

## Overview

# Combined Modality Treatment of Early Rectal Cancer — the UK Experience

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## ABSTRACT:

With the introduction of colorectal screening in the UK, more patients will probably be diagnosed with early rectal cancer. The UK has an increasingly elderly population and not all patients diagnosed with early rectal cancer will be suitable for radical surgery. Therefore, a national plan is needed to develop the provision of alternative local treatment with equity of access across the country. Here we review the Clatterbridge Centre for Oncology multimodality treatment policy, which has been in clinical practice since 1993 and we discuss its rationale. Clatterbridge is the only centre in the UK offering Papillon-style contact radiotherapy. In total, 220 patients have been treated over 14 years, most of whom were referred from other centres. One hundred and twenty-four patients received Papillon (contact radiotherapy) as part of their multimodality management. The guidelines of the Association of Coloproctology of Great Britain and Ireland recommend local treatment for T1 tumours < 3 cm in diameter, but this refers to treatment by surgery alone. There are no published national guidelines for radiotherapy. We plan each treatment in stages and achieve excellent local control (93% at 3 years) with low morbidity. We conclude that radical local treatment for cure can be offered safely to carefully selected elderly patients. Close follow-up is necessary so that effective salvage treatment can be offered. Because of a lack of randomised trial evidence, at present local radiotherapy is not yet accepted as an alternative option to the gold standard surgical treatment. Even with international collaboration, a randomised trial will be difficult to complete as the number of cases requiring local radiotherapy is small due to the highly selective nature of the treatment involved. However, an observational phase II trial is planned. In addition, the Transanal Endoscopic Microsurgery Users Group is also planning a phase II trial using preoperative radiotherapy. These studies will provide evidence to help establish the true role of radiotherapy in early rectal cancer. Sun Myint, A. *et al.* (2007). *Clinical Oncology* 19, 674–681

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**Key words:** Clatterbridge, contact radiotherapy, early rectal cancer, local treatment, Papillon, transanal endoscopic microsurgery (TEM)

## Background

Over the past decade there has been increasing interest in local treatment options for small tumours in the lower third of the rectum as an alternative to abdominoperineal excision of the rectum. This is offered mainly to elderly patients or younger patients with significant medical co-morbidity who are at increased operative risk. In addition, some patients are stoma averse and refuse conventional treatment despite understanding the risk of a lower cure rate.

For T1N0M0 tumours, local treatment with either radical radiotherapy or local surgery is now accepted as a possible alternative to radical surgery. However, for more advanced tumours this approach is not accepted as a standard

treatment in the UK. Opponents of local treatment argue that as lymph nodes are not removed, it is not possible to plan the management, as data on pathological staging are not available. Conversely, enthusiasts argue that it is not necessary as the probability of lymph node spread is relatively low (5–10%) in early rectal cancer. Therefore, they consider that removal of the primary tumour to preserve sphincter function is an acceptable initial treatment. The important question has to be: If tumour recurrence occurs after local treatment, is it possible to offer effective salvage treatment without compromising local control and survival? Currently, this question generates divided opinion.

## Selection Criteria for Local Treatment

The aim is to select patients with tumour confined to the rectal wall with a low probability of lymph node metastases.

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The most reliable method of assessment is digital rectal examination supplemented by endoscopy carried out by an experienced clinician. The assessment of lymph node metastases has to rely on radiology using endorectal ultrasound or endorectal magnetic resonance imaging (MRI). An experienced operator is also necessary in order to achieve a high accuracy of detection. The main drawback of radiological assessment is the necessary reliance on the abnormal shape and size of the lymph nodes [1]. So far, fluorodeoxyglucose (FDG)—positron emission tomography (PET) has shown disappointing results. Newer MRI imaging techniques using an ultrasmall super paramagnetic iron oxide contrast agent and molecular imaging may help in the future.

The selection criteria for local treatment are shown in Table 1.

## Local Treatment Options in the UK

There are several local treatment options and the choice of treatment depends on the initial staging (Table 2). The management decision is more difficult when a malignancy is detected unexpectedly in an apparently benign polyp with no prior investigations. The following are the local treatment options in the UK for early rectal cancer.

### Endoscopic Mucosal Resection

Endoscopic mucosal resection (EMR) is carried out under sedation without the need for general anaesthesia, which is usually necessary for transanal resection (TAR) or transanal endoscopic microsurgery (TEM). This is a major advantage for very unfit patients. However, EMR is usually reserved for benign pedunculated or flat polyps, and is only suitable for very early malignant T1 tumours (sm1 or selected sm2) [2].

The polyp is assessed endoscopically and its base is infiltrated by either saline or gel to elevate it away from the muscle. It is then resected using diathermy or a hot loop and pinned on corkboard for histological examination. If the polyp cannot be raised, the tumour is probably more locally advanced and EMR may be inappropriate. However, some reports indicate that 'extended' EMR for selected malignant rectal lesions is as effective as TAR or TEM [3].

### Transanal Endoscopic Microsurgery

TAR enables the excision of tumours in the lower rectum. Tumours higher than this have been traditionally removed

**Table 1 – Selection criteria for suitability of local treatment**

- |   |  |
|---|--|
| 1 | Mobile non-ulcerative exophytic tumours <10 cm from anal verge (clinical assessment: digital rectal examination) |
| 2 | Tumour <3 cm or occupying less than one-third of the circumference (endoscopic assessment)                       |
| 3 | cT1/Tx/cN0/cM0 (radiological assessment: endorectal ultrasound/magnetic resonance imaging)                       |
| 4 | Well- to moderately well-differentiated tumours (histological assessment)  |
| 5 | No lymphovascular or venous invasion (histological assessment)   |

**Table 2 – TNM staging of rectal cancer (AJCC/UICC)**

Primary tumour (T)	
Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma <i>in situ</i>
T1*	Tumour invades the submucosa (sm)
T2	Tumour invades the muscularis propria (MP)
T3	Tumour invades through the muscularis into the subserosa or into the non-peritonealised perirectal tissue
pT3a	Minimal invasion <1 mm beyond MP
pT3b	Slight invasion 1–5 mm beyond MP
pT3c	Moderate invasion >5–15 mm beyond MP
pT3d	Extensive invasion >15 mm beyond MP
T4	Tumour directly invades other organs or structures (T4a)
	Tumour perforates the visceral peritoneum (T4b)
Regional lymph nodes (N)	
Nx	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastases
N1	Metastases in one to three lymph nodes
N2	Metastases in four or more lymph nodes
Distant metastasis (M)	
Mx	Presence of distance metastasis cannot be assessed
M0	No distant metastasis
M1	Distance metastasis

\*pT1 tumours can be subdivided according to the depth of invasion into the submucosa (sm) [7]: sm1, slight submucosal invasion from the muscularis mucosa (200–300 µm); sm2, intermediate between sm1 and sm3; sm3, carcinoma invasion near the inner surface of the muscularis propria.

by major open operations (Kraske, York Mason or anterior resection), which have significant mortality and morbidity. TEM is a minimally invasive procedure, first reported in 1983 [4], which enables the excision of rectal tumours up to 20 cm from the anal verge, much higher than can be achieved with TAR. TEM is usually carried out for benign rectal lesions, but can be used for early cancers, as unlike EMR, a full-thickness excision is carried out, which can include perirectal tissue. TEM uses a specially designed 40 mm diameter operating rectoscope with a three-dimensional optical system of 6× magnification power. The dissection is precise and the direct magnified vision enables sufficient margins of the surrounding normal healthy tissue to be removed (Fig. 1). TEM has a low complication rate and postoperative recovery time is much quicker than after conventional surgery.

### Radical Contact Radiotherapy (Papillon Technique)

Lamarque and Gros [5] were the first to use the Phillips RT 50 kV machine to treat rectal cancers. This work was extended and popularised by Papillon [6]. Currently, over 1200 patients have been treated worldwide. Gerard *et al.* [7] reported an overview of results that showed

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