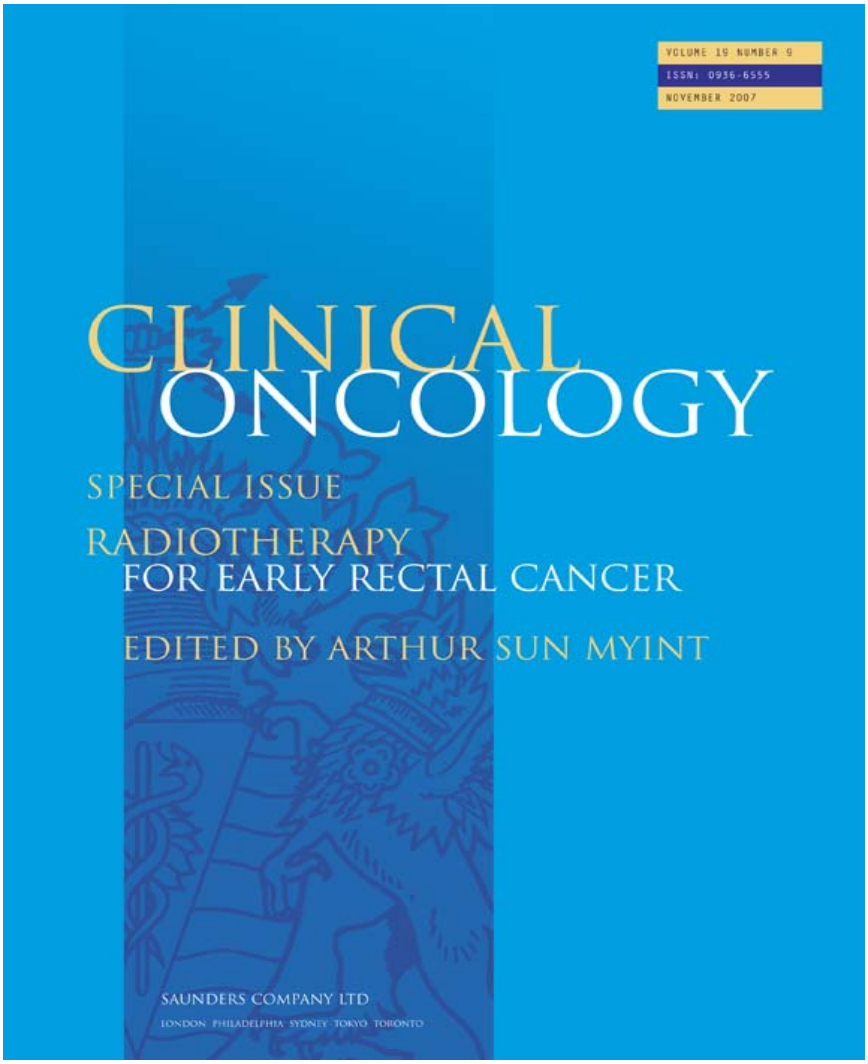

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Overview

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

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 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.

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 *in situ*
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.

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

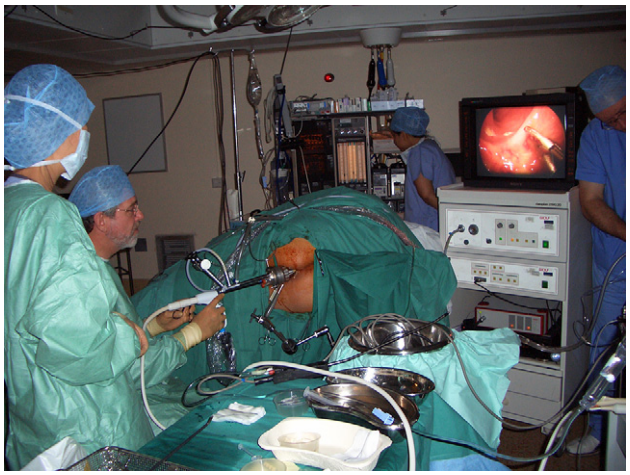

Fig. 1 — Transanal endoscopic microsurgery.

a 50—70% 5-year overall survival with 80—90% local control (Table 3).

Evolution of Contact Radiotherapy as Part of Local Treatment in the UK

In 1992, the Papillon technique was introduced at Clatterbridge, which is currently the only centre offering Papillon treatment in the UK. The TEM technique was also introduced into the UK about the same time and there are now about 25 centres using TEM for early rectal cancers in the UK [8]. Since 1993 the management plan in Liverpool has included either TEM or contact radical radiotherapy for cT1N0M0 tumours smaller than 3 cm in elderly patients or those who are not medically fit for major radical surgery. For cT1TX/N0M0 tumours larger than 3 cm, preoperative chemoradiotherapy or radiotherapy has been used to downstage and downsize the tumours followed 2—4 weeks later by further assessment. If there is no residual tumour detected by rectal examination, sigmoidoscopy or radiological examination, then the management options are either to 'watch and wait' or to offer immediate radical surgery. If there is a small residual tumour, a Papillon boost of 30 Gy is offered followed by TEM to remove the residual tumour for histological examination. If the resection margin is involved by tumour (<1 mm) after TEM, then radical surgery is offered. If the patient is not medically fit for the operation or refuses major surgery, then a Papillon boost giving a further 50 Gy is offered, to bring the total Papillon boost to 80 Gy in three fractions [9]. An iridium implant giving 20 Gy or high dose rate brachytherapy (10 Gy) can be given initially for bulky (>5 mm thickness) residual disease after external beam radiotherapy (EBRT) [10] (see HDR paper in this issue, pp. 711—719 [27]).

Contact Radiotherapy — Technique at Clatterbridge

Contact radiotherapy can be delivered as a day case, provided the patient is thoroughly prepared with enemas at home to clear the bowel, which is essential for successful treatment. The patient is placed in a jack knife prone position supported on a belly board. A rectoscope is inserted using local anaesthetic gel (lidocaine 2%). After assessment, if the tumour is suitable for contact treatment, the first dose of 30 Gy is delivered. At Clatterbridge, the Therapax 50 kV machine is used with a 0.5 mm Al filter (Fig. 2), whereas in Lyon and Nice a 50 kV Phillips machine is used. The Clatterbridge facility delivers a 100% D_{max} on the surface of the tumour with the dose falling to about 45% at 5 mm and about 30% at 10 mm depending on the size of the treatment applicator used. The comparison of machine facilities between the centres is discussed by Fletcher *et al*. [28] in this special issue (see pp. 655—660). A second fraction of 30 Gy is delivered after 1—2 weeks (usually 2 weeks) and a third fraction of 20 Gy (80 Gy total) can be delivered after a further 2 weeks, if required (4—5 weeks from the start). Assessment before the third session is very important. If the tumour is still visible or palpable, this suggests that the

Table 3 — Results of patients with T1/T2 rectal adenocarcinoma treated by radical radiotherapy including contact (Papillon) treatment with curative intent

References	City (country)	Year	No. of patients	Dose	Local failure	Survival
[6]	Lyon (France)	1951—1987	312 (contact)	80—130/4—7	9%	75% (OS 5)
[30]	Dijon (France)	1970—1996	151	90—150/3—5	15%	60% (OS 5)
[7]	Lyon/Nice (France)	1980—1998	116 (contact)	80—110/4	12%	83% (OS 5)
[31]	Nancy/Paris (France)	1981—1989	97	100/4	10%	64% (OS 5)
[32]	Rochester (USA)	1973—1990	244	110/4	9%	96% (CSS 5)
[33]	St Louis (USA)	1980—1995	199	120/4	1.8% (pT1) 25% (pT2)	94% (DFS 3)
[34]	Hamilton (Canada)	1973—1992	126		21%	91% (DFS 5)
[35]	Mayo (USA)	1986—1993	37		16%	77% (DFS 3)
[36]	Montreal (Canada)	1986—1994	20	155/3—4	10%	70% (OS 5)
[37]	Liverpool (UK)	1993—2007	220 124 (contact)	90—110/3—4	10% 7%	71% (OS 4.6)

OS, overall survival (years); DFS, disease-free survival (years).

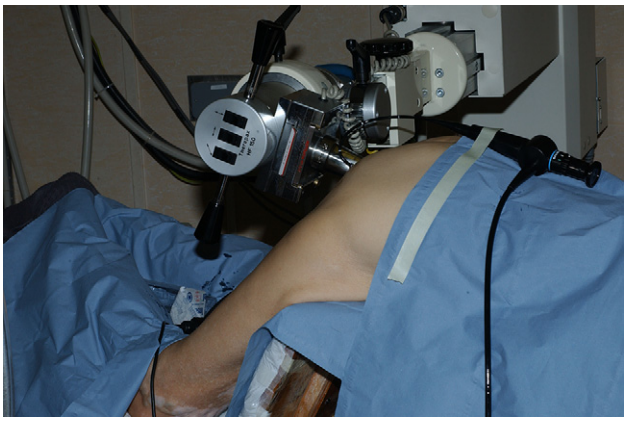

Fig. 2 — Contact radiotherapy: Clatterbridge technique.

tumour is more deeply infiltrating than had been thought, despite radiological staging of the tumour as T1 or T2, and continuing treatment with contact radiotherapy alone would be inadequate. Patients who do not respond well to initial contact radiotherapy are offered EBRT alone, delivering 45 Gy in 20 fractions over 4 weeks or chemoradiotherapy with 45 Gy in 25 fractions over 5 weeks with 5-fluorouracil (5-FU) infusion 750—1000 mg/m^2 in weeks 1 and 5. Recently, 5-FU has been replaced by oral capecitabine 825 mg/m^2 only on the days of radiotherapy (Monday to Friday). EBRT or chemoradiotherapy is offered either before or after the third fraction. If the tumour initial response is favourable (i.e. no palpable tumour after two sessions) then two further fractions of contact radiotherapy are offered, 2 weeks apart, which bring the total dose to 90—110 Gy (given in four to five fractions over 6—8 weeks).

Results

Since 1993 we have treated 242 patients with early rectal cancer using the multimodality approach. Out of the total, 220 patients were treated radically with the intent to cure and 124 had Papillon contact radiotherapy as part of the treatment. There were 24/220 patients (11%) with residual disease after initial radiotherapy. These were non-responders. Twenty-one patients (87.5%) had immediate rescue surgery. There were 22 patients with late recurrences (10%) and 11 patients had local recurrence alone. Nine of the 11 patients (82%) had delayed salvaged (see Salvage for Recurrence [29], pp. 720—733). At a median follow-up of 4.6 years (range 0.25—11.25), only 71% of patients are still alive, which reflects the advancing age and the poor general condition due to medical co-morbidity of the cohort of patients that were treated. However, cancer-specific survival was 93% with only 15 patients (12%) requiring permanent colostomy.

Follow-up

Patients who are offered local conservative treatment should be followed closely in the first 2—3 years, when the risk of recurrence is highest. The patients should be seen every 2—3 months for the first 2 years with a digital rectal examination and sigmoidoscopy. A biopsy is carried out if there is suspicion of residual disease or recurrence. Computed tomography is carried out at 12, 24 and 36 months and if there is any suspicion of recurrence, MRI is carried out. This close follow-up policy was observed carefully at Liverpool and this may be one of the reasons why we were able to offer successful salvage surgery before the recurrent tumour became fixed and inoperable [11]. Although most of the recurrences developed within the first 2 years, our experience has shown that late recurrence can occur up to 5 years after treatment. Therefore, it is important to follow these patients carefully beyond 5 years so that recurrences can be detected early enough to enable curative salvage surgery. This is discussed in this issue by Hershman and Sun Myint [29] (see pp. 720—733).

The Role of Contact Radiotherapy in Improving the Outcome for Rectal Cancer

There are two strategies to make radiation more effective, i.e. to combine chemotherapy with radiation or to increase the dose of radiation.

Increasing the Radiation Dose

It has been established from historical studies that a minimum of 40 Gy or its biological equivalent is required to have any effect on local control in rectal cancer. The standard dose schedule used in most randomised chemoradiotherapy trials is 45 Gy in 25 fractions over 5 weeks. Some give an additional 5.4 Gy to 9 Gy as a reduced field boost to the primary tumour. A randomised trial from the Princess Margaret Hospital assessed the dose response of rectal tumours [12]. Three dose levels were chosen: 40, 46 and 50 Gy. There was significant improvement in local recurrence-free survival of 77, 89.8 and 91.3%, respectively ($P = 0.036$). However, with increasing dose, the complication rate increased from 12.5 to 39.4% ($P < 0.009$). To reduce complications, an alternative treatment option is to increase the dose of radiation within the tumour without increasing the dose to the normal surrounding tissues. This can be achieved by the use of contact superficial X-ray (50 Kv) therapy given as a boost to the residual primary tumour. This will lead to higher pathological complete or near complete remission and will also improve the chance of a clear resection margin.

Contact 50 kV X-ray Therapy Boost

Papillon popularised contact radiation as a radical treatment for small rectal tumours in elderly patients who were medically compromised. Gerard later expanded and developed combined treatment with EBRT and contact radiotherapy. The patients were treated with contact radiation initially, delivering 60—80 Gy, then followed by a course of EBRT giving a further 39 Gy in 13 fraction over

2.5 weeks, using a small planned volume to include the primary tumour and adjacent perirectal lymph nodes. He reported the efficacy of contact radiation in 116 patients with T1/T2 tumours and showed local control in 88%, with 83% of the patients surviving 5 years [7].

This has been tested in a randomised trial (Lyon R96-02) comparing EBRT alone (39 Gy/13 fractions/17 days) against the same EBRT with a contact boost, giving a further 60–80 Gy. Between 1996 and 2001, 88 patients with T2/T3 rectal tumour <6 cm from the anal verge and less than two-thirds the circumference were enrolled into the study. Significant improvements were seen in favour of the contact X-ray boost for complete or near complete sterilisation of the operative specimen (23% vs 15%; $P=0.027$) with a significant increase in sphincter preservation observed in the boost group (76% vs 44%; $P=0.004$). There was no significant increase in early acute and late complications.

The main obstacle to this approach is the lack of availability of a contact radiotherapy machine. This problem has now been addressed and a new mobile contact 50 KV machine (Papillon 50) jointly manufactured by Anglo-French company Ariane will shortly be available for clinical use.

Discussion

The decision to offer local treatment for rectal cancer must involve all members of the multidisciplinary team. Currently, the number of patients with early rectal tumours is relatively small (8%), but when colorectal screening is introduced, many more patients will be diagnosed ($>30\%$). It will then become a major logistical problem to offer all suitable patients the full range of local treatment options. In addition, the elderly population will continue to increase and significant numbers of them will either not be suitable for radical surgery because of co-morbidity or may refuse it. Moreover, some patients of all ages are totally stoma averse and will refuse any surgery that involves a stoma, even a temporary one. Therefore, a national framework to develop equity of access to contact radiotherapy across the UK is proposed.

Local Surgical Resection: Transanal Endoscopic Microsurgery or Transanal Resection?

In the USA, high rates of local recurrence (up to 21% for T1 tumours and 45% for T2 tumours) have been reported after local surgical excision only, notably by the Minnesota group [13] and the Intergroup studies [14]. The opponents of local treatment often use these almost historical data to criticise high local failure rates after local treatment. However, several important factors may have contributed to this. First, the Minnesota series spanned 20 years and preoperative staging investigations in the early period were often incomplete, perhaps understaging some advanced cases with nodal disease. Second, TAR was carried out in all cases and not TEM, which enables a more accurate dissection. Third, surgery alone was used in most cases and some high-risk patients with T1 or T2 tumours were not offered immediate postoperative radiotherapy or chemoradiotherapy in the initial stages of the study.

More recently, TEM has been increasingly used for local resection of early rectal cancer with ever-improving technology, notably for dissection. Winde *et al*. [15] reported a prospective randomised trial comparing TEM with radical surgery for T1 rectal tumours, which showed no difference in local control or survival (96% at 5 years). However, the TEM group had significantly less operative trauma and morbidity. Also, the hospital stay was reduced significantly.

In the UK, 25 centres have prospectively reported their results to the TEM Users Group since 1996 [16]. These data are held centrally in Oxford and the updated results are presented regularly. The TEM Users Group data for 296 patients with early rectal cancer who had TEM alone without adjuvant treatment are poor. The local recurrence rate for pT1 and pT2 tumours was 23% and 34%, respectively [17]. There are several possible reasons for this. The patients treated were heterogeneous and not carefully selected. Many patients had benign-looking polyps and TEM was carried out as a 'big biopsy' instead of definitive initial surgical treatment. Consequently, many had incomplete preoperative staging and some had partial thickness excision only. In addition, TEM has a long learning curve and some surgeons initially had very little experience with the technique. Finally, like the Minnesota group, not all of the 'high-risk' patients were offered immediate radical surgery or postoperative radiotherapy. Those who had were excluded from the analysis. Interestingly, the subgroup of high-risk patients who were offered immediate surgery had few recurrences. The UK TEM Users Group is now planning a feasibility study of short-course preoperative radiotherapy followed by immediate or delayed TEM. Our approach at Clatterbridge has always emphasised combined treatment, which is the essence for the management of early rectal cancer. In our experience, the morbidity from the combined treatment is minimal and only by using this approach will the local recurrence rate of 'high-risk' patients be reduced.

Controversies on the Management of T2 Tumours

The Association of Coloproctology of Great Britain and Ireland guidelines accept local excision as 'standard treatment' for T1 tumours. However, the management of T2 rectal cancer remains controversial. Lezoche *et al*. [18] from Rome reported long-term results of 106 patients with T2 rectal cancer treated by preoperative chemoradiotherapy followed by TEM and observed only one recurrence (2.8%) at a median follow-up of 38 months (range 24–96). This group has subsequently conducted a randomised trial of preoperative chemoradiotherapy followed by TEM vs radical surgery alone. This trial has shown equivalent local control and survival at a median follow-up of 4 years, but

with only 20 patients in each arm this trial has very limited power. It is important to note that MRI cannot reliably differentiate between T1 and T2 tumours and sometimes between T2 and early T3a tumours. Because of these uncertainties, it is our policy to treat patients with the multimodality approach, even in pT2 patients with clear resection margins, as we believe that local surgical resection alone is inadequate treatment in patients who are not suitable for more radical surgery.

Can External Beam Radiotherapy or Chemoradiotherapy Sterilise Lymph Nodes?

The main drawback of local treatment alone is inadequate oncological assessment and treatment for lymph nodes, which may harbour unrecognised micrometastases. Unlike breast cancer, these lymph nodes cannot be readily sampled. Some have attempted to yield mesorectal lymph nodes for histological examination, using laparoscopic techniques through the perineum, with limited success. The question of whether EBRT or chemoradiotherapy can sterilise these lymph nodes was addressed by Bujko's group [19] from Poland, who reported a randomised trial of short-course vs long-course chemoradiotherapy. They showed that chemoradiation when compared with short-course radiotherapy resulted in significant greater downstaging of both primary tumours ($P < 0.001$) and nodal disease ($P = 0.007$). In the chemoradiotherapy group, for patients with complete pathological response ypT0 and ypT1 categories, the rate of nodal metastases was low, 5% (95% confidence interval 0—14) and 8% (95% confidence interval 0—24), respectively. They concluded that for patients with tumours that were downstaged by chemoradiotherapy to ypT0 and ypT1, full-thickness local excision can be considered as an acceptable approach, because the risk of mesorectal lymph node metastases is low. It is important to note that the cohort of patients in this trial had cT3—T4 low rectal tumours before treatment and many of these patients could harbour a high number of lymph node metastases (>30—50%).

Is a 'Watch and Wait' Policy an Option?

The optimal management of patients who have achieved complete remission after preoperative chemoradiotherapy is an interesting one. In our series, there were seven patients who achieved this. After careful discussion with the patients, we adopted a watch and wait policy in five patients, whereas two patients underwent anterior resection at their request. In both patients there was no residual tumour on histology (See Fig. 3a, b). None of the seven patients had recurrence at a median follow-up of 54 months (range 24—144 months). A similar experience is reported from Sao Paulo, where 71 patients (26.8%) who achieved a complete clinical response after chemoradiotherapy were observed (observation group) and compared with 22 patients (8.3%) who initially showed an incomplete clinical response and had surgery, but achieved a complete pathological response (yPT0, yPN0, M0) on histology (resection group) [20]. There was no difference between patient demographics and tumour characteristics between the two groups. The median follow-up was 57.3 months in the observation group and 48 months in the resection group. There were three systemic recurrences in each group and two endorectal recurrences in the observation group. Two patients in the resection group died of disease. The 5-year overall survival and disease-free survival rates

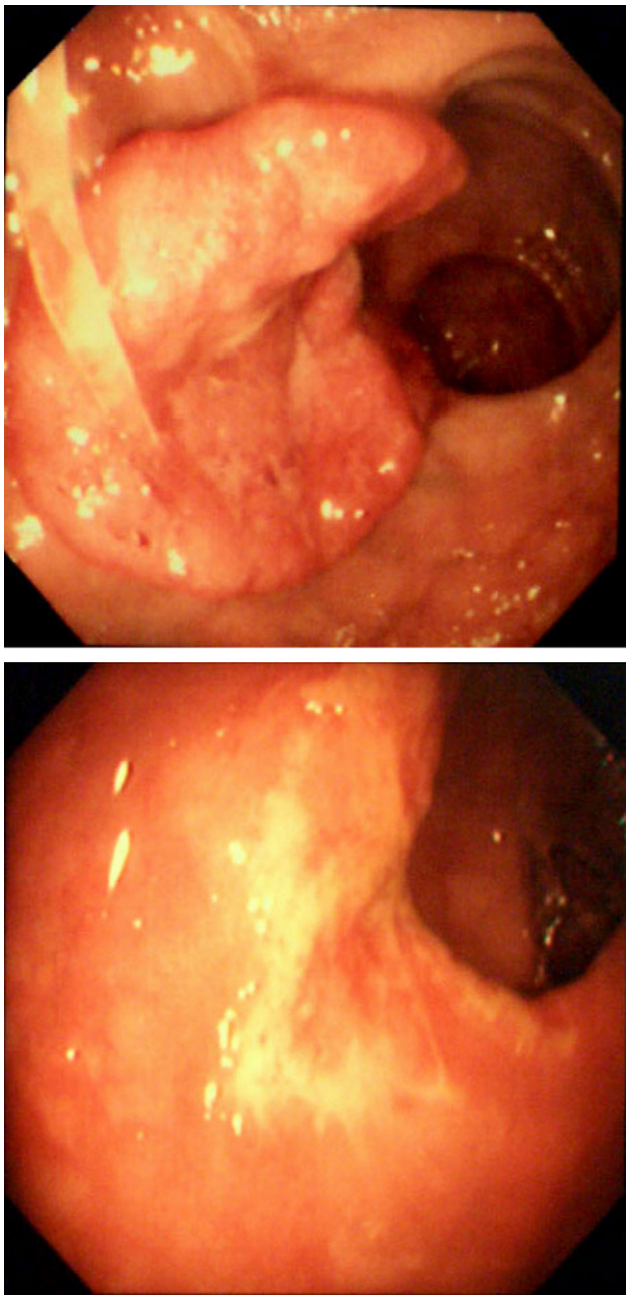

Fig. 3 — (a) Rectal adenocarcinoma (T2N0M0). (b) The appearance after chemoradiotherapy followed by Papillon boost. There was no residual tumour (ypT0 ypN0) at surgery.

were 88 and 83%, respectively, in the resection group and 100 and 92% in the observation group. The investigators concluded that stage T0 rectal cancer disease is associated with excellent long-term results, irrespective of the treatment strategy. Surgical resection may not lead to an improved outcome in this situation and may be associated with high rates of temporary or definitive stoma formation and unnecessary morbidity and mortality. However, a clinical response (no palpable tumour on digital rectal examination and endoscopic regression) is not always a reliable indication of a complete pathological response, as there can be a residual microscopic nest of tumour cells beneath the healed mucosa. Our policy at Clatterbridge is to boost the tumour-bearing area with either Papillon or high dose rate brachytherapy [21] given before full-thickness TEM of the tumour-bearing area to confirm a pathological response.

Other investigators have confirmed that pathological complete remission can be achieved in 10—20% of cases after preoperative chemoradiotherapy using 5-FU and radiotherapy and those who were downstaged to achieve pathological complete remission have better long-term disease-free and overall survival [22]. Preoperative chemoradiotherapy using newer agents such as oxaliplatin [23] or irinotecan [24] with 5-FU or capecitabine can achieve higher pathological complete remission in the region of 20—30% and it would be interesting to see whether this could lead to higher sphincter-sparing operations. One can postulate that if contact radiotherapy can be offered as a boost (Lyon R96-02 trial) this could increase the chance of sphincter preservation. However, most surgeons are still reluctant to change their decision at the time of surgery and so far only a few trials have shown increased sphincter preservation after preoperative chemoradiation [25]. In the UK, the demand for sphincter preservation is not a great problem at present, but could become an issue in the near future, with better information and improved health education of the patients and their relatives [26].

Conclusion

The local treatment of early rectal cancer is a controversial and complex issue of explaining all the treatment options that are available to the patient without personal bias. The advantages and disadvantages of each treatment should be clearly explained to patients and their relatives to enable informed discussion.

At present, unlike breast cancer, large randomised trial evidence (level 1a) for local treatment as a standard for early rectal cancer is not yet available. A multicentred international effort to establish the true role of local treatment in early rectal cancer is urgently needed and this is currently being planned. Until firm evidence is available, the controversy for local treatment for early rectal cancer (other than T1) will probably continue.

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