COLORECTAL CLINICAL SUBGROUP

RECTAL CANCER
APPARENT COMPLETE RESPONSE (aCR)
AFTER LONG COURSE CHEMORADIOTHERAPY

Finalised by:

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Introduction

Long course chemoradiotherapy (LCCRT) followed by an 8-12 week gap has become the dominant neo-adjuvant therapy for locally advanced and lower 1/3 rectal carcinoma. This has the capacity to downstage (shrink) rectal cancer prior to surgery to try and ensure that the circumferential resection margin is clear. An important consequence of this development is that approximately 20%of rectal cancers will respond extremely well to LCCRT and on clinical examination apparently disappear from the rectal lumen after chemotherapy - **apparent Complete Response (aCR)**. A single centre clinical series of patients with aCR (Sao Paulo, Brazil) has shown that a third of rectal cancer patients with aCR will still have residual cancer however, perhaps two thirds may have achieved a true pathological complete response (ypCR) resulting in a local cure and who are therefore are unlikely to benefit from surgical excision of the rectum

Surgical excision of the lower 1/3 rectal cancer is associated with major illness (up to 5% mortality, 40% morbidity) and a permanent stoma in many patients. Therefore an unnecessary rectal excision in a patient, who might have achieved local cure by chemoradiotherapy alone, should ideally be avoided. However, balanced against this desire to avoid unnecessary resection - one third of patients with an apparent complete response still have a cancer. The surgical management of these latter patients still requires rectal excision. Therefore any policy of aCR observation (watch and wait) must involve rigorous and regular patient re-assessment of the apparent Complete Response to successfully salvage those patients that still have residual cancer. In these circumstances the evidence from the single centre Brazilian study is that delayed rectal excision, after a period of watch and wait, is not associated with any survival disadvantage.

This guideline aims to clarify important aspects of the management of the apparent complete response after long course chemoradiotherapy for lower third rectal cancer:

- timing and definition of what constitutes an apparent complete response aCR
- role of the MDT in the management of apparent complete response aCR
- an audit mechanism for registering the apparent complete response aCR
- patient information required for an informed decision – resection or watch and wait
- the framework of assessment if the patient opts for watch and wait

1) Timing and Definition of apparent Complete Response

The evidence is that the longer the assessment of the rectal cancer is delayed after long course chemoradiotherapy, then the greater is the reduction in the tumour volume. The current UK consensus is that the optimal delay between completion of chemoradiotherapy and assessment of rectal cancer response is between 8 and 12 weeks (recent published long course chemoradiation papers from the UK plus survey of UK oncologists at recent national NCRI research meetings). Whereas earlier assessment may indicate whether a tumour is or is not responding by reducing in size after chemoradiotherapy – the presence or absence of an apparent complete response is best judged 12 weeks after the completion of chemoradiotherapy.

The methodology of defining an apparent complete response is:

- clinical examination under anaesthetic - with palpation of the tumour site and endoscopic examination including biopsy of the residual scar.

Plus:

- MRI scan of the rectum showing either no evident tumour mass compared to baseline assessment or a small amount of residual tissue which in the opinion of the MDT is most likely to represent residual scar tissue rather than tumour.

2) The Role of the MDT in apparent Complete Response (aCR)

The role of the MDT in the management of apparent Complete Response includes:

- the formal recognition of aCR based on the presented results of clinical examination, biopsy and MRI imaging 12 weeks after the completion of long course chemoradiotherapy

- registration of the aCR on the central audit database – Christie Hospital Fax Form

- discussion of possible therapeutic options to be put to the patient, including both the usual option of surgical resection and option of waiting with close observation.

- if the patient opts for waiting and close observation the MDT will formally review the clinical and MRI follow up data on that patient at 3 monthly intervals for the first 12 months.

3) The Audit Mechanism for apparent Complete Response (aCR)

The Audit Mechanism for aCR will be in the form of a centralized database hosted at the Christie Hospital. The registration form is enclosed and the date will be collected on a data base to allow a more detailed examination of this cohort of patients. The data will be available to all networks.

4) Patient Information after apparent Complete Response (aCR)

Not removing the rectum in a patient with aCR, after long course chemoradiotherapy for rectal cancer, is a novel step. That it is reasonable to discuss this course of action with a patient, stems from the considerable disadvantages associated with surgery, especially for the patient who has no cancer in the removed rectum.

A patient information leaflet has been developed (Appendix 1) - but this is not a substitute for careful documented clinician discussion of all the potential advantages and disadvantages of each course of action, with the patient. There is uncertainty as to what is the correct course of action after aCR has been established. The patient and the family require full participation in the decision as to whether they wish to follow conventional practice and proceed immediately to surgery or to whether they wish to defer surgery until there is evidence of residual cancer in the rectum.

5) Follow up after apparent Complete Response (aCR)

It is essential that the patient who opts for "watch and wait" in the setting of aCR is subjected to careful and structured follow up. The components of follow up for the patient with aCR in the first 12 months should be:

- 3 monthly EUA/ Endoscopy and site biopsy and / MRI scan; this is for the first 12 months after recognizing aCR with programmed MDT 3 monthly review of follow up investigations for the first 12 months.

- after 12 months of negative follow up – 3-monthly follow-up out patient appointments (with CEA) for the first 2 years with MRI scans at 12, 18 and 24 months and an EUA if any abnormality is seen or felt.

- if recurrent rectal cancer is discovered during follow up of aCR the patient should be systemically restaged and offered surgical resection, if this is appropriate after anaesthetic assessment. [The outcome in any case at 24 months should be faxed to the Data Centre].

REGISTRATION: RECTAL CANCER and COMPLETE RESPONSE (CR) AFTER LONG COURSE CHEMORADIOTHERAPY (CRT)

Fax Form to 0161 446 8148 – Christie Hospital

Today's DATE	**__/__/____**
nhs no	
dob	
MDT Trust	
Cancer Diagnosed DATE	**__/__/____**
Consultant	

Eligibility:	**YES**	**NO**
Has the patient had a long course of CRT for the treatment of rectal cancer?		
Pre Chemo- Radiotherapy staging	**YES**	**NO**
Discussed at the MDT?		
Initial stage of the tumour?	**T…...**	**N…...**
Post Chemo-Radiotherapy imaging:	**YES**	**NO**
Discussed at the MDT?		
CT: - Any distant disease ?		
MRI: Good response but not radiological CR?		
MRI: Radiological CR?		
Post Chemo-Radiotherapy Clinical Examination:	**YES**	**NO**
No palpable disease on EUA?		
No visible disease on Endoscopy?		
Negative Biopsies		
Complete Clinical Response ?		
COMMENTS		
Decision - post MDT and informed patient discussion	**YES**	**NO**
Radical Surgical Resection		
Close follow-up*		
Was formal consent documented for "close FU"?		
Other Decision		
COMMENTS:		

*** We recommend 3-monthly follow-up out patient appointments (with CEA / endoscopy) for the first 2 years with MRI scans at 3, 6, 9, 12, 18 and 24 months and an EUA if any abnormality is seen or felt.**

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