Rectal cancer

ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up

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*For details of author affiliations, correspondence and versions, please see the full version at esmo.org/Guidelines/Gastrointestinal-Cancers/Rectal-Cancer
Diagnosis and pathology

Categorisation

Diagnosis is based on a DRE and endoscopy, with biopsy for histopathological confirmation.

There is a wide overlap of molecular genomic profiles of left-sided / sigmoid with rectal cancer; so rectal cancer cannot be seen as a molecularly defined different entity.
Management should be by an MDT of radiologists, surgeons, radiation oncologists, medical oncologists and pathologists.
## Staging and risk assessment

Diagnostic work-up in primary rectal cancer

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method of choice</th>
</tr>
</thead>
</table>
| Location (distance from anal verge) | DRE/Palpation  
  Rigid sigmoidoscopy (flexible endoscopy)* |
| Morphological verification     | Biopsy                                                |
| cT stage                       | ERUS  
  MRI  
  MRI (ERUS)*                                      |
| Intermediate/advanced          | MRI (ERUS, palpation, EUA)*                           |
| Sphincter infiltration         | MRI (ERUS, palpation, EUA)*                           |
| cN stage                       | MRI (CT, ERUS)*                                       |
| M stage                        | CT, MRI (or US)* of the liver/abdomen  
  CT of the thorax  
  PET-CT if extensive EMVI for other sites |
| Evaluation for all patients    | MDT discussion                                        |

*Methods within brackets are less optimal
## Staging and risk assessment

The UICC TNM staging (8th edition) classification for colon and rectal cancer

### TNM Clinical Classification

<table>
<thead>
<tr>
<th>T – Primary Tumour</th>
<th>T0</th>
<th>No evidence of primary tumour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tis</td>
<td>T1</td>
<td>Tumour invades submucosa</td>
</tr>
<tr>
<td></td>
<td>T2</td>
<td>Tumour invades muscularis propia</td>
</tr>
<tr>
<td></td>
<td>T3</td>
<td>Tumour invades subserosa or into non-peritonealised pericolic or perirectal tissues</td>
</tr>
<tr>
<td></td>
<td>T4</td>
<td>Tumour directly invades other organs or structures* and/or perforates visceral peritoneum</td>
</tr>
<tr>
<td></td>
<td>T4a</td>
<td>Tumour perforates visceral peritoneum</td>
</tr>
</tbody>
</table>
|                   | T4b| Tumour directly invades other organs or structures

### TNM Clinical Classification

<table>
<thead>
<tr>
<th>N – Regional Lymph Nodes</th>
<th>N0</th>
<th>No regional lymph node metastasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N1</td>
<td>N1a</td>
<td>Metastasis in 1 regional lymph node</td>
</tr>
<tr>
<td>N1b</td>
<td>N1b</td>
<td>Metastasis in 2–3 regional lymph nodes</td>
</tr>
<tr>
<td>N1c</td>
<td>N1c</td>
<td>Tumour deposit(s), i.e. satellites,(\parallel) in the subserosa, or in non-peritonealised pericolic or perirectal soft tissue without regional lymph node metastasis</td>
</tr>
<tr>
<td>N2</td>
<td>N2a</td>
<td>Metastasis in 4–6 regional lymph nodes</td>
</tr>
<tr>
<td>N2b</td>
<td>N2b</td>
<td>Metastasis in 7 or more regional lymph nodes</td>
</tr>
</tbody>
</table>

### M – Distant Metastasis

<table>
<thead>
<tr>
<th>M0</th>
<th>No distant metastasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>Distant metastasis</td>
</tr>
<tr>
<td>M1a</td>
<td>Metastasis confined to one organ (liver, lung, ovary, non-regional lymph node(s)) without peritoneal metastases</td>
</tr>
<tr>
<td>M1b</td>
<td>Metastasis in more than one organ</td>
</tr>
<tr>
<td>M1c</td>
<td>Metastasis to the peritoneum with or without organ involvement</td>
</tr>
</tbody>
</table>

\* The UICC TNM staging (8th edition) classification for colon and rectal cancer

\*\, †, ‡, §, \(\parallel\)

For details please see following slide


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### Staging and risk assessment

**Tis**  
*Carcinoma in situ: invasion of lamina propria*  
*Includes cancer cells confined within the mucosal lamina propria (intramucosal) with no extension through the muscularis mucosae into the submucosa*

**T4**  
*Tumour directly invades other organs or structures†,‡,§ and/or perforates visceral peritoneum*  
†Involves through to visceral peritoneum to involve the surface  
‡Direct invasion in T4b includes invasion of other organs or segments of the colorectum by way of the serosa, as confirmed on microscopic examination, or for tumours in a retroperitoneal or subperitoneal location, direct invasion of other organs or structures by virtue of extension beyond the muscularis propria  
§Tumour that is adherent to other organs or structures, macroscopically, is classified cT4b. However, if no tumour is present in the adhesion, microscopically, the classification should be pT1–3, depending on the anatomical depth of wall invasion

**N1c**  
*Tumour deposit(s), i.e. satellites,‖ in the subserosa, or in non-peritonealised pericolic or perirectal soft tissue without regional lymph node metastasis*  
‖Tumour deposits (satellites) are discrete macroscopic or microscopic nodules of cancer in the pericolorectal adipose tissue’s lymph drainage area of a primary carcinoma that are discontinuous from the primary and without histological evidence of residual lymph node or identifiable vascular or neural structures. If a vessel wall is identifiable on H&E, elastic or other stains, it should be classified as venous invasion (V1/2) or lymphatic invasion (L1). Similarly, if neural structures are identifiable, the lesion should be classified as perineural invasion (Pn1). The presence of tumour deposits does not change the primary tumour T category, but changes the node status (N) to pN1c if all regional lymph nodes are negative on pathological examination

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Subclassification of T3 rectal cancer

<table>
<thead>
<tr>
<th>T3 Stage</th>
<th>Depth of invasion beyond the muscularis propria, in mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3a*</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>T3b</td>
<td>1–5</td>
</tr>
<tr>
<td>T3c</td>
<td>6–15</td>
</tr>
<tr>
<td>T3d</td>
<td>&gt; 15</td>
</tr>
</tbody>
</table>

*This subclassification, based on pretreatment decision MRI evaluation, is clinically valuable and can be used also in the histopathological classification, although it is not validated nor incorporated in any of the TNM versions.

**TNM Pathological Classification**

<table>
<thead>
<tr>
<th>Stage</th>
<th>pT</th>
<th>pN</th>
<th>pM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>Tis</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage I</td>
<td>T1, T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage II</td>
<td>T3, T4</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIA</td>
<td>T3</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIB</td>
<td>T4a</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIC</td>
<td>T4b</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage III</td>
<td>Any T</td>
<td>N1, N2</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIIA</td>
<td>T1, T2</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIIB</td>
<td>T1, T2</td>
<td>N2b</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIIC</td>
<td>T3, T4a</td>
<td>N2a</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Any T</td>
<td>Any N, N1, N2</td>
<td>M1</td>
</tr>
<tr>
<td>Stage IVA</td>
<td>Any T</td>
<td>Any N</td>
<td>M1a</td>
</tr>
<tr>
<td>Stage IVB</td>
<td>Any T</td>
<td>Any N</td>
<td>M1b</td>
</tr>
<tr>
<td>Stage IVC</td>
<td>Any T</td>
<td>Any N</td>
<td>M1c</td>
</tr>
</tbody>
</table>

The pT and pN categories correspond to the T and N categories. The historical examination of a regional lymphadenectomy specimen will ordinarily include 12 or more lymph nodes. If the lymph nodes are negative, but the number ordinarily examined is not met, classify as pN0.
## Histopathology

### Summary of recommendations

| T1 tumours classification | • According to Haggitt's sub-classification if the cancer is pedunculated  
<table>
<thead>
<tr>
<th></th>
<th>• According to Kudo/Kikuchi (sm)-system if in a sessile adenoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resection en bloc</td>
<td>Recommended for accurate assessment of invasion in the resection margin and the deepest area</td>
</tr>
<tr>
<td>Radical surgery</td>
<td>According to Japanese guidelines, radical surgery and removal of lymph nodes is recommended for high-risk pathological features</td>
</tr>
<tr>
<td>Surrogate</td>
<td>Involved CRM rate (i.e. &lt; 1 mm) and TME quality are surrogates for good oncological outcomes</td>
</tr>
<tr>
<td>Lymph node examination</td>
<td>At least 12 regional lymph nodes should be examined and their margins documented</td>
</tr>
<tr>
<td>Mesorectal resections</td>
<td>Histopathological examination should include a photographic record of the surgical specimen and assessment of TME quality</td>
</tr>
<tr>
<td>Evaluation</td>
<td>ENE of nodal metastases, EMVI, PNI and tumour budding should be evaluated</td>
</tr>
</tbody>
</table>

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Histopathology

The specimen is examined as a whole (fresh) and as cross-sectional slices (fixed) to make an adequate interpretation.

A TME specimen ideally should have a smooth surface, without incisions, defects or cracks, as an indication of successful surgical excision of all mesorectal tissue. ‘Coning’ represents the tendency for the surgeon to cut inwards towards the central tube of the rectum during distal dissection, rather than staying outside the visceral mesorectal fascia. The specimen then shows a tapered, conical appearance representing suboptimal surgical quality.

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**Objective grading of technical quality of TME surgery specimen**

<table>
<thead>
<tr>
<th>Plane of Surgery Achieved</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesorectal plane (good plane of surgery achieved)</td>
<td>Intact mesorectum with only minor irregularities of a smooth mesorectal surface; no defect deeper than 5 mm; no coning; and smooth circumferential resection margin on slicing</td>
</tr>
<tr>
<td>Intra-mesorectal plane (moderate plane of surgery achieved)</td>
<td>Moderate bulk to mesorectum, with irregularities of the mesorectal surface; moderate distal coning; muscularis propria not visible with the exception of levator insertion; and moderate irregularities of circumferential resection margin</td>
</tr>
<tr>
<td>Muscularis propria plane (poor plane of surgery achieved)</td>
<td>Little bulk to mesorectum with defects down onto muscularis propria; very irregular circumferential resection margin; or both</td>
</tr>
</tbody>
</table>

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Treatment recommendations

Very early, early and intermediate disease

Very early disease cT1, sm1 cN0
- Local RT may be used as an alternative to local surgery (+/- CRT)
  - TEM if pT1 and no adverse features
  - TEM plus perioperative CRT if adverse features present
  - TME if adverse histopathology (sm ≥ 2, G3, V1, L1)

Early disease cT1–cT2; cT3a/b if middle or high cN0 (cN1 if high), MRF clear, no EMVI
- TEM, CRT or ‘watch-and-wait’ for fragile, high-risk patients or those rejecting radical surgery
  - MRI to re-evaluate tumour
- TME in most cases (plus photographic record of specimen and assessment of TME quality)

Intermediate disease cT3a/b very low, levators clear, MRF clear, cT3a/b in mid- or high rectum, cN1–2 (not extranodal), no EMVI
- TME alone or SCPRT/CRT if good quality mesorectal excision cannot be assured
  - MRI to re-evaluate tumour
- ‘Watch-and-wait’ may be considered in high-risk patients if cCR achieved with CRT
  - TME in most cases (plus photographic record of specimen and assessment of TME quality)
Treatment recommendations

Locally advanced and advanced disease

- Locally advanced disease cT3c/d or very low, levators not threatened, MRF clear cT3c/d mid-rectum, cN1-N2 (extranodal), EMMI+
  - SCPRT or CRT
  - MRI to re-evaluate tumour
  - ‘Watch-and-wait’ may be considered in high-risk patients if cCR achieved with CRT
  - TME (plus photographic record of specimen and assessment of TME quality)

- Advanced disease cT3 with any MRF involved, cT4b, levators threatened, lateral node+
  - CRT
  - SCPRT plus FOLFOX and delay to surgery
  - MRI to re-evaluate tumour
  - TME (plus photographic record of specimen and assessment of TME quality)
  - Further surgery if needed due to tumour overgrowth
Management of local/locoregional disease

Risk of recurrence according to postoperative histology

Summary of recommendations

Postoperative histopathological features with an impact on the risk of local recurrence, include:

- pathological TNM stage
- T substage
- CRM status
- the number/proportion of involved lymph nodes
- extracapsular extension
- extranodal deposits
- tumour differentiation
- lymphovascular invasion
- extramural vascular invasion
- perineural invasion

The risk of local recurrence in patients with histologically involved nodes is reduced with good quality mesorectal excision, ensuring removal of all mesorectal lymph nodes.
Considerations for selection of the most adequate (C)RT regimen

Management of local/locoregional disease

Summary of recommendations

The standards of care for preoperative treatment are SCPRT:

- 25 Gy total dose at 5 Gy/fraction during 1 week, then immediate surgery (< 10 days from the first radiation fraction) and CRT with a recommended dose of 45–50 Gy in 25–28 fractions
- To be considered for preoperative RT, if CRM is threatened: boost of 5.4 Gy in 3 fractions
- Postoperative RT: routinely with 5.4–9.0 Gy in 3–5 fractions according to CRM

CRT is recommended where CRM and/or R0 resection status are predicted by the MDT to be at risk

Routine addition of oxaliplatin to fluoropyrimidine-based CRT is not recommended

5-FU IV infusion / oral capecitabine, are recommended in preference to bolus 5-FU during CRT and as adjuvant systemic treatment

Preoperative RT or CRT reduces the rate of local recurrence for mid/low stage II/III rectal cancers, but is associated with significantly worse postoperative intestinal and sexual functions

Upper rectal cancers above the peritoneal reflection should be treated as colon cancer

Patients with cT4 tumours falling back into the pelvis might benefit from neoadjuvant CRT or NACT alone

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Management of local/locoregional disease

Preoperative (neoadjuvant) chemotherapy

<table>
<thead>
<tr>
<th>Preoperative chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoropyrimidine and oxaliplatin-based NACT, either alone or combined with targeted agents, instead of preoperative CRT in cT3 tumours not threatening the CRM and cT4 tumours in the mid- and upper rectum, is associated with pCR in 25% of early-stage cases</td>
</tr>
<tr>
<td>(NACT alone is not recommended for localised, non-metastatic disease outside clinical trials)</td>
</tr>
<tr>
<td>Situation</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Assessment of the primary tumour response</td>
</tr>
</tbody>
</table>
| Clinical complete response and a watch-and-wait approach | - An initially raised CEA level which returns to normal (< 5 ng/mL) after CRT is associated with an increased likelihood of cCR and pCR  
- Further validation of a watch-and-wait approach is required |
| Patients planned for surgery | - In LARC, the primary tumour/CRM should be re-evaluated with MRI after CRT prior to resection  
- mriTRG can predict survival outcomes but does not correlate well with histopathological TRG  
- CT has relatively low value in assessing local response  
- PET should not be routinely used as a response tool and surgery should not be modified based on the findings  
- Patients with persistent potential CRM involvement on imaging following CRT should be referred to a MDT for tumour removal en bloc |
### Management of local/locoregional disease

#### Preoperative (neoadjuvant) chemotherapy

<table>
<thead>
<tr>
<th>Situation</th>
<th>Reassessment/response assessment after preoperative (chemo)radiotherapy</th>
</tr>
</thead>
</table>
| **Distant metastases**           | Routine restaging of chest and abdomen after neoadjuvant CRT is not recommended, but patients with cT4 cancers, threatened CRM and EMVI should be re-staged within 3 months of original staging  
**NB:** Applicable only for earlier stage tumours when clinical progression is observed |
| **Pathological assessment of response** | • As a minimum, tumours should be graded as having either pCR, some response or no response  
• Other dynamic histopathological features, i.e. amount of necrosis, regression of EMVI and downstaging of T and N stage, may also help to define outcomes  
• Interval to surgery  
• For SCPRT in resectable cancers not requiring downstaging, immediate surgery (within 7 days from the end of neoadjuvant treatment, and within 0–3 days if the patient is ≥ 75 years [≤ 10 days from the first radiation fraction]) is recommended |
### Management of local/locoregional disease

**Postoperative therapy**

#### Postoperative chemoradiotherapy

May be used selectively in patients with unexpected adverse histopathological features after primary surgery, including:
- positive CRM
- perforation in the tumour area
- incomplete mesorectal resection

or in other cases with high risk of local recurrence if preoperative RT has not been given.

#### Postoperative chemotherapy

- Adjuvant ChT after preoperative CRT/RT with postoperative histology (ypTNM) stage III (and ‘high-risk’ yp stage II) can be considered (level of evidence is lower than in colon cancer)
- The decision to use postoperative ChT (fluoropyrimidine alone or combined with oxaliplatin) should take into account the predicted toxicity and the risk of relapse

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## Management of local/locoregional disease

Potential indications for postoperative CRT if preoperative CRT not given

<table>
<thead>
<tr>
<th>Sufficient and necessary</th>
<th>Insufficient and unnecessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRM ≤ 1 mm</td>
<td>pT1/pT2</td>
</tr>
<tr>
<td>pT4b</td>
<td>pT3</td>
</tr>
<tr>
<td>pN2 extracapsular spread close to MRF</td>
<td>CRM &gt; 2 mm</td>
</tr>
<tr>
<td>Extranodal deposits (N1c)</td>
<td>pT4a above peritoneal reflection</td>
</tr>
<tr>
<td>pN2 if poor mesorectal quality/defects</td>
<td>pN1</td>
</tr>
</tbody>
</table>

### Sufficient

- pN2 low tumours within 4 cm of anal verge (risk of involved LPLN)
- Extensive extramural vascular invasion/perineural invasion close to MRF

### Borderline sufficient

- pN2 in mid/upper rectum if good mesorectal quality
- CRM 1–2 mm
- Circumferential obstructing tumours
Management of local recurrence

Summary of recommendations

Surgical salvage should be carried out by specialist team

If RT has not already been administered, patients should be considered for standard dose preoperative CRT (45–50 Gy in 5–6 weeks), or SCPRT followed by a fluoropyrimidine and oxaliplatin-based ChT, prior to attempted resection

In patients previously irradiated, re-irradiation to lower doses (with concomitant ChT) is safe and can be used to facilitate a curative resection or to palliate symptoms

Systemic palliative ChT to downstage a tumour and enable salvage surgery may be considered

Palliative surgical diversion procedures and brachytherapy are effective palliative options
Management of local recurrence

- Local recurrence
  - Curative approaches
    - Preoperative CRT
    - Re-irradiation in previously irradiated patients to facilitate a curative resection
    - SCPRT
    - Fluoropyrimidine and oxaliplatin-based ChT
  - Surgical salvage by specialist team
  - Palliative approaches
    - Re-irradiation in previously irradiated patients to palliate symptoms
    - Systemic palliative ChT to downstage tumour
    - Palliative surgical diversion procedures in patients with reasonable life expectancy
    - Brachytherapy
## Management of advanced/metastatic disease

### Summary of recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic rectal cancer management should reflect tumour-, disease-, patient- and treatment-related factors</td>
</tr>
<tr>
<td>ChT alone may be insufficient where the primary tumour remains <em>in situ</em> and untreated and local RT palliation of rectal symptoms may be required</td>
</tr>
<tr>
<td>SCPRT is preferable to CRT</td>
</tr>
<tr>
<td>Rapid local control with effective systemic ChT and appropriate sequence/timing of metastasectomy is the aim of treatment where cure is a possibility</td>
</tr>
<tr>
<td>SPCRT with capecitabine/oxaliplatin/bevacizumab can be used to facilitate resection borderline resectable liver metastases and primary tumour</td>
</tr>
<tr>
<td>The MDT should be responsible for critical treatment decisions in patients with potentially curable metastatic disease</td>
</tr>
</tbody>
</table>

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Management of advanced/metastatic disease

Metastatic disease

Refer to ESMO consensus guidelines on metastatic colorectal cancer

*RAS* and *BRAF* mutational status testing should be carried out at the time of diagnosis of metastatic disease, before treatment with EGFR-targeted monoclonal antibodies

Curative approaches

Palliative approaches

Systemic ChT

SCPRT plus triplet ChT (capecitabine, oxaliplatin and bevacizumab)

SCPRT

Metastasectomy

Systemic chemotherapy +/- targeted agents
<table>
<thead>
<tr>
<th>Summary of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no molecular markers to guide treatment approaches or to predict response to RT or CRT</td>
</tr>
<tr>
<td>Rectal cancers with distant metastases should be studied for RAS and BRAF mutational status and the other requirements addressed in the ESMO consensus guidelines on metastatic colorectal cancer</td>
</tr>
</tbody>
</table>
Follow-up, long-term implications and survivorship

Surveillance and follow-up

- Clinical assessment every 6 months for 2 years
- Completion colonoscopy within the first year if not done at the time of diagnostic work-up (e.g., if obstruction was present)
- Regular serum CEA tests (at least every 6 months in the first 3 years)
- Minimum of two CT scans of the chest, abdomen, and pelvis in the first 3 years for distant metastases
- History of colonoscopy with resection of colonic polyps every 5 years up to the age of 75 years
- High-risk patients (CRM+) may merit more proactive surveillance for local recurrence

Long-term side effects of treatment should be monitored, including assessment of lower genitourinary toxicities

Late effects/survivorship clinics for patients who have received pelvic RT
Disclaimer and how to obtain more information

This slide set provides you with the most important content of the full ESMO Clinical Practice Guidelines (CPGs) on the management of rectal cancer. Key content includes diagnostic criteria, staging of disease, treatment plans and follow-up.

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