



Colorectal Cancer Association of Canada consensus meeting: raising the standards of care for early-stage rectal cancer

Colorectal Cancer Association of Canada

ABSTRACT

The purpose of the meeting reported here was to develop a set of national evidence-based standards for assessing and managing patients with potentially resectable rectal cancer. This report represents the consensus of the multidisciplinary group of Canadian rectal cancer experts attending that meeting.

KEY WORDS

Early-stage rectal cancer, consensus statement, raising the standard for rectal cancer, multidisciplinary guidelines for early rectal cancer

1. TERMS OF REFERENCE

1.1 Purpose

The purpose of the meeting reported here was to develop a set of national evidence-based standards for assessing and managing patients with potentially resectable rectal cancer. This report represents the consensus of the multidisciplinary group of Canadian rectal cancer experts attending that meeting.

1.2 Participants

A representative group of Canadian rectal cancer experts from the key disciplines (surgical, medical and radiation oncology, pathology, radiology) involved in managing resectable rectal cancer were invited (Table 1).

1.3 Target Audience

- Health care professionals involved in the care of patients with potentially curable rectal cancer
- Stakeholders (provincial cancer agencies, hospitals, and so on) responsible for program and funding decisions related to the management of potentially resectable cancer
- Patient advocacy and education groups such as the Colorectal Cancer Association of Canada

1.4 Basis of Recommendations

All recommendations are based on a structured presentation and discussion of the best available evidence.

2. PREAMBLE

2.1 Application of Recommendations

These standards provide the basis for a discussion with patients regarding management options. Treatment plans will depend on a more complete discussion of the risks and benefits of proposed therapies with individual patients.

Significant progress has been made in improving outcomes for patients with potentially resectable rectal cancer; however, further improvement is necessary. Offering patients the option of participating in clinical trials should be a priority.

Optimally, the approach for assessing and managing patients with rectal cancer should involve a collaborative, multidisciplinary team (including all relevant medical specialties and allied health professionals). For example, optimal rectal cancer management is predicated on open communication and quality assurance between the surgeon and the pathologist describing the extent of disease of the surgical specimen for optimal postsurgical treatment choices.

Radiologic assessment and imaging should be completed within 2–3 weeks to ensure that the appropriate information is available to make timely management decisions.

3. QUESTIONS AND CONSENSUS STATEMENTS

Question 1

For complete clinical staging of rectal cancer, what should the standard diagnostics and reporting be (preoperative assessment)?

TABLE 1 Participants in the Colorectal Cancer Association of Canada consensus meeting, December 8, 2008, Montreal, Quebec

Chairs	
Scott Berry	Medical Oncologist, Sunnybrook Health Sciences Center, Odette Cancer Center, Toronto, ON
Te Vuong	Radiation Oncologist, McGill Cancer Center, Montreal, QC
Andy Smith	Surgeon, Sunnybrook Health Sciences Center, Odette Cancer Center, Toronto, ON
Carole Richard	Surgeon, Centre hospitalier de l'Université de Montréal, Montreal, QC
Celia Marginean	Pathologist, Ottawa Hospital, Ottawa, ON
Advisory Board members	
Shun Wong	Radiation Oncologist, Sunnybrook Health Sciences Center, Odette Cancer Center, Toronto, ON
Jean Maroun	Medical Oncologist, Ottawa Hospital Cancer Center, Ottawa, ON
Barb Melosky	Medical Oncologist, British Columbia Cancer Agency, Vancouver, BC
Thierry Alcindor	Medical Oncologist, McGill Cancer Center, Montreal, QC
Rasmy Loungnarath	Surgical Oncologist, Centre hospitalier de l'Université de Montréal, Montreal, QC
Ralph Wong	Medical Oncologist, Cancer Care Manitoba, Winnipeg, MB
Kartik Jhaveri	Radiologist, University Health Network, Princess Margaret Hospital, Toronto, ON
Sophie Lavertu	Radiation Oncologist, Centre hospitalier de l'Université de Montréal, Montréal, QC
Erin Kennedy	Surgeon, University Health Network, Princess Margaret Hospital, Toronto, ON
Pierre Major	Medical Oncologist, Juravinski Cancer Center, Hamilton, ON
Eric Chen	Medical Oncologist, University Health Network, Princess Margaret Hospital, Toronto, ON
Audet Pascale	Radiologist, Centre hospitalier de l'Université de Montréal, Montreal, QC
David Donath	Radiation Oncologist, Centre hospitalier de l'Université de Montréal, Montreal, QC
Hugo Villeneuve	Radiation Oncology Resident, Centre hospitalier de l'Université de Montréal, Montreal QC
Aaron Pollett	Pathologist, Mt. Sinai Hospital, Toronto, ON
Eugene Hsieh	Pathologist, Sunnybrook Health Sciences Center, Odette Cancer Center, Toronto, ON
Christine Cripps	Medical Oncologist, Ottawa Hospital Cancer Center, Ottawa, ON
Host	
Colorectal Cancer Association of Canada	Barry Stein, President
Meeting organizer and scribe	
Shaniah Leduc	CancerInsight
Observers	
Charles Pitts	OroAlliance
Patricia Brooks Lemoine	Colorectal Cancer Association of Canada
Manon Jobin	Amgen
Barb Burgess	Amgen
Nermine Ibrahim	Sanofi-Aventis
Therese Boucher	Sanofi-Aventis
Scott Leduc	CancerInsight

Consensus Statement 1

All diagnostics should be completed within a *timely* period (42 days to treatment, including imaging within the first 2–3 weeks), starting from the date of biopsy.

Services should include:

- Colonoscopy
- Imaging
 - Computed axial tomography of thorax, abdomen, and pelvis AND magnetic resonance imaging (MRI)
 - Slices of 3–4 mm should be routine
 - Mesorectal margin measurements or circumferential resection margin (CRM) with tumour distance should be reported

- Measurements for staging criteria should be provided (see the radiology protocol in Appendix A)
- When available, endorectal ultrasonography may be complementary to MRI in some T1/2 patients to better delineate T-stage

This statement utilizes Beets–Tan *et al.* 2001¹, Brown *et al.* 2003², Filippone *et al.* 2004³, Nagtegaal *et al.* 2002⁴, Iafate *et al.* 2006⁵, Kapiteijn *et al.* 2001⁶, and Harisinghani *et al.* 2003⁷.

Question 2

For complete clinical staging of rectal cancer, what should constitute standard pathology reporting?

Consensus Statement 2

For complete clinical staging of rectal cancer, synoptic reporting in accordance with the College of American Pathologists (CAP) protocol for the examination of specimens from patients with primary carcinomas of colon and rectum, based on the American Joint Committee on Cancer and International Union Against Cancer TNM, to include these points:

- Total mesorectal excision (TME) quality
 - Macroscopic assessment of mesorectum (complete, partially complete, or incomplete)
- CRM status
 - Positive if tumour is at 1 mm or less from the CRM or if a lymph node with metastasis is at 1 mm or less from the CRM
- If neoadjuvant therapy was received, pathologic tumour response grading should be recorded

For the complete protocol, see the CAP template (Appendix B).

This statement utilizes Nagtegaal and van Krieken 2002⁸, Quirke 1998⁹, Heald and Ryall 1986¹⁰, Dworak *et al.* 1997¹¹, Washington *et al.* 2008¹³, Smith *et al.* 2008¹⁴, Kapiteijn *et al.* 2001¹⁵, Nagtegaal and Quirke 2008¹⁶, Rödel *et al.* 2005¹⁷, Glynne-Jones *et al.* 2006^{18,19}, Ruo *et al.* 2002²⁰, Nagtegaal *et al.* 2002²¹, and Parfitt and Driman 2007²².

Question 3

Which neoadjuvant radiation protocol or protocols should be standard when combined with chemotherapy?

Consensus Statement 3

Preoperative neoadjuvant radiotherapy is the standard of care for clinically staged II and III patients. Long-course radiation (minimum of 45 cGy over 5 weeks) with fluoropyrimidine chemotherapy or short-course radiation without chemotherapy can be considered. A multidisciplinary team approach (with or without a tumour board) is important to review individual cases and reach consensus on the appropriate course of treatment (short- vs. long-course radiation).

This statement utilizes Bujko *et al.* 2004²³, Marijnen *et al.* 2003²⁴, Swedish Rectal Cancer Trial 1997²⁵, Bosset *et al.* 2006²⁶, Gérard *et al.* 2006²⁷, and Sauer *et al.* 2004²⁸.

Question 4

Which neoadjuvant chemotherapy protocol or protocols should be standard when combined with long-course radiation?

Consensus Statement 4

The optimal fluoropyrimidine-based chemotherapy is based on extrapolation of data from randomized trials of combined-modality chemoradiation used in the postoperative setting. Use fluoropyrimidine-based chemotherapy with long-course radiation. Protracted fluoropyrimidine is preferable to bolus 5-fluorouracil because of improved tolerability and similar efficacy, as seen in the largest and most recent randomized trial (INT 0144)²⁹.

This statement utilizes Smalley *et al.* 2006²⁹, Wong *et al.* 2008³⁰, and O'Connell 1994³¹.

Question 5

What should be the surgical standard of care for rectal cancer?

Consensus Statement 5

All stage II–III rectal cancers should be considered for neoadjuvant treatment. For all rectal cancers undergoing radical surgery, TME principles must be followed. Surgeons treating rectal cancer patients should be familiar with the TME surgery. Quality should be assured through independent evaluations by the surgeon and the pathologist. Synoptic operative reporting is encouraged.

Trans-anal excision represents an oncologic compromise for most rectal cancer patients. Consider it only in patients with comorbidities, realizing that it requires excellent preoperative assessment and high intraoperative expertise.

Because trans-anal endoscopic microsurgery is a new approach for local excision, patients being treated using this approach should preferably be enrolled in trials or prospective follow-up studies.

This statement utilizes MacFarlane *et al.* 1993³², Cecil *et al.* 2004³³, Dahlberg *et al.* 1998³⁴, Martling *et al.* 2000³⁵, Brown and Daniels 2005³⁶, Dubé *et al.* 1997³⁷, Karanjia *et al.* 1992³⁸, Ricciardi 2007³⁹, Murphy 2008⁴⁰, Ptok 2007⁴¹, van den Brink 2004⁴², Wibe 2002⁴³, Okabe 2004⁴⁴, and Nash 2009⁴⁵.

Question 6

What criteria should be standard for handling, evaluating, and reporting on the surgical specimen?

Consensus Statement 6

The surgeon should be aware of the standard macroscopic evaluation (grades 1, 2, 3) of the surgical specimen immediately after removal of the rectum. The pathologist receiving the specimen should also grade the macroscopic quality of the excision, independently of grading by the surgeon. Optimal management is predicated on productive, open

communication between the surgeon and the pathologist so that quality assurance and appropriate mechanisms for evaluation and improvement can be achieved (see also consensus statement 5). Collaboration is mandatory for optimal evaluation; that is, margin assessment, surgical difficulty encountered, neoadjuvant treatment given to the patient must be communicated. (For optimal assessment of the specimen, the pathologist has to be informed if neoadjuvant therapy was administered.)

This statement takes account of Nagtegaal and van Krieken 2002⁸, Quirke 1998⁹, Dworak 1997¹¹, Washington *et al.* 2008¹³, Smith 2008¹⁴, Kapiteijn 2001¹⁵, Nagtegaal and Quirke 2008¹⁶, Nagtegaal 2002²¹, and Parfitt and Driman 2007²².

Question 7

What is the standard adjuvant chemotherapy post neoadjuvant treatment and surgery?

Consensus Statement 7

All patients should be considered for 4–6 months of fluoropyrimidine-based therapy. Based on extrapolation of phase III trials for adjuvant treatment of colon cancer, adjuvant oxaliplatin-based therapy should be considered for patients at high risk for recurrence, including, but not limited to those who are

- ypN-positive.
- CRM-positive.

This statement utilizes Sauer *et al.* 2004²⁸, Wong *et al.* 2008²⁹, André *et al.* 2009⁴⁶, and Kuebler *et al.* 2007⁴⁷.

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5. CONFLICTS OF INTEREST

Participants disclosed potential conflicts of interest within the past 2 years:

- Scott Berry: Advisory boards for Sanofi–Aventis
- Celia Marginean: None
- Carole Richard: None
- Andrew Smith: None
- Te Vuong: Work as a consultant for Sanofi–Aventis

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APPENDIX A RADIOLOGY REPORTING TEMPLATE

MAGNETIC RESONANCE IMAGING PROTOCOL

- Phased-array coil
- Field strength: 1.5 T or more
- High-resolution matrix T2 images
- Small field of view (<25 cm)
- Thin section (3–4 mm)
- Axial, coronal, and sagittal planes
- Oblique planes perpendicular to the tumour
- Gadolinium-enhanced imaging

STANDARDIZED IMAGING REPORT

All Tumours

- Craniocaudal tumour extent
- Distance from anal verge
- T stage
- Circumferential (radial) margin–tumour distance
- Pelvic viscera and bones

Additions for Low-Rectal and Anorectal Tumours

- Distance from levator ani
- Distance from anorectal junction
- Involvement of sphincter complex
- Internal sphincter (partial or full)
- External sphincter and beyond

APPENDIX B COLLEGE OF AMERICAN PATHOLOGISTS PATHOLOGY REPORTING TEMPLATE

Note: This consensus guideline is based on College of American Pathologists (CAP) guideline version 6 from early 2009. An updated CAP guideline (version 7) is expected to be available at the end of 2009 and should be consulted for additional pathology reporting recommendations.

- Procedure type
 - Rectal/rectosigmoid colon (low anterior resection)
 - Abdominoperineal resection
 - Trans-anal disk excision (local excision)
 - Other

- Tumour size
- Macroscopic tumour perforation
- Macroscopic assessment of mesorectum (Note 1)
 - Complete
 - Partially complete
 - Incomplete
 - Cannot be assessed
- Histologic type
 - Adenocarcinoma
 - Mucinous adenocarcinoma
 - Signet-ring cell carcinoma
 - Small cell carcinoma
 - Squamous cell carcinoma
 - Adenosquamous carcinoma
 - Medullary carcinoma
 - Undifferentiated carcinoma
 - Other (specify)
- Histologic grade
 - Cannot be assessed
 - Low grade (well differentiated to moderately differentiated)
 - High grade (poorly differentiated to undifferentiated)
- Tumour depth of invasion (pT)
 - pTX: Cannot be assessed
 - pT0: No evidence of primary tumour
 - pTis: Carcinoma *in situ*, intraepithelial (no invasion)
 - pTis: Carcinoma *in situ*, invasion of lamina propria
 - pT1: Tumour invades submucosa
 - pT2: Tumour invades muscularis propria
 - pT3: Tumour invades through the muscularis propria into the subserosa or the nonperitonealized perirectal soft tissues
 - pT4a: Tumor penetrates the visceral peritoneum
 - pT4b: Tumor directly invades adjacent structures
- Lymph node status (pN)
 - pN0: No metastases in ____ lymph nodes
 - pN1: ____ (1–3) nodes involved of ____ (total number)
 - pN2: ____ (≥4) nodes involved of ____ (total number)
- Proximal margin
 - Cannot be assessed
 - Uninvolved by invasive carcinoma
 - Involved by invasive carcinoma
- Distal margin
 - Cannot be assessed

- Uninvolved by invasive carcinoma
- Involved by invasive carcinoma
- Circumferential (radial) margin (Note 2)
 - Cannot be assessed
 - Uninvolved
 - Involved by invasive carcinoma or a positive lymph node [tumour or positive lymph node present 0–1 mm from margin (or both); specify distance to margin (millimetres or centimetres)]
- Lateral margin (for noncircumferential trans-anal disk excision)
 - Cannot be assessed
 - Uninvolved by invasive carcinoma [specify distance of invasive carcinoma from closest lateral margin (millimetres or centimetres)]
 - Involved by invasive carcinoma
- Neoadjuvant therapy received
 - Yes
 - No
 - Information not available
- Tumour response to neoadjuvant treatment (Note 3)
 - Present (% of fibrosis)
 - No response identified
- Vascular (large vessel) invasion
 - Not identified
 - Present
 - Indeterminate
- Lymphatic (small vessel) invasion
 - Not identified
 - Present
 - Indeterminate
- Discontinuous extramural extension (irregular tumour nodules in pericorectal adipose tissue without histologic evidence of residual lymph node)
 - Not identified
 - Present
 - Cannot be determined

NOTES

1. Mesorectal Envelope

The nonperitonealized surface of the fresh specimen is examined circumferentially, and the completeness of the mesorectum is scored as complete, partially complete, or incomplete^{8–10}. The entire specimen is scored according to the worst area.

- **Complete:** Intact bulky mesorectum with a smooth surface. Only minor irregularities of the mesorectal surface. No surface defects greater than 5 mm in depth. No coning towards the distal margin of the specimen. After transverse sectioning, the circumferential margin appears smooth.

- **Nearly complete:** Moderate bulk to the mesorectum. Irregularity of the mesorectal surface with defects greater than 5 mm, but none extending to the muscularis propria. No areas of visibility of the muscularis propria except at the insertion site of the levator ani muscles.
- **Incomplete:** Little bulk to the mesorectum. Defects in the mesorectum down to the muscularis propria. After transverse sectioning, the circumferential margin appears very irregular.

2. Circumferential (Radial) Margin

In addition to addressing the proximal and distal margins, the circumferential (radial) margin (CRM) must be assessed for any segment either unencased or incompletely encased by peritoneum. The CRM represents the adventitial soft tissue margin closest to the deepest penetration of tumour and is created surgically by blunt or sharp dissection of the retroperitoneal or subperitoneal aspect respectively. The serosal surface (visceral peritoneum) does not constitute a surgical margin.

The distance between the tumour and the CRM should be reported. The CRM is considered negative if the tumour is more than 1 mm from the inked nonperitonealized surface, but should be recorded as positive if tumour is located 1 mm or less from the nonperitonealized surface. This description includes both tumour within a lymph node and direct tumour extension; however, if CRM positivity is based solely on intranodal tumour, this fact should be stated (CAP protocol).

3. Pathologic Tumour Response to Neoadjuvant Therapy (ypN)

The tumour response to neoadjuvant chemoradiation therapy should be recorded at least as present, recording the percentage of fibrosis in respect to residual tumour (or no response identified).

The entire scarred area of the rectum has to be blocked and scrutinized meticulously for any foci of residual tumour cells. Acellular mucin pools post neoadjuvant therapy are considered to represent a pathologic complete response. Tumour regression should be assessed only in the primary tumour; lymph node metastases should not be included in the assessment.

Several grading systems for tumour response are available^{11,12}. A 3-point system showed good inter-observer reproducibility¹² and may be clinically important, but it is not yet validated or regularly used in patient management and is not required for accreditation purposes for the Commission on Cancer.