

Three large, teal-colored arcs of varying radii are positioned on the left side of the page, partially overlapping each other.

Contact x-ray brachytherapy for rectal cancer (Papillon)

Radiotherapy

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This information is for patients who have cancer of the rectum (back passage) and who are considered suitable for local treatment as an alternative to radical surgery. We hope that the information in this leaflet will help you and your relatives understand the process involved in making a decision before consenting for your treatment with contact x-ray brachytherapy (Papillon). There is a video on consenting and treatment on our 'Clatterbridge Cancer Centre' hospital website, if you or your carers wish to watch. Usually, the first treatment is offered (if you are suitable) following your initial consultation but please let us know if you need more information or more time to decide before consenting for contact x-ray brachytherapy (Papillon).

This leaflet will explain:

- Local treatment options (the term local defines treatment in an area at or close to the original tumour site)
- Complications and possible side effects of all treatment options
- Follow-up after contact x-ray brachytherapy (Papillon) treatment

Your doctor will have already informed you that all the tests carried out so far have shown no signs that the cancer has spread. Therefore, your cancer is still at an early stage and there is a very good chance of curing it. Your doctor/surgeon has informed us that you fully understand that the standard treatment is major surgery.

However:

- He/she feels that you are not suitable for the standard treatment due to your medical problems which puts you at a very high anaesthetic risk (approved by NICE)

Or

- You do not want any surgery that involves either a permanent or a temporary stoma (bag)

We also understand that you/your doctor have requested information about alternative treatment options to major surgery and a possible stoma. Your doctor has asked us to explain and discuss these treatment options with you and your family.

It is important you understand that:

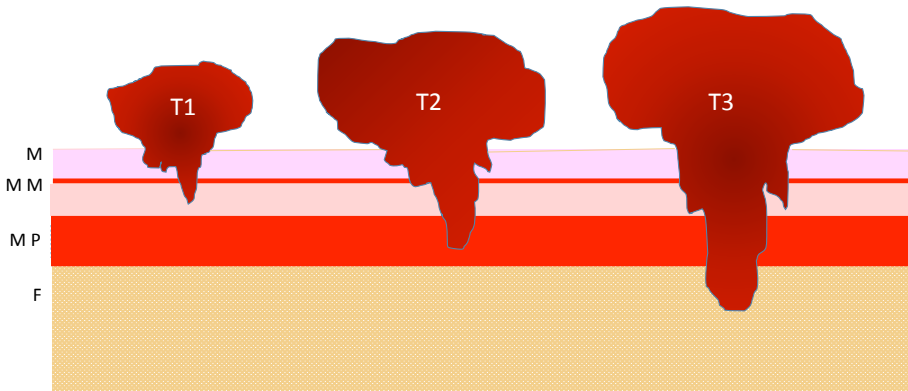
- (1)** Not all rectal cancers are suitable for 'local treatment' and therefore it may not be possible to offer you this treatment.
- (2)** There is a higher risk of recurrence following 'local treatment' (approximately 11%) compared to the standard treatment (1-4% patients).
- (3)** Should the cancer recur (usually in the first 2-3 years), you will need to consider the standard treatment option of major surgery that may involve a permanent or a temporary stoma (bag) (1-3 in every 10 patients).



Investigations at the start of treatment

Following your diagnosis of rectal cancer, you will have an MRI and a CT scan to stage and exclude spread of cancer. You may also have an intra-anal ultra sound scan (probe inserted into your back passage) to find out the depth of invasion of your tumour. Blood tests will also be carried out.

Figure 1 - Rectal Cancer Staging



Abbreviations M=Mucosa, MM=Muscularis Mucosa,
MP= Muscularis Propria, F= Perirectal fat

T1 Tumour invades through muscularis mucosa [MM](superficial muscle)

T2 Tumour invades into muscularis propria [MP] (deep muscle)

T3 Tumour invades through muscularis propria [MP] into perirectal fat

Treatment options for early rectal cancer

1) Local Surgery

If your rectal cancer is small (less than three centimetres) and in very early stage cT1 (not involving the deep muscle: see Figure 1 - Rectal Cancer staging diagram above), then it may be possible to remove this through your back passage without major surgery or a stoma.

This can be done by:

1.1) Transanal Endoscopic Micro Surgery (TEMS)

This procedure usually requires a general anaesthesia. Your surgeon will insert a small operating instrument into your rectum so that he/she can see the cancer (tumour) more clearly and remove it with a clear margin around it.

The area where the cancer was removed is repaired in some cases using stitches.

An experienced pathologist will then examine the removed tissue and also the cut ends (margins) of the bowel wall under a microscope to establish what kind of cancer you have. If the cancer is very close to the cut ends, there is a possibility that not all the cancer cells were removed. You will then be offered standard surgery to remove any remaining cancer together with the surrounding lymph nodes. If you are not fit for major surgery, or if you decide not to have major surgery, then post-operative radiotherapy including contact radiotherapy (Papillon) can be considered. It is important to understand that your chance of



cure is higher with major surgery. If the cut ends show no sign of cancer, then no further treatment is necessary other than regular follow-up.

1.2) Transanal Resection (TAR)

This procedure also requires a general anaesthesia and is used when the tumour is situated very low in the rectum where it is not possible to use the TEMS method mentioned above.

This procedure is not suitable if the tumour is situated high in the rectum. TEMS is the preferred option for local resection but TAR can be used if TEMS facility is not available in your local surgical colorectal unit.

Some patients may need to start their treatment with local surgery if there is no histological proof of cancer with your initial biopsies or if you or your surgeon prefers to have it first. This may be followed by post-operative radiotherapy if you do not want major surgery if cancer is finally diagnosed after local surgery.

2) Radiotherapy using the Papillon technique (contact x-ray brachytherapy [CXB])

Contact x-ray brachytherapy (low energy x-rays treatment) also known as contact radiotherapy (Papillon) is recommended for patients who are not fit enough for general anaesthesia or who do not want major surgery and formation of a stoma. If your cancer is small (less than three centimetres) and in very early stage cT1 (Fig 1) with no evidence of lymph node spread, then local contact x-ray brachytherapy using the Papillon technique can be considered as an alternative treatment option to either local or major surgery. Papillon is the name of the French professor from Lyon who popularised this technique. Unlike the surgical options described above, this treatment does not involve general anaesthesia and may be more suitable for you. If your cancer is cT2 (cancer invasion into deeper muscles - Fig 1), you may need external beam radiotherapy with or without chemotherapy (drug treatment) as well, as there is higher risk of lymph node spread which is not treated by contact radiotherapy (CXB) on its own.

Not all rectal cancer treated with Papillon method (CXB) responds to treatment. If there is still some cancer left following radiotherapy, you may need local surgical resection (TEMS or TAR) to remove the residual cancer. A small number of patients who do not respond to radiotherapy will need immediate salvage surgery and your doctor will discuss the surgical treatment options with you.



Papillon Treatment procedure

You will normally receive your treatment as an out-patient. You will be advised to follow a low fibre diet for three days before your treatment (see Papillon Dietary Advice Sheet). You may need to stop all your anticoagulants (blood thinning tablets) for a few days before your treatment. If you are not sure, please check with your doctor or get some advice from the Papillon team at Clatterbridge Cancer Centre as you may need alternative treatment. Your treatment is usually in the afternoon following your initial consultation with the Consultant in the morning. The treatment procedure is explained to you again in more detail and you will be given another chance to ask more questions, if you have any. A small enema will be given to clear your bowels. The radiographer will explain and show you the position that you need to be in for the treatment. The actual treatment usually takes just over two minutes but you will be in the treatment room for about half an hour.

You will be asked to kneel and bend over on the treatment couch or lay on your back. Local anaesthetic gel will be applied around your anus to numb the area and ease any discomfort. You will also have a cream to relax the muscles around your anus. Your doctor will then examine your back passage to locate the cancer. He/she will then insert a small instrument (sigmoidoscope) to examine the cancer carefully. Your doctor will then remove the instrument and insert a rectal applicator into your back passage, placing it over the tumour. Then the treatment x-ray tube is inserted through the rectal applicator to deliver contact radiation directly

onto the tumour. There is a camera to check the treatment tube position over your tumour. When the treatment applicator is in the correct position, the staff will leave the treatment area and the radiographer will commence the treatment with low energy x-rays. During the treatment, you will be watched carefully and your treatment can be interrupted, if necessary. The low energy (50 KV) x-rays can only penetrate a few millimetres and therefore, the deeper normal tissues are not damaged. Therefore, there are very few side effects from this superficial x-rays treatment. The second treatment is given usually about two weeks after the first treatment and the same procedure is repeated.

Each treatment application kills the cancer cells, layer by layer, while the normal tissues recover during the break between each treatment. The tumour will reduce in size as the treatment progresses as shown in the diagram - See Rectal Cancer response diagrams opposite Fig 2: 2a), 2b), 2c).

The number of treatments needed depend on the response of your tumour and the type of previous treatment (local surgical excision or external beam radiotherapy) you have received. Papillon treatment is usually given fortnightly for two (post-surgery) or three treatments (maximum four treatments, if necessary).

During your course of treatment, assessments will be made, and photographs taken, with your consent, to record how your cancer is responding to treatment. Your consultant will explain your treatment progress and tell you what will happen next when you finish your treatment.





Papillon treatment machine

Depending on the stage of your rectal tumour Fig 1 (cT2/ cT3), you may need external beam radiotherapy with or without chemotherapy. The type of treatment depends on your general fitness and any other medical problems you may have. The doctor will discuss if you need external beam radiotherapy and this can be done in your local radiotherapy centre closer to where you live.

Figure 2: Rectal cancer response



Fig. 2a) Malignant polyp at the start of contact treatment (Big tumour)



Fig. 2b) After one contact radiotherapy (Tumour shrinks)



Fig. 2c) Complete response at the end of treatment (No tumour visible)

3) Combination treatment

For larger (>3 centimeters) or more advanced rectal cancers (cT2 or cT3), you may receive a course of External Beam RadioTherapy (EBRT) - see Fig 1 or combined Chemo-radiation (EBCRT) treatment. If your surgeon or you feels that you are not suitable for surgery, contact therapy may be indicated if your cancer responded well to external beam radiation treatment. This may help to improve local control, but is not currently the standard of care in the UK except in patients who are not suitable for surgery for whom this treatment is now approved by NICE.

Some large rectal cancers may not be suitable for contact x-ray brachytherapy and an alternative treatment with High Dose Rate Brachytherapy may be offered.

Post-treatment outcomes

What happens next following your treatment depends on how well your cancer responds to the contact x-ray radiotherapy (CXB) which you have just received. There are three possible outcomes:-

- If there is still a small cancer left, this can be removed locally either by TEMS or TAR (please see page 3 for more details)
- If there is no response (no shrinkage of the tumour), then we would advise you to have the standard surgery, as any further attempt at local treatment is very unlikely to be successful
- If there is good response, with no residual tumour, then no further treatment may be necessary other than a regular follow-up. Surgery is only offered if there is evidence of recurrence



Participating in a clinical trial (OPERA [Organ preservation for early rectal Adenocarcinoma])

Although CXB (Papillon) treatment has been around for more than 80 years, many clinicians do not regard this as a standard of care as there is no large randomised trial evidence to support this. Therefore, we have started a large multi-centred (phase 3) European trial known as OPERA which compares external beam chemo-radiotherapy (EBCRT) with external beam boost and EBCRT followed by CXB (Papillon) boost. This trial when matured will provide the much-needed evidence to regard CXB (Papillon) as the standard of care in rectal cancer treatment. You may be invited into this trial or if you are not and you are interested, please ask for further information on this trial.

Possible complications and side effects

1) Surgery

Any surgical procedure carries some risk of complications. The risk of death due to standard radical surgery is below 5% and the risk of death due to local surgical excision with either TEMS or TAR is much lower at less than 1%.

Complications such as bleeding, pain, infections, delay in wound healing and fistulas (abnormal connection between front and back passage) are much lower (1 in 100 patients) with local surgery, compared to the standard radical surgery (1 in 10 patients).

You may experience incontinence (loss of control) of your motions for a few weeks following local surgical treatment, but this usually

gets better in the majority of patients. We may advise you to do pelvic floor exercises to strengthen the muscles around the anus, which may help to prevent further leakages. You will be in hospital around 3-5 days following local surgery, compared to 1-2 weeks for the standard radical surgery.

2) Contact X-ray brachytherapy (Papillon)

There have been no deaths reported as a direct result of this treatment. Radiation can cause some discomfort in the rectum due to inflammation caused by radiation. This usually settles down 2-6 weeks after completion of treatment. We may give you steroid enemas to reduce the inflammation and you need to use them twice a day for a few weeks.

You may experience rectal bleeding (30% of patients), but this usually settles down within 3-6 months. If it persists longer, you may need treatment to control this (less than 10% of patients).

You may develop an ulcer in the area where the cancer was situated before the start of your treatment (30% of patients). There is no pain usually associated with it and this should heal within 3-6 months. No special treatment is usually necessary for this unless you have symptoms.

You may experience pain/discomfort around the anus when the doctor inserts the rectal applicator. The local anaesthetic gel and the cream to relax the muscle will help to ease the discomfort. The pain/discomfort usually settles within a few minutes. If you



can't tolerate the pain/discomfort, you can request for stronger pain killers to be given prior to your next treatment. Please discuss this with your doctor or a radiographer before treatment.

Diarrhoea (loose motions) is not common after only contact x-ray brachytherapy, but can occur if you have external beam radiation, especially when this is combined with chemotherapy. We will give you advice on what to eat and what type of foods to avoid. You may need some medication (e.g. Loperamide) to control the frequency of motions.

Late side effects of radiation include narrowing of the back passage. This can occur usually following local surgery and CXB in about 1% of patients. Gentle stretching (dilatation) to widen the narrowing may be necessary. Your surgeon will arrange this for you. Persistent severe bleeding occurs in less than 10.5% of patients due to dilated blood vessels. This occurs more frequently in patients who are on anticoagulants, e.g. warfarin, clopidogrel or aspirin. Laser (Plasma Argon) treatment may be necessary to control the bleeding (Laser Plasma Argon is simply the name given to this particular medical technique).

Fistula (connection between rectum and other structures, e.g. vagina) is a rare radiation side effect that can occur in less than 1% of patients (usually in patients who had previous surgery). However, only a few patients need surgery to correct the fistula, as this heals naturally in most patients.

Investigations after treatment

You will have a six monthly CT scan for three years. MRI scan will be repeated usually 3-6 monthly in the first two years, or more frequently as necessary. You may have a PET/CT scan if there is any suspicion of recurrence. Examination under anaesthesia and biopsy may be necessary to exclude recurrence.

Further treatment

There is approximately a 11% risk of your cancer coming back in the same place (depending on the stage of your tumour) and less than an 8.5% chance of it spreading to other parts of your body. Depending on where the cancer has recurred, you may be offered further surgical treatment. Standard surgery may not be possible due to the nature of the recurrence in some patients.

Follow-up

It is very important that you attend regular follow-up appointments for a number of years after the treatment.

We will make an appointment to see you every 12 weeks in the first and second year. This will then be extended to every six months for the next three years, followed by yearly appointments for the next five years. These clinic appointments will alternate between us and your local referring clinicians.

During follow-up, you will be asked if you are having any problems, e.g. pain, bleeding and excessive bowel movements. The doctor will then examine you using a sigmoidoscope (an instrument for



viewing the inside of the rectum) followed by rectal digital (finger) examination. A biopsy is only carried out if there is a suspicion that the cancer has recurred. Flexible endoscopy will be carried out every six months in the first two years by your referring surgeon locally. Colonoscopy will be carried out five yearly.

Please note:

Whilst we do everything possible to cure your cancer, we cannot guarantee that local treatment will cure your cancer and therefore you may need to have further treatment.

It is important that you understand that this is not a standard treatment and should the tumour recur at a later date, you will usually be offered radical salvage surgery which may involve a permanent stoma, provided you agree and are considered fit for general anaesthesia.

We make every effort to prevent immediate and long-term side effects, but we cannot guarantee that rare and unusual complications will not occur.

You have the right to refuse treatment or withdraw from the treatment offered at any time and this will not affect your future treatment in any way.

The Clatterbridge Cancer Centre Hotline 0800 169 5555

If you are unwell during or up to six weeks following your cancer treatment, please call The Clatterbridge Cancer Centre Hotline.

Your call will be answered by a dedicated nurse advisor. This line is available 24 hours a day, 7 days a week.

Additional resources

For more information and/or to view a patient information video prior to attending please visit: [www.clatterbridgecc.nhs.uk /patients / treatment and support /papillon](http://www.clatterbridgecc.nhs.uk/patients/treatment-and-support/papillon)

Contact details

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Specialist Services Co-ordinator

Direct line: 0151 556 5529

Email: ccf-tr.papillon.clatterbridgecc@nhs.net

If you require information regarding accomodation please contact the Specialist Services Co-ordinator.

The Clatterbridge Cancer Centre NHS Foundation Trust

0151 556 5000 or www.clatterbridgecc.nhs.uk

Macmillan Cancer Support

0808 808 0000 or www.macmillan.org.uk

Macmillan Cancer Information and Support at

Clatterbridge Cancer Centre - Wirral 0151 556 5570

Clatterbridge Cancer Centre - Aintree 0151 556 5959

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We rely on a number of sources to gather evidence for our information. All of our information is in line with accepted national or international guidelines where possible. Where no guidelines exist, we rely on other reliable sources such as systematic reviews, published clinical trials data or a consensus review of experts. We also use medical textbooks, journals and government publications.

References for this leaflet can be obtained by telephoning 0151 556 5570.

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