

Evidence-Based Series 17-8

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Optimization of Preoperative Assessment in Patients Diagnosed with Rectal Cancer

E. Kennedy, E. Vella, D. B. MacDonald, S. Wong, R. McLeod, and the Preoperative Assessment for Rectal Cancer Guideline Development Group

Report Date: January 20, 2014

An assessment conducted in January 2024 deferred the review of Evidence-based Series (EBS) 17-8. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

EBS 17-8 is comprised of 3 sections. You can access the summary and full report here:

https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2241

Section 1: Guideline Recommendations

Section 2: Evidentiary Base

Section 3: Development Methods, Recommendations Development and

External Review Process

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PEBC Report Citation (Vancouver Style): Kennedy E, Vella E, MacDonald DB, Wong S, McLeod R, et al. Optimization of preoperative assessment in patients diagnosed with rectal cancer. Toronto (ON): Cancer Care Ontario; 2014 January 15. Program in Evidence-Based Care Evidence-Based Series No.: 17-8.

Journal Citation (Vancouver Style): Kennedy E, Vella ET, MacDonald DB, Wong CS, McLeod R. Optimisation of preoperative assessment in patients diagnosed with rectal cancer. Clin Oncol. 2015 Apr;27(4):225-245.

Evidence-Based Series #17-8: Section 1

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Optimization of Preoperative Assessment in Patients Diagnosed with Rectal Cancer

Guideline Recommendations

E. Kennedy, E. Vella, D. B. MacDonald, S. Wong, R. McLeod, and the Preoperative Assessment for Rectal Cancer Guideline Development Group

Report Date: January 20, 2014

GUIDELINE OBJECTIVE

To provide the optimal strategy to assess patients diagnosed with rectal cancer prior to treatment. This includes:

- 1. Investigations [chest X-ray or computed tomography (CT) thorax/abdomen/pelvis, colonoscopy, serum carcinoembryonic antigen] to assess for distant metastases and synchronous lesions in patients with rectal cancer
- 2. Imaging [magnetic resonance imaging (MRI) pelvis, endoscopic ultrasound (EUS), transrectal ultrasound (TRUS), CT pelvis] for local staging of rectal cancer
- 3. The optimal MRI protocol to locally stage rectal cancer
- 4. The optimal MRI criteria to locally stage rectal cancer
- 5. The optimal MRI criteria to select patients for neoadjuvant therapy
- 6. The role of multidisciplinary cancer conferences (MCCs)
- 7. The role of restaging MRI after neoadjuvant therapy

TARGET POPULATION

Newly diagnosed patients with rectal cancer¹ undergoing elective treatment comprise the target population.

INTENDED USERS

This guideline is intended for radiologists, surgeons, radiation oncologists, medical oncologists, and pathologists. This guideline coincides with the introduction of colorectal cancer Diagnostic Assessment Programs in Ontario. Diagnostic Assessment Programs provide coordination of care using a clinical navigator, fast tracking of diagnostic tests and a multidisciplinary team approach. They are an Ontario-wide strategic priority designed to

¹ Rectal cancers are defined as adenocarcinomas that lie between the termination of the sigmoid colon, usually at the level of the sacral promontory, and the dentate line. The mesorectum and its enveloping mesorectal fascia end at the pelvic floor or top of the puborectalis sling, while the most distal aspect of the rectum ends at the dentate line. The rectum is divided into three sections: lower rectum (0-5 cm from anal verge), mid rectum (5-10 cm from anal verge) and upper rectum (10-15 cm from anal verge). Rectal tumours are classified according to their location relative to the peritoneal reflection anteriorly, i.e., entirely above, astride or entirely below the peritoneal reflection.

improve patient access and outcomes, and are outlined in *Ontario Cancer Plan 2005-2011* and *Ontario Cancer Plan 2011-2014* (1).

RECOMMENDATIONS AND KEY EVIDENCE/JUSTIFICATION

RECOMMENDATION 1

- Staging for all rectal cancer patients should include:
 - CT of the abdomen and pelvis
 - CT of the chest or chest X-ray.
- Complete colonic examination by colonoscopy should be performed preoperatively, if possible.
- Serum carcinoembryonic antigen (CEA) should be assessed preoperatively.

Qualifying Statements

- While CT chest is preferred, chest x-ray may be used as an alternative method of chest imaging. The choice of CT of the chest or chest X-ray should be consistent with the modality used for postoperative surveillance. If CT of the chest is used for postoperative surveillance, then CT of the chest should be done at the same time as staging CT of the abdomen and pelvis. If chest X-ray is used for postoperative surveillance, then CT of the chest is recommended only if abnormalities requiring further investigation were found on chest X-ray.
- When CT of the chest is performed in combination with CT of the abdomen and pelvis, intravenous contrast is recommended. However, when CT of the chest is the sole investigation, intravenous contrast is potentially helpful but not required.
- If the use of intravenous contrast is contraindicated, abdominal MRI or ultrasound may be used to supplement CT to further assess for liver metastasis.
- Colonoscopy is preferred but CT colonography can be used to complete the assessment when the colonoscopy is incomplete. If not completed preoperatively, a complete colonoscopy should be performed postoperatively.
- This recommendation applies to patients undergoing elective treatment only (i.e., does not include patients with obstruction or perforation).

Key Evidence/Justification

This recommendation was adapted from the NICE 2011, NZGG 2011, SIGN 2011 and PEBC 2006 guidelines, which were based on consensus, as there were no high-quality studies to support this recommendation (2-5). While NICE 2011 and SIGN 2011 have recommended CT of the chest, NZGG 2011 and PEBC 2006 have recommended chest X-ray. The main advantages of CT of the chest discussed by the Guideline Development Group include: (i) the early detection of pulmonary nodules that may lead to a change in management (i.e., first-line chemotherapy, metastasectomy) (6) and (ii) a baseline CT of the chest for comparison if CT of the chest is used for postoperative surveillance. The main disadvantage of CT of the chest discussed by the Guideline Development Group included the high sensitivity and low specificity of CT to detect indeterminate pulmonary nodules and lack of consensus as to how these nodules should be managed (7). The cost of performing a CT of the chest was discussed by the Guideline Development Group and was considered to be neither an advantage nor disadvantage, as the added cost and time required to conduct a CT of the chest in conjunction with a CT of the abdomen/pelvis is minimal. Although there is limited evidence, the Guideline Development Group has made the recommendation to endorse CT of the chest for pulmonary staging. The main reasons for this were the increased risks of pulmonary metastases alone with rectal cancer compared to colon cancer (8,9) and the ability to have a baseline CT chest for comparison during the surveillance period.

Serum CEA was recommended preoperatively only by the NZGG 2011 and postoperatively by NZGG 2011, NICE 2011 and SIGN 2011 (2-4). The evidence for these recommendations were based on four meta-analyses that show intensive follow-up programs that include CEA testing lead to significantly improved overall survival and detection of asymptomatic recurrences compared to a less intensive follow-up. The advantages of preoperative CEA testing discussed by the Guideline Development Group include: (i) the recommendation and evidence for CEA testing for postoperative surveillance and (ii) limited value of postoperative CEA testing if no preoperative CEA is available for comparison. The Guideline Development Group did not identify or discuss any disadvantages to use of preoperative CEA testing. Therefore, a recommendation to perform preoperative CEA was made and is consistent with the colorectal cancer Diagnostic Assessment Programs in Ontario.

RECOMMENDATION 2

• Patients with rectal cancer should undergo MRI pelvis in order to assess T and N categories and the distance to the MRF [(i.e., potential circumferential resection margin (CRM)].

Qualifying Statements

- For the purpose of this guideline, the distance to the mesorectal fascia (MRF) will be used and represents the potential CRM. The use of the term MRF is more appropriate, because CRM is a pathologic term determined by the extent of surgical resection.
- For low rectal cancer, defined as 0-5 cm from the anal verge, if local excision (with transanal excision or transanal endoscopic microsurgery) is being considered, transrectal ultrasonography (TRUS) performed by those with demonstrated expertise is preferred to MRI, in order to more accurately discriminate between T1 and T2 lesions. TRUS should not be used to predict CRM involvement.
- For upper rectal cancers, defined as 10-15 cm above the anal verge, in which the mesorectal fascia is not threatened, MRI may not provide significantly more information than CT of the pelvis.
- MRI is used for local staging of the rectum and does not adequately assess regional disease
 at the level of the inferior mesenteric artery or distant disease; CT of the abdomen and
 pelvis should be used to assess for distant metastases and regional disease including lymph
 node involvement along the inferior mesenteric artery.
- If there are contraindications to MRI, CT of the pelvis and/or TRUS are recommended.

Key Evidence/Justification

The evidence for this recommendation was based on the NICE 2011, NZGG 2011, SIGN 2011 and PEBC 2006 guidelines (2-5). These guidelines discussed the results of two systematic reviews by Kwok et al 2000 and Bipat et al 2004 that assessed the diagnostic accuracy of MRI, CT and US for T and N category (10,11). These studies showed that ultrasound had the highest sensitivity and specificity for T-category, followed by MRI and CT, respectively. Two additional systematic reviews assessing the diagnostic accuracy of MRI only to assess MRF involvement have shown that MRI has good sensitivity and specificity to predict MRF involvement (12,13). Taken together, these studies suggest that transrectal ultrasound has the best diagnostic accuracy for T-category, in particular T1 and T2 tumours, followed by MRI and CT, and MRI has the best diagnostic accuracy to detect MRF involvement. Therefore, based on these studies, we have recommended MRI as the modality of choice for preoperative staging of rectal cancer. To date, there are only a few, poor-quality studies that have directly compared the diagnostic accuracy of CT and MRI for the prediction of MRF involvement, and

therefore, there is currently insufficient evidence to support the use of CT to assess distance to the MRF and MRF involvement. However, many experts would likely consider the added benefit of MRI relative to CT relatively small for the assessment of upper rectal and rectosigmoid tumours in which the mesorectal fasica (i.e., potential CRM) is not threated or involved.

The reviews by Kwok et al 2000, Bipat et al 2004, and Lahaye et al 2005 also show that all modalities have moderate accuracy to detect nodal involvement (10-12). Therefore, the Guidelines Development Group endorsed the recommendations from the NICE 2011, SIGN 2011 and NZGG 2011 guidelines to use MRI for local staging of rectal cancer.

RECOMMENDATION 3

• At a minimum, axial, coronal and sagittal T2-weighted images of the pelvis and high-resolution T2-weighted sequences perpendicular to the long axis of the rectum at the level of the tumour using phased-array coil are required.

Qualifying Statements

- A high-resolution MRI meets the specifications outlined by the MERCURY Group Protocol and is shown in Appendix 1.
- For low rectal cancer, coronal high-resolution images along the long axis of the anal canal should be considered in addition to or instead of the long axis of the rectum in order to better assess the relationship of the tumour to the sphincter components.
- Additional sequences, bowel preparation, anti-peristaltics, luminal distension, and intravenous contrast are believed to be supplemental and are not a mandatory requirement for a high-quality MRI.

Key Evidence/Justification

A review of the literature for MRI protocols including optimal sequences, bowel preparation, enemas, anti-peristaltic agents, and intravenous contrast was performed. There was only one study that suggested rectal distension may improve the accuracy of T-category assessment while having little effect on MRF or lymph node involvement (14).

Four studies assessed use of gadolinium-enhanced T1 images compared to T2 unenhanced images (10,15-17). However, these studies generally found no difference in T or N staging, and therefore, use of gadolinium was not recommended as a mandatory component of the MRI protocol. Two meta-analyses demonstrated that multiple readers resulted in better prediction of T category and MRF involvement than when these criteria were assessed by single readers (13,18). While consensus reading is preferred, due to issues with respect to work load and feasibility, The Guideline Development Group also did not recommend this manoeuvre as a mandatory component of the MRI protocol.

Based on these limited data, the Guideline Development Group endorsed the MRI protocol used by the MERCURY study group, which was a prospective, European, multidisciplinary project that demonstrated the accuracy and feasibility of MRI as a method of assessing rectal cancer. The evidence to support this recommendation can be found in Appendix 1. This is also the MRI protocol endorsed by the Surgical Oncology Program (available here: https://www.cancercareontario.ca/en/guidelines-advice/modality/surgery) (19).

RECOMMENDATION 4

 The MRI report for preoperative, local staging of rectal cancer should include the elements outlined in the CCO Synoptic MRI Report for Rectal Cancer (available here: https://www.cancercare.on.ca/cms/One.aspx?portalId=1377&pageId=80771) (see Appendix 2) (20).

Key Evidence/Justification

The Guideline Development Group endorsed the synoptic MRI report, which was based on evidence and multidisciplinary consensus. The evidence and justification to support these MRI criteria are available here https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=133269 (19). It is important to note that the overall rationale for the synoptic MRI report was to provide clear definition for each item on the synoptic report and to improve overall consistency and completeness (but not necessarily accuracy) of MRI reports across the province.

RECOMMENDATION 5

• According to current practice, patients with stage II or III rectal cancer should be offered preoperative therapy using T and N categories to preoperatively stage patients.

Qualifying Statement

• To date, there is insufficient evidence to change the current selection criteria from T and N categories to distance to the MRF (i.e., potential CRM), extramural depth of invasion (EMD) and/or extramural vascular invasion (EMVI).

Key Evidence/Justification

Several RCTs have been done showing that preoperative radiation or chemoradiation leads to a decrease in the risk of local recurrence (21-24). These RCTs assessed T and N category with digital rectal examination and/or TRUS to select patients for neoadjuvant therapy. While there have been no RCTs that have used MRI criteria to select patients for preoperative therapy, more recently, two prospective non-randomized cohort studies used distance to the MRF of less than 1 mm on MRI to select patients for preoperative therapy (25,26). In these studies, patients with distance to the MRF of greater than or equal to 1 mm on MRI, regardless of T and N category, were treated with surgery alone. The results for these patients suggested that the rate of positive CRM was 1.5% (2/134) (25), and local recurrence was 3.3% (4/122) (26). These studies are clinically relevant because they suggest that preoperative radiation or chemoradiation may not be necessary in as many patients when MRI is used to select patient for preoperative therapy. This has significant clinical implication because preoperative radiation has been shown to lead to poorer bowel and sexual function compared to surgery alone (27). While these findings are important, the Guideline Development Group recommended that higher quality evidence is required before a change in the selection criteria can be recommended.

RECOMMENDATION 6

• All rectal cancer patients in Ontario, independent of their geographic locale, should have their case presented at a multidisciplinary cancer conference (MCC).

Qualifying Statement

 Alternatively, each case should be reviewed through collaborative discussion(s) and/or multidisciplinary clinic with appropriate clinicians (surgeon, radiation oncologist, radiologist, medical oncologist and pathologist). The goal is to provide clinical correlation, decide on an individualized treatment plan, and provide feedback to the radiologist and other members of the team.

Key Evidence/Justification

The effect of having an MCC discussion on patient outcomes was weak and conflicting. One study did find fewer positive CRM rates for those patients who were discussed at an MCC, but another study did not (28,29). Three studies investigated the effect of having an MCC on survival and did not find an association (30-32). Four studies suggested that patients were more likely to receive appropriate therapy if they were reviewed at an MCC (33-36). The Guideline Development Group chose to recommend that all patients with rectal cancer be discussed at an MCC, which is consistent with CCO's MCC standards document (37).

RECOMMENDATION 7

• Restaging MRI following preoperative chemoradiation is optional.

Qualifying Statement

 No recommendation can be made to support or refute the routine use of restaging MRI following neoadjuvant therapy. However, restaging MRI may be appropriate in cases where there is suspected MRF involvement or when complete response would change management, on a per patient basis.

Key Evidence/Justification

The Guideline Development Group did not recommend routine use of restaging MRI following neoadjuvant therapy due to lack of evidence. In particular, there were no studies assessing the effect of restaging MRI on surgical management or patient outcomes. However, two studies have shown that a lower tumour regression grade score (i.e., TRG 1 and 2) on restaging MRI was an independent and positive predictor of overall and disease-free survival (38,39). In addition, one of these studies showed that MRF involvement on restaging MRI was an independent and positive predictor of local recurrence (38). Two other studies found that tumour reduction volume was a significant predictor of disease-free survival (40,41) and overall survival (41). Due to lack of evidence, the Guideline Development Group does not recommend routine use of restaging MRI. However, the Guideline Development group believed that restaging MRI in select patient populations where observation following a complete response on MRI would be considered a reasonable treatment option (e.g., high-risk surgical patients, patients requiring abdominoperineal resection) or in patients with a potentially threatened CRM to ensure adequate response to chemoradiation prior to surgery.

FUTURE RESEARCH

Future high-quality studies need to:

- Assess the effect of preoperative chest CT in the management of rectal cancer patients: in particular how to manage indeterminate pulmonary nodules and the effect of this on clinical outcomes;
- Evaluate new approaches to selection of rectal cancer patients for pre-CRT using MRI to predict distance to the MRF (i.e., potential CRM) instead of T and N category;
- Compare the diagnostic accuracy of CT and MRI to predict distance to the MRF (i.e., potential CRM) for upper rectal tumours above the anterior peritoneal reflection where the improved resolution of MRI may not provide significant advantage over CT compared to mid and low rectal cancers;
- MRI protocols for restaging MRI to assess the diagnostic accuracy for predicting complete clinical response.

RELATED GUIDELINES

- CCO's Radiology: Synoptic MRI Report for Rectal Cancer available here: https://www.cancercare.on.ca/cms/One.aspx?portalld=1377&pageId=80771 (19)
- CCO's MCC standards document available here: https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/286 (37)

Funding

The PEBC is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from the Ontario Ministry of Health and Long-Term Care.

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Appendix 1

To achieve optimal visualization of the rectum and surrounding structures for staging of rectal tumours, the protocol utilized by the MERCURY study group ¹ is recommended (Table).

Hardware

Different field strengths may be used with equally good results but require adjustment of imaging parameters to obtain an adequate signal-to-noise ratio. Although endoluminal coil MRI may provide superior imaging resolution , due to its limited usefulness in stricturing rectal tumours and increased cost, it is less widely used across Ontario. On this basis, the evidence and recommendations outlined in this document are intended specifically to guide the use of pelvic phased array coil MRI.

Sequences

Four fast-spin echo, T2-weighted sequences without fat saturation are recommended, as summarized below (Table). Sequences 1 and 2 give a crude visualization of the primary tumour, possible sites of nodal involvement, and orientation of the tumour. They are used to plan sequences 3 and 4, which are the high-resolution sequences. These sequences enable characterization of nodes and detailed staging of the extent of the primary tumour. T1-weighted sequences are not mandatory as they prolong the study and do not provide additional information.

Table

Tuble								
Sequence	Imaging plane	TR/T E	FOV (cm)	Section thickness (mm)	Matrix size	ETL	NSA	Comment
1	Sagittal	25005000/ 85	24	5-0	512x256	8	2	Allow visualization of the tumour
2	Axial	4000/ 85	24	5-0	512x256	8	2	Pelvic sidewall to sidewall, from iliac crest to symphysis pubis
3	Oblique axial	4000/ 85	16 (20 for 1.0T machines)	3-0	256x256	8	4	Through tumour and perirectal tissues, perpendicular to long axis of rectum
4	Coronal oblique	4000/ 85	16 (20 for 1.0T machines)	3-0	256x256	8	4	For low rectal tumours (at or below origin of levators)

(Source: MERCURY Study Group. Extramural depth of tumor invasion at thin-section MR in patients with rectal cancer: results of the MERCURY study. Radiology 2007;243:132-9.)

^{1.} Extramural depth of tumor invasion at thin-section MR in patients with rectal cancer: results of the MERCURY study. Radiology. Apr 2007;243(1):132-139.

^{2.} Bipat S, Glas AS, Slors FJ, Zwinderman AH, Bossuyt PM, Stoker J. Rectal cancer: local staging and assessment of lymph node involvement with endoluminal US, CT, and MR imaging--a meta-analysis. Radiology. Sep 2004;232(3):773-783.

Appendix 2





This document was developed by Drs Eisar Al-Sukhni, Laurent Milot, Mark Fruitman, Gina Brown, Sellna Schmocker and Erin Kennedy for the Cancer Services
Innovation Partnership — a joint initiative of Cancer Care Ontario and the Canadian Cancer Society

MRI PROTOCOL Overall image qua	ality: Adequate	Suboptimal	☐ Non-diagnostic				
Z. TUMOUR LOCATION Tumour location (from anal verge): Low (0-5.0 cm) Mid (5.1-10.0 cm) High (10.1-15.0 cm)							
Distance of the lowest extent of tumour from anal verge: cm Distance of lowest extent of tumour from top of the anal sphincter: cm Relationship to anterior peritoneal reflection: Above At or straddles Below Not able to assess							
Craniocaudad extent	nt/location (clock face):						
☐ T3 ☐ T3/possible T4* ☐ T4*	s spiculation of the perirectal fa ures with possible invasion: _		ee list below)				
GU bladder left ureter; right ureter prostate uterus vagina	PELVIC SIDE WALL Obturator internus Piriformis LEVATOR ANI Pubococcygeus Ileococcygeus Coccygeus	BONE/VASCULAR sacrum (specify level) left internal iliac vessels; right internal il left external iliac vessels; right external					
*If yes, please compl of puborectalis: Possible confineme	f the tumour at or below t ete the following section f nt to the submucosa; no defi ernal sphincter; no involveme	inite involvement of internal sphir ent of intersphincteric fat or exter	onent of the tumour below the top border ncter (suspected T1) rnal sphincter (early T2)				

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5.	DISTANCE TO THE MRF AND EXTRAMURAL DEPTH OF INVASION (EMD)					
i)	Shortest distance of the definitive tumour border to the MRF = $\phantom{aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa$					
ii)	Extramural depth of invasion (EMD) at this level = mm [Record 0 mm for T1 and T2 tumours]					
iii)	Are there any tumour spiculations closer to the MRF? No Yes*					
	*If yes, please specify distance = mm and location (on clock face)					
iv)	Is there any other component of the tumour (any T2-3) closer to the MRF? No Yes*					
	*If yes, please specify distance = mm and location (on clock face)					
6. EXTRAMURAL VASCULAR INVASION (EMVI)						
	EMVI: Absent Equivocal Present					
7.	MESORECTAL LYMPH NODES AND TUMOUR DEPOSITS					
	Any suspicious mesorectal lymph nodes and/or tumour deposits? ☐ No ☐ Yes* (suspicious = irregular border, mixed signal intensity and/or ≥ 8 mm)					
	*If yes: (please complete a and b)					
	(a) Shortest distance of any suspicious mesorectal lymph node/tumour deposit to MRF =(b) Please indicate location of the lymph node/deposit closest to the MRF:					
	At level of tumour; at o'clock					
	Above tumour; at o'clock					
	Below tumour; ato'clock					
8. EXTRAMESORECTAL LYMPH NODES						
	y extramesorectal lymph node(s) with suspicious morphology or signal? ☐No ☐Yes* spicious = irregular border, mixed signal intensity and/or ≥ 1 cm)					
*	f yes, please specific location (free text):					
9. FREE TEXT/ADDITIONAL COMMENTS						

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