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Rectal Cancer Radiotherapy Protocol

1. Introduction

There is a clear and established role for the use of neoadjuvant radiotherapy in resectable rectal cancer.

Pre-operative chemo radiotherapy has demonstrated a significant reduction in local recurrence and improvement in cancer-specific survival. This evidence base consists of 8,500 patients in 28 randomised trials.

Recent trials have established that pre-operative 5FU based concurrent Chemo RT (CRT) is superior to long course radiotherapy alone and that pre-operative CRT is superior to post-operative CRT.

Definitive surgery should be planned at 6-10 weeks after completion of radiotherapy.

2. Pre-operative Long course Chemoradiotherapy

Prescription:

45 Gy in 25 daily fractions over a total time of 5 weeks. Treating 5 days per week, 1 fraction per day, using 1.8 Gy per fraction. Alternative fractionation includes 50.4Gy/28#.

3. Concurrent Chemotherapy

Prescription:

Capecitabine oral chemotherapy should be prescribed alongside radiotherapy assuming no contra indications to chemotherapy.

4. Recurrent re-irradiation

Prescription:

Based on M D Anderson protocol: 30-36Gy in 16-20 fractions. All cases need to be referred to CAT (clinical advisory team) for Peer Review as per policy (RT-POL-136).

5. Patient Selection

- 5.1. Diagnosis of primary rectal cancer confirmed histologically.
- 5.2. Pelvic MRI (or CT if patient unable to undergo MRI) demonstrating at least one of the following adverse features:

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- Mesorectal fascia involved or breached
- Includes involvement of adjacent organ
- Mesorectal fascia threatened (tumour ≤ 1 mm from mesorectal fascia) includes:
 - Nodes at Circumferential margin (CRM), recurrent rectal cancers (anastomotic / pelvic side wall recurrences with no previous pelvic RT/CRT)
 - Primary tumour \leq 1 mm from mesorectal fascia, or
 - Extra-mural vascular invasion ≤ 1 mm from mesorectal fascia, or
 - Tumour deposit with irregular border and mixed signal intensity ≤ 1 mm from mesorectal fascia
- Low tumours at/below level of levators where:
 - Tumour ≤ 1 mm from levator on two imaging planes, or
 - Tumour through full thickness of muscularis propria or beyond at level of puborectalis sling or below, or
 - Tumour involving the inter-sphincteric plane, or
 - Tumour involving the external anal sphincter

6. Rectal Radiotherapy

6.1. Radiotherapy planning

The use of a planning CT scan with target volumes delineated on each slice and pixel-based inhomogeneity correction is considered standard practice and is a mandatory requirement.

Anal canal, inguinal and external iliac LNs to be outlined in tumours invading below the dentate line Follow 'Aristotle' trial Protocol delineation guidelines:

https://www.birmingham.ac.uk/Documents/collegemds/trials/bctu/trec/TREC-RT-QA.pdf

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6.2. Patient positioning and localisation

Immobilisation Device	Set-Up	Suggested Practice	Localisation	Tattoo/reference mark Location	Bladder/rectal status
Head on scoop & rectangle; arms on chest; Combi-fix	Supine, head to gantry; Hands on chest	Mandatory AP/Lat MOSAIQ set-up photograph (Tattoo location visible. All CT wire removed); Clothing & jewellery removed as necessary	Prostate/Bladder only: L4/5 vertebrae to 3cm inf to ischial tuberosities Primary+Nodes: L1/2 vertebrae to 3cm inf to ischial tuberosities	Anteriorly on m/l at approx. 5cm Sup to BOP (male) or at planner discretion depending on patient size Lt & Rt Lat rotation tattoos at approx. HATT 10-12cm	Bladder comfortably full Rectum, Empty

Supine and an 'anal marker' should be considered.

6.3. Contrast

Intravenous contrast should be used if not contraindicated by the patient. Intravenous contrast allows easy identification of the internal iliac arteries and associated lymph nodes.

6.4. Patient data acquisition

The scan limits are the superior aspect of L5 superiorly to 4 cm below the anal verge or the inferior extent of tumour. The recommended slice thickness is 3 mm.

6.5. Definition of target volumes Gross target volume (GTV)

All macroscopic tumour (primary, nodal, extramural vascular invasion) are outlined on each CT slice and any intervening normal rectal wall.

6.6. Clinical target volume (CTV)

This is defined in two parts CTVA and CTVB and then combined to form the Final CTV (CTVF).

6.7. CTVA

This consists of the GTV with a 1 cm margin applied in the superior, inferior, lateral, anterior and posterior direction.

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6.8. CTVB

This includes the mesorectum (and therefore the mesorectal nodes), the presacral and internal iliac nodal structures.

6.9. Superior limit

This is the S2/3 interspace (determined on the sagittal or scout view on the planning system) providing there is a 2 cm margin above the most superior limit of GTV. The CTVB superior border should extend above the S2/3 interspace if necessary to achieve a minimum 2 cm margin above the most superior aspect of GTV.

6.10. Inferior limit

The inferior limit of CTVB is either 1 cm inferior to CTVA or at the superior limit of puborectalis (seen on CT scans where the mesorectum stops) whichever is the more inferior.

6.11. Lateral limit

This is the medial aspect of obturator internus in the absence of internal iliac nodal enlargement. In the presence of involved pelvic side wall nodes, the limit is the bony pelvic side wall.

6.12. Anterior limit

This is defined superiorly as 7 mm anterior to internal iliac arteries. Lower down in the pelvis it is either 1 cm anterior to the mesorectal wall or 1 cm anterior to the lateral (internal iliac) pelvic lymph node "compartment" whichever is more anterior.

6.13. Posterior limit

This is the anterior margin of the sacrum or coccyx.

6.14. Final CTV (CTVF)

This is derived by combining CTVA and CTVB.

6.15. Planning target volume (PTV)

This is derived by adding a 1 cm margin anteriorly, posteriorly, laterally, superiorly and inferiorly to CTVF.

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6.16. Treatment

Radiation therapy should be delivered with photon energies \geq 6 MV using a linear accelerator.

Equipment capable of 10 MV or higher is recommended, as is the use of simple IMRT radiotherapy. The field arrangements require a minimum of three fields.

Utilise IMRT/VMAT technique with patient in supine position with prostap.

7. Dose

Prescription:

45 Gy in 25 daily fractions over a total time of 5 weeks. Treating 5 days per week, 1 fraction per day, using 1.8 Gy per fraction. Alternative fractionation includes 50.4Gy/28#.

IMRT SIB technique:

50Gy/25# for tumour and 45Gy/25Fractions for pelvis. Treating 5 days per week, 1 fraction per day, using 1.8 Gy per fraction. Alternatively, 53.2Gy/28# for tumour and 50.4Gy/28# for pelvis. The latter indicated when T3c/d or T4 or CRM threatened or presence of extra mesorectal LNs or post TEO/TEMS as part of a non-operative approach to managing rectal cancer usually T1/2 tumours.

8. Organ at risk (OAR) dose constraints

Needs included:

- Bladder
- Small Bowel
- Penile Bulb
- Femoral head
- Other

9. Concurrent chemotherapy

Prescription:

Capecitabine 850mg/m2 orally twice daily on days of radiotherapy only (normally Mon – Fri) for five weeks.

Neoadjuvant Oxaliplatin and capecitabine chemotherapy 4 cycles based on EXPERT and EXPERT-C trial for high risk LA rectal cancer before ChemoRT (LVI+ve, high nodal burden, etc.).

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10. Chemotherapy Investigations

- FBC Every week
- U&Es Day 1 and during Week 3
- LFTs Day 1 and during Week 3

Notes:

If capecitabine is omitted due to capecitabine-related toxicity the radiotherapy should continue.

Once RT completed, capecitabine treatment should not continue, even if patient has not taken the full course.

11. PRN Supportive medication

- Loperamide tablets for diarrhoea
- Metoclopramide or Domperidone for nausea

12. Pre-operative Rectal Radiotherapy Short Course Radiotherapy

Prescription:

Short course radiotherapy (SCRT) 25Gy in 5 fractions (5 Gy per fraction) over 5 days over 5-7 days.

12.1. Indications for SCRT

As alternative down staging regime in combination with full dose systemic chemotherapy. (e.g. 4 cycles FOLFOX).

The indications are the same as for 45Gy in 25 fractions down staging chemoradiotherapy. Planned surgery at 8-10 weeks after completion of radiotherapy.

As an adjuvant for a high risk but resectable rectal cancer. In this case the radiotherapy is scheduled in the week immediately prior to the definitive surgery. As a high dose palliative treatment for patients with metastatic or inoperable disease for local disease control.

13. Target definition and planning

These are same as for long course chemo radiotherapy.

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14. Post-operative Rectal Chemo-Radiotherapy

Prescription:

45 Gy in 25 daily fractions over a total time of 5 weeks. Treating 5 days per week, 1 fraction per day, using 1.8 Gy per fraction.

15. Concurrent Capecitabine oral chemotherapy

Should be prescribed alongside radiotherapy assuming no contra indications to chemotherapy.

16. Indications for Post-Operative CRT

Post-operative CRT can be considered for patients who are found post operatively to have an involved (<1mm) circumferential resection margin.

Post-operative radiotherapy is inferior to pre-operative treatment and is not to be considered as an alternative but has demonstrated reduction in local disease recurrence for patients who did not receive pre-operative treatment in patients with close or involved surgical margins.

17. Definition of target volumes Post-operative treatment

17.1. Gross target volume (GTV)

No GTV.

17.2. Clinical target volume (CTV)

To cover the posterior pelvis covering the area occupied pre-surgically by the mesorectum and the presacral and internal iliac nodal structures.

17.3. Superior limit

To extend to the sacral promontory.

17.4. Inferior limit

To cover 1cm below surgical anastomosis.

17.5. Lateral limit

This is the medial aspect of obturator internus in the absence of internal iliac nodal enlargement. In the presence of involved pelvic side wall nodes, the limit is the bony pelvic side wall. Document Owner: Head of Radiotherapy Document Authoriser: Radiation Oncology Committee Version Number: 3.1 First Issued: July 2017 Date Next Review: June 2022



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17.6. Anterior limit

This is defined superiorly as 7 mm anterior to internal iliac arteries. Lower down in the pelvis it is either 1 cm anterior to the mesorectal wall or 1 cm anterior to the lateral (internal iliac) pelvic lymph node "compartment" whichever is more anterior.

17.7. Posterior limit

This is the anterior margin of the sacrum.

17.8. Planning target volume (PTV)

This is derived by adding a 1 cm margin anteriorly, posteriorly, laterally, superiorly and inferiorly to CTV.

18. Palliative Rectal Radiotherapy

Prescription:

SCRT 25Gy/5 fractions can be used as a palliative treatment in patients with good prognosis. Alternatively, 20GY/5 fractions or 8Gy single fraction may help with bleeding or pelvic pain.

Revision History

Version	Revision Date	Revised By (Position Title)	Description of change
1.0	July 2017	Governance Administrator	New document
2.0	April 2018	Penny Kechagioglou	Clinical updates
3.0	June 2020	Dr Penny Kechagioglou Chief Medical Officer	Review of policy
3.1	June 2021	Jo Summersell, Regional Principal Radiographer	Annual review