

CONSENT FORM FOR ESOPHAGECTOMY

PROPOSED TREATMENT

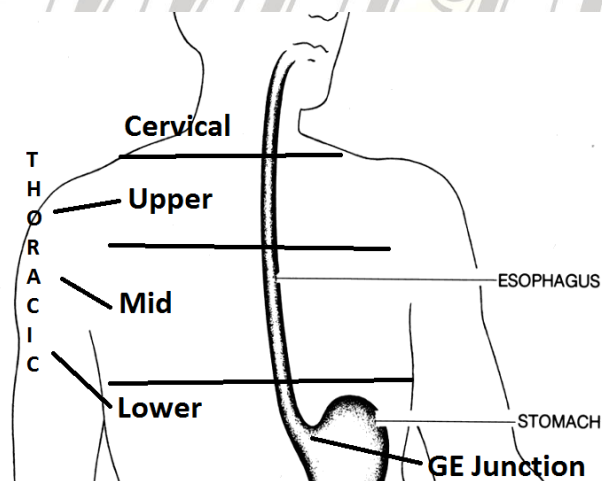
The doctor has explained that I, (name),
have and that this
condition requires

About oesophagectomy

You have been advised to have surgery to remove most of the oesophagus – termed an oesophagectomy. An oesophagectomy is nearly always performed for a cancerous growth and sometimes for long standing benign problems.

The main function of the oesophagus is to transport food and liquid from your throat to your stomach. A replacement oesophagus has to be made so that you can continue to eat and drink and this is usually made from your stomach.

Location of your tumor:



General Preparations:

In preparation for surgery a thin flexible tube would be passed through your nose into stomach (nasogastric tube) to clear the contents in the stomach. This tube will be maintained for few days after surgery. To prevent complications such as infection, you will be given antibiotics at the time of your operation. To stop a blood clotting in your legs from happening a small injection of a drug known as anticoagulant will be given daily after the operation. You will be given some form of therapy in-order-to clear your bowel (if required). **Under a general anesthesia**, a urinary catheter is placed in the bladder and you would be positioned for access to the chest, abdomen and pelvis. A thin tube will be passed into your stomach through your nose to drain the stomach (if not passed before). This may be kept in place for few days after surgery.

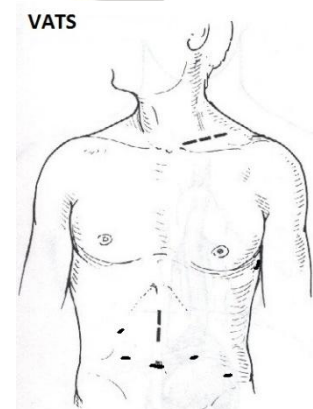
Modalities of Surgery:

Staging Thoracoscopy: This means inspecting the inside of the chest, the organs and supporting tissues using a special tube (thoroscope). One or more tubes are put into and instruments passed down the tube to examine the inside of your chest using a camera and video monitor. Sometimes, bands of fibrous tissue grow around lung. If so, the doctor may need to cut these. The surgeon looks for any signs that may make major surgery not viable (like spread of disease). If definite signs of spread of cancer or inoperability are found the procedure would be abandoned.

Staging Laparoscopy: One or more tubes are put into the abdomen and instruments passed down the tube to examine the inside of the abdomen and pelvis using a camera and video monitor. Sometimes, bands of fibrous tissue grow around the bowel or other organs. If so, the doctor may need to cut these. The surgeon looks for any signs that may make major surgery not viable (like spread of disease). If definite signs of spread of cancer or inoperability are found the procedure would be abandoned.

Thoraco-Laparoscopic Esophagectomy: The surgeon proceeds & completes the surgery using thoraco-laparoscopic (MACS) techniques. The surgical steps of open & laparoscopy are same. Only the modality & equipment used differ. During laparoscopic procedure if the surgeon perceives that it is not advisable to proceed thoraco-laparoscopically, the surgeon may decide to open the chest or abdomen (covert). Sometimes abdomen or chest will have to be opened before deciding inoperability. A further plan would be discussed with you in these cases. When surgery is feasible, the surgeon may decide to proceed laparoscopically depending on the amount of disease.

Open Surgery: A cut is made in the chest & abdominal wall. The

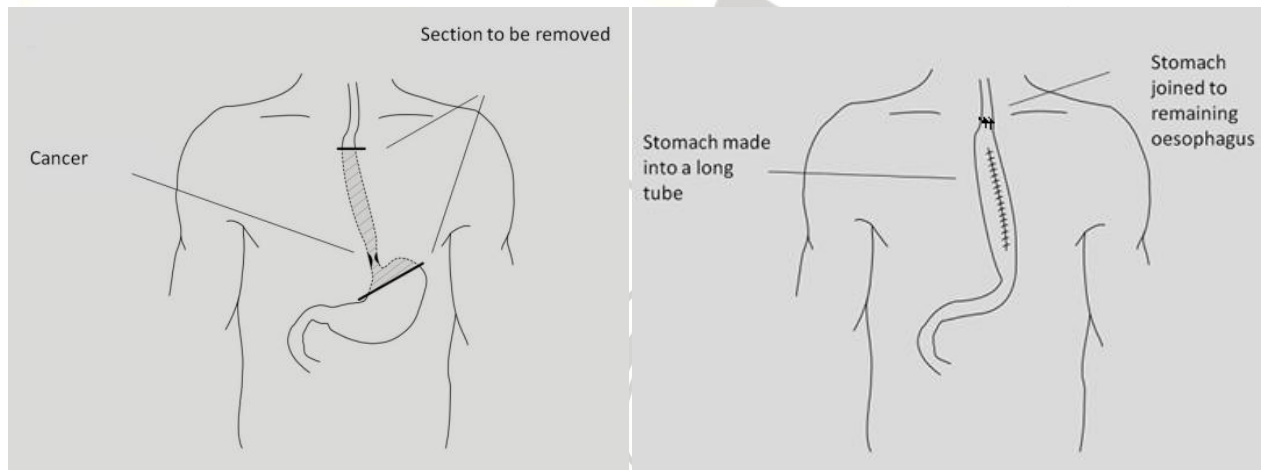


surgeon examines the chest & abdominal organs, looking for any suspicion of disease spread. If any such areas are found, small samples may be taken for microscopic examination.

The Procedure:

The object of the operation is to remove most of the oesophagus and associated lymph glands. This is performed using thoraco-laparoscopic or open or combination of two. We usually use the stomach to replace it but occasionally part of the colon (large bowel) is used instead. The stomach tube is brought up into the chest and joined onto the remaining upper oesophagus, at the very top of the chest using a small cut on the left side of your neck.

You may find the following diagrams useful in understanding the operation.



One or more drains may be left close to the operation site to remove secretions (chest, neck & abdomen). A **feeding tube (feeding jejunostomy)** may be placed into your abdomen to continue feeding if there are problem associated with your bowel. This may be maintained to few days after surgery. The wounds are then closed.

After the procedure

After operation you will be transferred to the intensive care unit (ICU/ITU). These are areas where you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. You will be **placed on ventilator** (machine that helps you breath) for at least overnight after surgery. You may be retained in ICU till such time when you are fit to be shifted to ward.

If there is no bed or ventilator free in the ICU on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.

It may be 10-12 days (depending on your recovery) after surgery for you to be discharged.

Intended benefits of the surgery:

The aim of the surgery is to remove the cancer or abnormality– completely if possible. For cancer operations, surgery gives the best chance of cure, but the treatment may need to be combined with chemotherapy and/or radiotherapy.

Alternative procedures that is available

Surgical removal of the gullet is currently the only known way of curing most oesophageal cancers. In many cases surgery is combined with chemotherapy +/- radiotherapy before, and sometimes after, surgery to maximise the chances of cure. You may be one of the patients who will benefit from this and it will be discussed with you once the microscopic examination results of your tumor are received. Not everyone is suitable for this treatment so do not worry if you are just having surgery.

Radiotherapy with chemotherapy in a combination alone has been tried. But, this cannot completely cure the disease.

Some very early, small oesophageal cancers can be removed via a gastroscopy that is passed via the mouth and therefore does not require any cuts. This technique is only appropriate for very early or precancerous growths.

RISKS

The following are the commoner risks. There may be other unusual risks that have not been listed here. Please ask your doctor if you have any general or specific concerns.

I understand there are risks associated with any **anaesthetic** (see separate Anaesthetic Consent Form).

I may have side effects from any of the drugs used. The commoner side effects include light-headedness, nausea, skin rash and constipation.

I understand the procedure has the following **general risks and limitations:**

- Infection can occur, requiring antibiotics and further treatment.

- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- I may develop a clot in a leg vein (deep vein thrombosis), causing pain and swelling. Part of this may break free and move to my lungs (pulmonary embolus), making me breathless. There is a small risk I could die.
- I may develop areas of minor collapse in the lungs, increasing my risk of getting a chest infection. I may require treatment with physiotherapy.
- Heart attack or stroke could occur from strain of surgery.
- Rarely death as a result of this procedure is possible

I understand the procedure has the following **specific risks and limitations**:

- Chest infection – Major surgery carries with it a risk of developing an infection in the lungs or pneumonia and it is quite common following this procedure (25%). This is usually because you are a little immobile and not breathing deeply following surgery, resulting in the lower part of the lungs becoming stagnant. Chest infections are treated with antibiotics and physiotherapy.
- It is very important that you get up and move as soon as possible and work closely with the nursing staff or physiotherapist in making sure you are taking regular, deep breaths. You will be given deep breathing exercises to undertake. The risk of developing a chest infection is greatly increased if you smoke cigarettes (particularly within three months of surgery).
- Anastomotic leak – This is the most important, serious complication following an oesophagectomy. Fortunately, it is rare (approx 5% risk). An anastomosis is where the gastro-intestinal tract is rejoined after the operation. Surgeons take great care and time in constructing a water tight anastomosis that will not leak. However, in rare cases the anastomosis does not remain water tight. This is often because of a poor blood supply rather than any particular problem with the surgery. If a leak does occur, there is a significant risk of infection and you will require antibiotics and possibly a fine drain tube to be inserted (under local anaesthetic) next to the anastomosis to get rid of any excess fluid or infection. With an anastomotic leak you are not usually permitted to take anything by mouth as this may worsen the leak. Most anastomotic leaks are very small (pin head size) and resolve spontaneously after 10-14 days, without too many problems. In rare cases, patients can become very ill and need to be transferred to the intensive care unit or require further surgery.
- Pleural effusion – Fluid that collects between the lung and the chest wall is called a pleural effusion. The chest drains are designed to allow this fluid to drain out. After the drains are removed there is a small risk that fluid can collect again around the lung and you will become breathless. If this happens it will need to be drained under local anaesthetic.

- Chyle leak – A chyle leak is a rare (3%) but serious complication of surgery performed in the chest. In order to remove all the appropriate lymph glands it is necessary to also take out the “thoracic duct” which is a vein like tube which drains fat from the intestines. If the clips or ligature used to seal it fail to do so, fluid called chyle accumulates in the chest. This fluid also contains immune cells and is critical in the absorption of necessary fats from the gut. If chyle leakage does occur we will feed you via the feeding jejunostomy as this will often dry up the chyle leak. In rare cases the chyle leak does not stop and another operation is required to find the leaking duct and ligate it again.
- Stomach necrosis – This severe complication is very rare (1% risk). If the blood supply to the stomach tube is very poor, over a few days it may die (“necrosis”). As a result, a second operation is required and the stomach tube needs to be removed from where it is has been brought up into the chest. If this problem is not dealt with by surgery there is a risk that you can become critically ill. If stomach tube necrosis occurs, the upper oesophagus is sewn to the skin in the neck and covered with a drainage bag. This means you temporarily will not be able to eat or drink. Swallowing liquids will be allowed as they will come out into the drainage bag. You will be fed via the feeding jejunostomy. After around three months another operation can be needed to reconnect the gut so that you are able to swallow normally again.
- Complications relating to the heart – Major surgery places considerable stress on the body and there is a small risk of a problem relating to the heart. This may take two forms and varies from very minor to severe. Firstly, the heart may develop an abnormal rhythm (usually beating excessively quickly). You may notice a fluttery feeling (palpitations) in the chest or nothing at all. Usually, simple measures such as balancing the body’s salt concentrations, or administering medications, resolves these problems. Secondly and more seriously, suffering a heart attack (damage to the heart muscle) is possible. Because of these risks you are very closely monitored (including continuously recording the rhythm of the heart) for the first five days following your surgery. Therefore, if a problem arises it can usually be treated early and effectively. The risk of developing a heart problem is increased if you have a history of heart problems, smoke cigarettes (particularly within three months of surgery) or have other risk factors for heart disease.
- Complications related to the feeding jejunostomy – A feeding jejunostomy is routinely inserted during this procedure. It is a fine tube that passes through the skin into the bowel beyond where the surgery has been performed. It allows us to feed you during the first week or so following surgery when you are unable to eat. There are, however, small risks of complications specifically relating to the feeding tube (1%). These risks include the tube moving or leakage from the bowel where the tube has been inserted. In rare cases, the bowel may twist around the tube causing an obstruction. These complications can sometimes be managed with antibiotics or removal of the tube. In rare cases an operation may be required to correct the problem.
- Deep vein thrombosis (DVT) and pulmonary embolus - All surgery carries varying degrees of risks of thrombosis (clots) in the deep veins of your leg. In the worst case a clot in the leg can break off and travel to the lung (pulmonary embolism). This can significantly impair your breathing. To prevent these problems around the time of your operation and following your operation we give you some special injections to ‘thin’ the blood. We also ask you to wear compression stockings on your legs

before and after surgery and also use a special device to massage the calves during the surgery. Moving about as much as you can, including pumping your calf muscles in bed or sitting out of bed as soon as possible reduces the risk of these complications.

- Altered Voice - A rare complication of oesophagectomy is damage to the nerves of the voice box. This can result in hoarseness of the voice. This is nearly always temporary and is due to bruising of the nerve. Very rarely, permanent damage is done, resulting in a change in the quality of the voice. It is not uncommon to have a slightly hoarse voice following your anaesthesia. This is because of slight swelling as a result of the breathing tube used in your operation. This will usually recover over a few days to weeks. In rare cases it may slowly resolve over several months.
- Damage to the spleen - During the operation, the small blood vessels between the spleen and the upper part of the stomach (fundus) are cut using special instruments that seal the blood vessels before they are divided. Very rarely, damage to the spleen can occur that results in bleeding. Most times, this is not serious and can be controlled simply, however, if the spleen were to sustain more severe injury the spleen may have to be removed to prevent further bleeding. Removing the spleen normally has few complications. If your spleen is removed you will be given some vaccinations prior to leaving hospital. Additionally, you will be advised to stay on a low dose of preventative antibiotic for at least two years.
- Bleeding – This very rarely occurs after any type of operation. Your pulse and blood pressure are closely monitored after your operation as this is the best way of detecting this potential problem. If bleeding is thought to be happening, you may require a further operation to stop it. This can usually be done through the same scar(s) as your first operation. It is possible that you also may require a blood transfusion.
- Wound haematoma - Bleeding under the skin can produce a firm swelling of blood clot (haematoma), this may only become apparent several days after the surgery. It is essentially a bruise. This may simply disappear gradually or leak out through the wound without causing any major consequences to you.
- Wound Infection – This affects your scars ('wound infection'). If the wound becomes red, hot, swollen and painful or if it starts to discharge smelly fluid then it may be infected. It is normal for the wounds to be a little sore, red and swollen as this is part of the healing process and represents the body's natural reaction to surgery. It is best to consult your doctor if you are concerned. A wound infection can happen after any type of operation. Simple wound infections are easily treated with a short course of antibiotics.
- Deep Infection – A rarer and more serious problem with infection is where an infection develops inside your tummy or chest cavity. This will often need a scan to diagnose, as there may be no obvious signs on the surface of your body. Fortunately, this type of problem will usually settle with antibiotics. Occasionally, it may be necessary to drain off infected fluid. This is most frequently performed under a local anaesthetic by our colleagues in the X-ray department. In the worst case scenario a further operation is required to correct this problem.

- Anastomotic stricture - The join between the remnant of your oesophagus and your new stomach tube (“anastomosis”) can sometimes narrow down during its healing phase during the first few months after surgery. A stricture is a technical term that simply means a narrowing. This narrowing can cause problems with swallowing, particularly with solid foods. If this happens you might need to have the join stretched gently to make it wider again. This can be done as an outpatient in the endoscopy unit under gentle sedation.
- Death – All major surgery carries a risk of death related to the procedure and the anaesthetic. The risk of death with this procedure at Addenbrookes Hospital is 1-2% for fit patients but may be higher for those with pre-existing medical conditions. The national average risk of death in hospital after oesophagectomy is 5%.
- Other complications – We have tried to describe the most common and serious complications that may occur following this surgery. It is not possible to detail every possible complication that may occur following any operation. If another complication that you have not been warned about occurs, we will treat it as required and inform you as best we can at the time. If there is anything that is unclear or risks that you are particularly concerned about, please ask.
- The spleen, pancreas or gall bladder may be damaged during the operation and require repair or removal. The spleen may also be removed deliberately as part of the procedure. If the spleen is removed, I will be more prone to infection in future and will require immunization.
- Food may not pass easily from the stomach into the small bowel through the new opening. This may require further intervention.
- I may find I get palpitations, dizziness, nausea and abdominal cramps after meals, especially with carbohydrates (eg. sugar, bread, pasta, potatoes). This is called dumping and happens because the food passes into the small bowel too quickly. Changes to my diet and eating smaller meals usually help.
- My bowel may not function temporarily after the operation and I will not be able to eat or drink normally until its activity returns in a few days
- My wounds may become infected and this may delay healing and may require antibiotics. Rarely the wound may give way (burst abdomen) & may need re-surgery.
- Loops of bowel may become stuck to the operation site (adhesions), causing blockages that may require further surgery. This can occur even years later. (mainly after open surgery)
- I may develop a weakness in the wounds (incisional hernia) that may require later treatment (mainly after open surgery). There can also be long term wound associated pain.
- I may never return to my normal weight.

I understand some of the above risks are more likely if I smoke, am overweight, diabetic, have high blood pressure or have had previous heart disease.

INDIVIDUAL RISKS:



DECLARATION BY PATIENT

I acknowledge I have read this form and the surgeon has informed me about the procedure, alternative treatments and answered my specific queries and concerns about this matter.

- I acknowledge that I have discussed with the surgeon any significant risks and complications specific to my individual circumstances that I have considered in deciding to have this operation.
- I understand my medical condition and agree to undergo the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- I understand that the disease could be inoperable (not possible to remove).
- The procedure may include a blood transfusion.
- I understand that a doctor other than the specialist surgeon may be part of the procedure.
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I have received a copy of this form to take home with me.

Signature of patient:

Date

Signature of witness or relative:

DECLARATION BY DOCTOR

- I declare that I have explained the nature and consequences of the operation to be performed, and discussed the risks that particularly concern the patient.
- I have given the patient an opportunity to ask questions and I have answered these.

Doctor's signature

Date

Dr Sandeep Nayak

