Colon Cancer Care Guideline Update: July 2011

COLON CANCER CARE GUIDELINES
NON-METASTATIC DISEASE

Guideline Authors: Todd S. Crocenzi, M.D.; Mark Whiteford, M.D.; Matthew Solhjem, M.D.; Carlo Bifulco, M.D.; Melissa Li, M.D.; Christopher Cai, M.D.; and James Durham, M.D.

Contents

Staging Evaluation

Pre-Treatment Supportive Care

Stage-Directed Treatment
  Stage I (T1-2 N0 M0)
  Stage IIA (T3 N0 M0)/ no high risk clinical-pathologic features
  Stage IIA (T3 N0 M0)/ high risk clinical-pathologic features
  Stage III (T1-4 N1-2 M0)

Stage IIB (T4 N0 M0)/ no high risk clinical-pathologic features
  Stage IIIB (T4 N0 M0)/ high risk clinical-pathologic features
  Stage IV (T1-4 N1-2 M0 + N0-3 M1)

Post-Treatment Supportive Care

Surveillance Care (average risk individuals)

Appendix 1. Pathologic Assessment Standards

Appendix 2. Colorectal Carcinoma Molecular Testing

Appendix 3. Providence Cancer Center Clinical Trials- Colon Cancer (non-metastatic)
Staging Evaluation

1. Pathologic review:
   a. Biopsy specimen
   b. Resection specimen (see Appendix 1. Pathologic Assessment Standards)
2. Endoscopy: Complete colonoscopy (if not done at diagnosis)
   a. Will need post-op completion colonoscopy 3-6 months post-op (or after completion of adjuvant chemotherapy) if tumor-related or clinical conditions precluded pre-op complete colonoscopy
3. Labs: CBC, complete metabolic panel, CEA
4. Imaging: CT-chest/abdomen/pelvis (with oral and iv contrast if no contraindication)
   a. PET/CT not routinely indicated, consider if iv contrast contraindicated
   b. CT-chest preferred over Chest x-ray

Pre-Treatment Supportive Care

1. Discuss fertility preservation/ early referral if clinically indicated
2. Offer cancer counseling services (Providence Cancer Support Services)
3. Consider genetic risk assessment if clinically indicated (Providence Cancer Risk Assessment Program)
   a. Colorectal cancer diagnosis at age <50
   b. Synchronous or metachronous hereditary non-polyposis colorectal cancer related tumors
      (colorectal, small bowel, gastric, biliary tract, pancreas, gastric, endometrial, ovarian, ureter/renal pelvis, brain (GBM), sebaceous gland, keratoacanthoma)
   c. Family member at young age (< 50) or more than one family member with hereditary non-polyposis colorectal cancer related tumor
4. If an ostomy is being considered, refer patient to ostomy nurse for counseling and siting. (Providence Wound and Ostomy Clinic)
Stage-Directed Treatment

Stage I (T1-2 N0 M0)

Primary Therapy
1. Carcinoma arising in a single polyp, completely removed at endoscopy, favorable histologic features (grade 1-2, no angiolymphatic invasion, negative polypectomy margins)
   a. Pedunculated polyp—proceed to surveillance
   b. Sessile polyp
      i. Consider colectomy with en bloc regional lymphadenectomy
      ii. Consider surveillance alone
2. Fragmented polyp specimen with indeterminate margin or any unfavorable histologic features (grade 3-4, angiolymphatic invasion, positive margin)
   a. Recommend colectomy with en bloc regional lymphadenectomy

Adjuvant Therapy
1. Encourage clinical trial participation
2. Recommend no adjuvant chemotherapy, proceed to surveillance

Stage IIA (T3 N0 M0)/ no high risk clinical-pathologic features *

Primary Therapy
Colectomy with en bloc regional lymphadenectomy

Adjuvant Therapy
3. Encourage clinical trial participation
4. Favor no adjuvant chemotherapy/proceed to surveillance
5. Consider adjuvant therapy (regimen options)
   a. Capecitabine x 6 months
   b. 5-FU/leucovorin (sLV5FU2) x 6 months

*High risk clinical-pathologic features: bowel obstruction, grade 3-4 or poorly differentiated carcinoma, lymphatic or vascular invasion, perineural invasion, localized perforation, close/indeterminate or positive margins, <12 regional lymph nodes examined.
Stage IIA (T3 N0 M0) / high risk clinical-pathologic features

**Primary Therapy**
Colectomy with en bloc regional lymphadenectomy

**Adjuvant Therapy**

1. **Encourage clinical trial participation**
2. Favor adjuvant chemotherapy (regimen options)
   a. Capecitabine + oxaliplatin (CapeOx/XELOX) x 6 months
   b. 5-FU/leucovorin + oxaliplatin (FOLFOX) x 6 months
   c. Capecitabine x 6 months
   d. 5-FU/leucovorin(sLV5FU2) x 6 months
3. Consider no adjuvant therapy/ proceed to surveillance

*High risk clinical-pathologic features: bowel obstruction, grade 3-4 or poorly differentiated carcinoma, lymphatic or vascular invasion, perineural invasion, localized perforation, close/indeterminate or positive margins, <12 regional lymph nodes examined.*

1 NSABP P5 Study (Study contacts: Yue-yun To, R.N. 503-215-2492; Laurie Delanty, R.N. 503-216-3067)
Stage III (T1-4 N1-2 M0)

Primary Therapy
Colectomy with en bloc regional lymphadenectomy

Adjuvant Therapy

1. Encourage clinical trial participation
2. Recommend adjuvant chemotherapy (regimen options)
   a. Good performance status
      i. Capecitabine + oxaliplatin (CapeOx/XELOX) x 6 months
      ii. 5-FU/leucovorin + oxaliplatin (FOLFOX) x 6 months
   b. Marginal performance status/ contraindication to oxaliplatin
      i. Capecitabine x 6 months
      ii. 5-FU/leucovorin (sLV5FU2) x 6 months

² CALGB 80702 Study
Colon Cancer Care Guideline Update: July 2011

Post-Treatment Supportive Care

1. Generate Cancer Treatment Summary
2. If available, offer patient referral to survivorship program (Providence Cancer Survivor Program)
3. Generate plan of care for any residual side-effects of cancer treatment

Surveillance Care (average risk individuals)

<table>
<thead>
<tr>
<th>Surveillance Intervention</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Years 4 and 5 a</th>
</tr>
</thead>
<tbody>
<tr>
<td>History/PE (from completion of “cancer therapy”)</td>
<td>Every 3 to 6 months</td>
<td>Every 3 to 6 months</td>
<td>Every 3 to 6 months</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>CEA (from completion of “cancer therapy”)</td>
<td>Every 3 to 6 months</td>
<td>Every 3 to 6 months</td>
<td>Every 3 to 6 months</td>
<td>Consider every 6 months</td>
</tr>
<tr>
<td>CT scan- chest, abdomen, pelvis (from date of initial staging study)</td>
<td>Every year</td>
<td>Every year</td>
<td>Every year</td>
<td>Consider every year</td>
</tr>
<tr>
<td>Colonoscopy (from date of initial diagnostic study)</td>
<td>End of year 1 b</td>
<td></td>
<td></td>
<td>End of year 4 b</td>
</tr>
</tbody>
</table>


a After year 5 of surveillance, the need for future tests and visits should be discussed on a case-by-case basis. Without evidence of recurrent cancer, consider discontinuation of scheduled surveillance testing.

b If year 1 colonoscopy is unremarkable (tubular adenoma or normal), then repeat colonoscopy at end of year 4 (or 3 year interval) and with same result, every 5 years thereafter. If advanced adenoma detected with surveillance colonoscopy, next colonoscopy is at 1 year or as defined in discussion with endoscopist.
Appendix 1. Pathologic Assessment Standards

Biopsy Specimen:

1. Presence of invasion.
2. Grade/differentiation.
3. Margin status and angiolympathic invasion (if potentially curative polypectomy specimen).

Resection Specimen:

1. Grade/differentiation
2. Depth of penetration (T stage)
3. Lymphovascular and perineural invasion
4. Margin (proximal, distal, radial) status
5. Number of lymph nodes evaluated and positive (N stage)
6. Extra-nodal tumor deposits
7. If risk for HNPCC, then microsatellite instability “screening” by immunohistochemistry
Appendix 2. Colorectal Carcinoma Molecular Testing

Colorectal Carcinoma Molecular Testing (version 1.0), Providence Molecular & Genetic Steering Committee, Providence Laboratory Service, Portland Service Area.
Appendix 3. Providence Cancer Center Clinical Trials- Colon Cancer (non-metastatic)

Clinical Trial contacts:

Yue-yun To, R.N. 503-215-2492
Laurie Delanty, R.N. 503-216-3067

1 NSABP P5:

stage I-II colon cancer s/p resection (and completion of any adjuvant chemotherapy)
rosuvastatin vs placebo for 5 years

2 CALGB 80702:

Stage III colon cancer s/p resection
adjuvant FOLFOX (6 mos vs 3 mos duration) AND
celecoxib vs placebo for 3 years