$
- Positive CRM: Tumor at or less than 1mm from the margin
  or maybe 2mm $^3$

1. Quirke P. Lancet 1986;2:996-9
Plane of Surgery (Mesorectal Integrity)

- Mesorectal: Complete mesorectum
- Intramesorectal: Near complete mesorectum
- Muscularis propria: Incomplete mesorectum

Direct tumor extension
Continuous/discontinuous foci of vascular invasion
Positive lymph node at CRM

MOST DEEP MESORECTAL TEARS THAT EXPOSE THE MUSCULARIS OCCUR ON THE ANTERIOR ASPECT OF THE MESORECTUM DUE TO THE SCARSE AMOUNT OF FAT IN THIS LOCATION
Expose muscularis propria in the anterior mesorectum

Neoadjuvant RX Response

Rectal Cancer Staging-Ongoing Issues

- Effect of Neoadjuvant Treatment
- Is response associated with overall survival?
- Four-point Tumor Regression Score (Ryan et al, Histopathology 2005;47:141-6 and CAP Guidelines)
Tumor Response Models

- Complete Response (CR): Disappearance of all target lesions
- Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions
- Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions
- Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD

Current AJCC Adapted from Ryan

<table>
<thead>
<tr>
<th>Description</th>
<th>Tumor Regression Grade Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>No viable cancer cells</td>
<td>0 CR</td>
</tr>
<tr>
<td>Single cells or small groups of cells</td>
<td>1 Clinical CR</td>
</tr>
<tr>
<td>Residual cancer outgrown by fibrosis</td>
<td>2 Clinical PR</td>
</tr>
<tr>
<td>Minimal or no tumor kill extensive residual cancer</td>
<td>3 NR</td>
</tr>
</tbody>
</table>

Does ypTo = ypNo
Relationship of ypT Category to ypN Category

\[
\begin{align*}
\text{ypT0} &= 2\% \text{ ypN+} \\
\text{ypT1} &= 4\% \text{ ypN+} \\
\text{ypT2} &= 23\% \text{ ypN+} \\
\text{ypT3} &= 47\% \text{ ypN+} \\
\text{ypT4} &= 48\% \text{ ypN+}
\end{align*}
\]


Neoadjuvant CRT decreases the number of lymph nodes harvested from rectal cancer specimens

Watch and Wait(1)
Does ypT0 = ypNo

What should your pathology be telling in rectal cancer reports?
- Integrity of the mesorectum:
- Pathological staging
- Other histopathological markers of prognosis
- Margins of resection: CRM
- Grading of tumor regression if patient received neoadjuvant therapy

Pathological indicators of the quality of surgery in TME specimens
- Integrity of the mesorectum
- Margins of resection
- Lymph node yield
Number of Lymph nodes and Prognosis in Rectal Cancer

- NCDB, 2006-2011, 25,447 patients
- Correlation of number of LNs dissected and outcomes
- Collected variables:
  - Demographics, treatment, histology and staging.
  - Hospital type, geographic distribution and hospital volume


“The greatest danger for most of us is not that our aim is too high and we miss it, but that it is too low and we reach it.”
—Michelangelo

“There is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to manage, than to initiate a new order of things.”
—Machiavelli

Change