

Patient agreement to investigation or treatment

Transanal Endoscopic Microsurgery (TEMS)

Authors: Department of Colorectal Surgery

Brief description:

- Transanal endoscopic microsurgery (TEMS) is a minimally invasive technique for the local resection of rectal polyps and tumours. The procedure is carried out using a special microscope to remove the polyp or tumour through the back passage without any cuts in the abdomen. It requires a general anaesthetic. Here, we explain some of the aims, benefits, risks and alternatives to TEMS.
- We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website:
<http://www.addenbrookes.org.uk/consent>
- Guidance for health professionals can be found on the Addenbrooke’s intranet site
<http://nww.addenbrookes.nhs.uk/consent>
- Remember, you can change your mind about having the procedure at any time even after you have signed the form.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

.....
.....

About Transanal Endoscopic Microsurgery (TEMS)

You will have been offered transanal endoscopic microsurgery to remove a polyp or tumour from your back passage under one of the following circumstances:

- It is not known yet whether the lesion is a cancer or benign (showing no signs of cancer). TEMS allows the lesion to be analysed under the microscope for diagnostic purposes.
- There is a cancer in the back passage that is thought to be an early cancer and potentially could be cured by removing just the cancer without major abdominal surgery.
- There is a polyp or cancer in the back passage which is causing symptoms and you have been advised to avoid a major operation either because of anaesthetic risks, to avoid a stoma (where the bowel is brought out through the abdominal wall and the bowel motion comes out into a bag), or due to spread from the cancer.
- There is a defect in the back passage which requires repair for example, a fistula.

Transanal endoscopic microsurgery (TEMS) resection is considered as a treatment for early rectal cancer based on the results of clinical examination, colonoscopy, transrectal ultrasound, magnetic resonance scans (MRI) and discussion at the multidisciplinary team meeting. It is only offered in selected cases and is not appropriate for all tumours. It is also important to be aware that TEMS will sometimes simply provide a 'big biopsy' and that analysis under the microscope may reveal features of a tumour that would not make it suitable for TEMS surgery alone. If this is the case, you may be advised to still have major conventional resectional surgery to remove the entire back passage as described above.

TEMS is performed transanally (through the back passage) with specially designed microsurgical instruments that makes it possible to excise lesions inside the rectum that otherwise would be accessible only by major abdominal surgery.

Before your procedure

- Patients attend a pre-admission clinic, when you will meet a member of the medical team.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring details with you of anything you are taking, for example, bring the packaging or a list of medications with you.
- This procedure involves the use of general anaesthesia. See below for further details about the type of anaesthesia we shall use.
- Most people who have this type of procedure will need to stay in hospital for one or

two nights after the operation. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decide to have the procedure.

- On the day of the procedure, you will be asked not to eat for six hours before the surgery and to only drink clear fluids between six hours and three hours prior to the surgery. Nothing is allowed by mouth after three hours.
- You will be given two enemas to clear the lower bowel prior to the operation in order to allow visualisation of the tumour with the operating microscope.

Prevention of Surgical Site Infection (SSI)

It may be necessary during the procedure to shave another area of your body e.g. your thigh to allow attachment of a pad for the diathermy machine (used to seal blood vessels), so that the pad sticks to your skin to achieve the best and safest performance.

Hair removal from the site of the operation up to sixty minutes before surgery reduces the risk of infection. This means that the hair removal procedure is usually carried out on the operating table. You must not shave the area yourself; this will be carried out in the operating theatre. Shaving at home, or the night before surgery, increases the risk of infection as no matter how careful you are the skin may become irritated and this could increase the risk of infection.

During the procedure (operation/treatment) itself

- Before your procedure, you will be given a general anaesthetic and may be advised to have a 'caudal block' to relax the sphincter (anal muscles) as well - see below for details of this.
- During the procedure, you will be positioned on the operating table to allow insertion of the operating microscope into the back passage. The back passage is inflated with carbon dioxide and the tumour is removed using specially designed instruments, with the surgeon looking down the operating microscope. Once the tumour/polyp is removed, the back passage is washed out, any bleeding is stopped and the defect in the wall of the back passage may be closed with stitches.

After the procedure (operation/treatment)

- After a general anaesthetic, you will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be

offered medicine to make you more comfortable.

- After this procedure, you will be allowed to eat or drink as soon as you feel able to do so (usually within an hour of surgery). We will encourage you to try and get up and about as soon as possible, in order to prevent complications from lying in bed. Typically, you will be able to get up after a couple of hours. If we think you will have problems getting about, we will arrange for extra assistance, for example, nursing help and physiotherapy advice/exercises.
- The effects of the caudal block may take up to a few hours to wear off. During this time you may find that your legs feel heavy and do not work properly, or that you are unable to pass urine. All should resolve within four to six hours.
- Most people who have had this type of procedure will be able to leave hospital after one or two nights. The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor's opinion.
- **When you can resume normal activities including work:** Most people who have had this procedure can resume normal activities after a couple of days. You might need to wait a little longer before resuming more vigorous activity. When you will be ready to return to work will depend on your usual health, how fast you recover and what type of work you do. Please ask your doctor for his/her opinion.
- **Special measures you need to take after the procedure:** It is important to keep your bowels regular after TEMS, using laxatives such as Milpar if necessary. You will be given more detailed information about any special measures you need to take after the procedure. You will also be given information about things to watch out for that might be early signs of problems (for example, infection). It is common to experience a little blood from the back passage after your operation; if this is severe, you will need to return to the hospital.
- **Check-ups and results:** Before you leave hospital, you will be given details of when you can expect to receive telephone communication of results or when need to return to see us, for example, in the outpatient clinics or for further tests. At this time, we can check your progress and discuss with you any further treatment we recommend.

Intended benefits of the procedure

The potential benefits of TEMS as compared to radical abdominal surgery are:

- Avoiding major surgery
- No large incision
- No colostomy
- Less pain
- Faster recovery
- Shorter hospital stay

TEMS may also provide a definitive answer as to whether a polyp is benign (non-cancerous) or malignant (cancerous), or be curative for some tumours.

Who will perform my procedure?

TEMS is a specialist procedure that will only be performed by a Consultant Colorectal Surgeon or Specialist Registrar in Colorectal Surgery under appropriate supervision.

Alternative procedures that are available

If it is not yet known whether a polyp is cancerous or not, it is sometimes possible to try and remove the polyp during a colonoscopy. However this frequently involves the polyp being removed in several pieces, rather than one specimen. This may therefore make interpretation of the polyp in the laboratory more difficult, for example, as to whether the polyp has been adequately removed or not.

Some tumours low in the back passage can be removed under direct vision. This procedure is known as transanal resection of tumour (TART). It can only be used for very low tumours and the cancer outcomes are not as good as they are with TEMS. It may however be the right procedure for a polyp that is prolapsing (dropping out) of the back passage.

Some people prefer not to have any treatment at all. The implications of deciding not to have surgery will be discussed with you.

The standard treatment for rectal cancer usually involves surgical resection of the entire back passage and its fatty covering with lymph nodes (this is known as 'total mesorectal excision'). The bowel is then joined back together again if there is enough distance below the cancer ('anterior resection'). If there is not enough distance below the cancer, this will result in closure of the back passage and a permanent stoma ('abdominoperineal excision of rectum'). Treatment often includes additional radiotherapy and/or chemotherapy.

Serious or frequently occurring risks

Although TEMS is a minimally invasive technique with lower risks than abdominal surgery, it still carries some risks associated with the technique. The risks or potential post-operative complications that may occur after TEMS are listed below.

- Bleeding may occur during the operation. After surgery, some bleeding will usually be noticed on having the bowels open. There is a one in a 100 risk of significant postoperative bleeding (haemorrhage) although this usually stops of its own accord. If not, it can be controlled with a colonoscope or repeat TEMS. A blood transfusion may occasionally be required if this happens.
- The performance of the anal sphincter muscle can be affected after TEMS, although this effect is almost always temporary. If this happens, you may find that you have difficulty controlling gas for about two to three months after surgery. Very occasionally, incontinence to liquid or solid stool occurs. Again, this is almost always temporary. The risk of long-term incontinence to stool is very low.
- Emptying of the bladder (urination) may be temporarily impaired due to the type of anaesthetic used and pressure from the operating microscope. This usually resolves

within a few hours or days at most. It may sometimes be necessary to temporarily insert a catheter into the bladder to drain the urine if this occurs.

- If you suffer from urinary symptoms due to a large prostate you might be at increased risk of urinary problems after surgery
- Removal of the tumour involves removal of the wall of the back passage. There is a one in 50 risk of infection of the TEMS wound that may give rise to fever or infection in the tissues surrounding the back passage. Most cases can be treated with antibiotics. Sometimes it is necessary to drain infection with a drain inserted under X-ray guidance or with surgery. A temporary stoma is very occasionally required to aid the healing process. Very rarely, the infection may cause generalised blood-poisoning and intensive care may be necessary.
- Operating on tumours situated high up the rectum can lead to an entry being made into the abdominal cavity. The opening is usually sealed during the operation with stitches placed through the operating microscope. However, there is about a one in 100 risk of the need to repair the defect through the abdomen (this is called a laparotomy). If these stitches later break down or leak, then it is possible for bacteria from the back passage to enter the abdominal cavity and cause infection, either an abscess (collection of pus) or peritonitis (infection in the abdominal cavity). This risk is about one in a 1000.
- Neighbouring organs can be damaged during an operation. A fistula (connection) towards the vagina in women or towards the urethra (tube connecting the bladder to the tip of the penis) in men can rarely occur, which will require further surgery to repair. This risk is about one in a 1000.
- The body must be situated in a particular position on the operating table. This can sometimes lead to problems such as numbness or odd sensations in the legs. This is temporary, but sometimes full recovery can take months.
- Scarring may occur after a TEMS operation, and this may cause narrowing of the bowel (stenosis). In most cases, a stenosis can be widened with dilation of the back passage.
- Risks associated with all operations include blood clots, pneumonias, heart problems and kidney problems. The risks associated with TEMS are relatively low as the procedure does not involve any cuts or a prolonged recovery time.
- There is a chance that you may be advised to undergo a further operation or other treatment, for example radiotherapy once the tumour or polyp has been analysed in the laboratory.

Information and support

- You might be given some additional patient information before or after the procedure, for example, leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of staff.
- If you have concerns or questions after leaving hospital, then please contact the Colorectal Specialist Nurses during working hours on 01223 217923, or leave a message on the answerphone after hours.

General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. If you are a day case patient, it may not be until just before your operation. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets, injections or liquids (to children). They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that you can forget your fears and worries.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe. It is common practice nowadays to allow a parent into the anaesthetic room with children: as the child goes unconscious, the parent will usually be asked to leave.

During your operation

While you are unconscious and unaware, your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel, and a Patient Controlled Analgesia (PCA) may occasionally be set up to continue pain control on the ward. It is unusual to need a PCA after TEMS.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and

soreness, confusion or memory loss.

- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



Addenbrooke's is smoke-free. You cannot smoke on site. For advice on quitting, contact your GP or the NHS smoking helpline free, 0800 169 0 169

Please ask if you require this information in other languages, large print or audio format: 01223 216032 or patient.information@addenbrookes.nhs.uk

Informacje te można otrzymać w innych językach, w wersji dużym drukiem lub audio. Zamówienia prosimy składać pod numerem: 01223 216032 lub wysyłając e-mail: patient.information@addenbrookes.nhs.uk

Polish

Se precisar desta informação num outro idioma, em impressão de letras grandes ou formato áudio por favor telefone para o 01223 216032 ou envie uma mensagem para: patient.information@addenbrookes.nhs.uk

Portuguese

Если вам требуется эта информация на другом языке, крупным шрифтом или в аудиоформате, пожалуйста, обращайтесь по телефону 01223 216032 или на вебсайт patient.information@addenbrookes.nhs.uk

Russian

若你需要此信息的其他語言版本、大字體版或音頻格式，請致電 01223 216032 或發郵件到: patient.information@addenbrookes.nhs.uk

Cantonese

Bu bilgiyi diger dillerde veya büyük baskılı ya da sesli formatta isterseniz lütfen su numaradan kontak kurun: 01223 216032 veya asagıdaki adrese e-posta gönderin: patient.information@addenbrookes.nhs.uk

Turkish

এই তথ্য বাংলায়, বড় অক্ষরে বা অডিও টেপে পেতে চাইলে দয়া করে 01223 216032 নম্বরে ফোন করুন বা patient.information@addenbrookes.nhs.uk ঠিকানায় ই-মেইল করুন।

Bengali

Document history

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Consent form 1

Patient agreement to investigation or treatment

<p>For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)</p>
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Responsible health professional/job title

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment
Transanal Endoscopic Microsurgery (TEMS)

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure: Avoiding major surgery; no large incision; no colostomy; less pain; faster recovery; shorter hospital stay. Other (please specify):

- Any serious or frequently occurring risks from the procedures including those specific to the patient:As described above.....

- Any extra procedures that might become necessary during the procedure:
 Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: TEMS.
 Version/Date/Ref:CF397 Version 2, March 2009

This procedure will involve:

- General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature: Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later):

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):.....

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** **If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature **Date:**

Name (PRINT): **Job Title:**

Copy accepted by patient: yes / no (please circle)