Cancer Association of South Africa (CANSA)

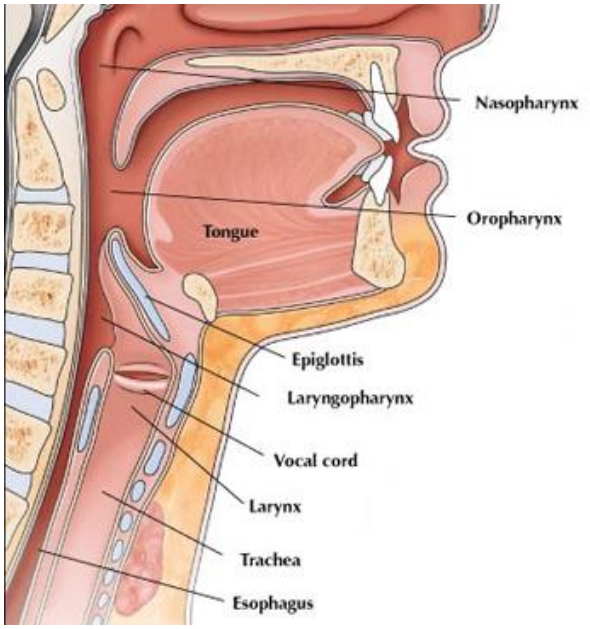
Research • Educate • Support

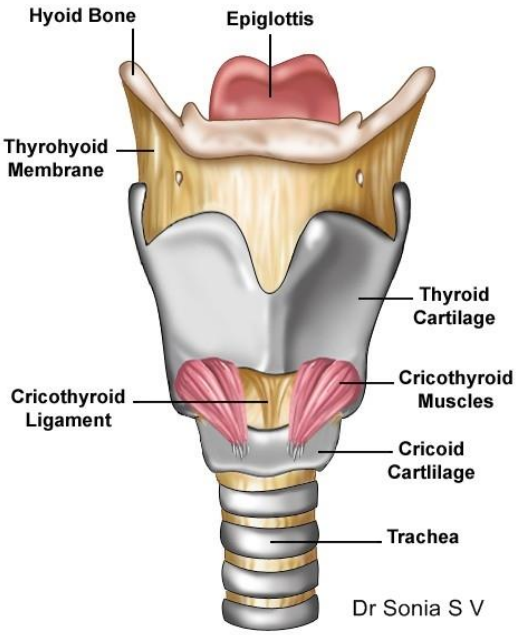
Fact Sheet
on
Cancer of the Larynx

Introduction

Laryngeal cancer is a disease in which malignant (cancer) cells form in the tissues of the larynx. Laryngeal cancer (also called cancer of the larynx or voice box – commonly referred to as the Adam's apple) is a type of head and neck cancer.

[Picture Credit: Head & Neck]





Larynx

The larynx is an organ in the neck of amphibians, reptiles and mammals (including humans) involved in breathing, sound production and protection of the trachea against food and liquid aspiration. It manipulates pitch and volume of sounds produced by the vocal chords which are found inside the larynx. In adult humans the larynx is situated in the front of the neck at the level of the 3rd to 6th neck vertebrae. It connects the lower part of the pharynx (throat) with the trachea (wind pipe).

[Picture Credit: Larynx]

In newborn infants the larynx is initially at the level of the 2nd to 3rd neck vertebrae and is further forward and higher relative to its position in adults. The larynx descends as the child grows (Wikipedia).

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Laryngeal Cancer

Laryngeal Cancer is a disease in which cancer cells grow in the larynx. Cancer of the larynx, can also be called laryngeal cancer, can develop in any part of the larynx, but most begins in the glottis. The inner walls of the larynx are lined with cells called squamous cells. Almost all laryngeal cancers begin in these cells.

If cancer of the larynx spreads, the cancer cells often spread to nearby lymph nodes in the neck. The cancer cells can also spread to the back of the tongue, other parts of the throat and neck, the lungs, and other parts of the body. When this happens, the new tumour has the same kind of abnormal cells as the primary tumour in the larynx (Medical News Today).

Incidence of Laryngeal Cancer in South Africa

According to the National Cancer Registry (2012) the following number of laryngeal cancer cases was histologically diagnosed in South Africa during 2012:

Group - Males 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	499	1:253	1,35%
Asian males	18	1:241	2,16%
Black males	288	1:281	2,47%
Coloured males	62	1:195	1,42%
White males	131	1:219	0,65%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	74	1:2 519	0,20%
Asian females	1	1:141 427	0,09%
Black females	30	1:4 592	0,18%
Coloured females	16	1:979	0,39%
White females	27	1:1 185	0,17%

The frequency of histologically diagnosed cases of laryngeal cancer in South Africa for 2012 was as follows (National Cancer Registry, 2012):

Group - Males 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	0	1	4	36	137	202	89	22
Asian males	0	0	0	1	5	7	3	0
Black males	0	1	4	18	80	125	44	10
Coloured males	0	0	0	10	17	25	5	3
White males	0	1	0	7	35	42	35	10

Group - Females 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	1	0	1	9	20	22	15	4
Asian females	0	0	0	0	0	0	1	0
Black females	1	0	1	5	7	6	6	1
Coloured females	0	0	0	1	4	6	2	3
White females	0	0	0	3	9	9	5	0

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

Risk Factors for Laryngeal Cancer
The following risk factors for laryngeal cancer has been recognised:

- use of tobacco products – there is a strong link between tobacco product use and the incidence of laryngeal cancer
- alcohol consumption – there is a link between the drinking of alcohol and the incidence of laryngeal cancer
- medical conditions and infections – persons with the following have an increased risk for laryngeal cancer:
    - gastro-oesophageal reflux disease - a recent meta-analysis concluded that a diagnosis of gastro-oesophageal reflux disease increases risk of laryngeal cancer by two–three times
    - immunosuppression - a meta-analysis reported an almost three-fold increased risk of laryngeal cancer in people with HIV/AIDS
    - transplant recipient – a meta-analysis reported a two-fold risk increase in transplant recipients for laryngeal cancer suggesting a role of immunosuppression
    - human papillomavirus infection - an increased risk of laryngeal cancer has been shown for people with evidence of human papillomavirus-16 (HPV-16)infection in the larynx (up to 19-fold risk increase) or in blood samples (up to a three-fold risk increase)
    - *helicobacter pylori* infection - a meta-analysis showed a doubling in risk of laryngeal cancer in people infected with helicobacter pylori infection
- personal history of previous cancers – There is a six-fold increased risk for laryngeal cancer in people with a history of previous head and neck cancer(s)
- family history of head and neck cancers - case-control studies showed a doubling in risk of laryngeal cancer in individuals with a history of head and neck cancer in first-degree relatives
- a high intake of red and processed meat – there is an associated increased risk for laryngeal cancer in case-control studies
- poor nutrition - as with all head and neck cancers, poor nutrition may increase the risk of laryngeal cancer. This heightened risk may be due to vitamin deficiencies, which are common among people who abuse alcohol and may partially explain the increased risk for these cancers among heavy drinkers
- genetic syndromes - some inherited genetic mutations, which cause different syndromes in the body, carry a high risk of laryngeal cancer. These include:
    - *Fanconi* anaemia - this blood condition is caused by inherited abnormalities in several genes. Problems can begin at an early age and often lead to leukaemia or aplastic anaemia. People with *Fanconi* anaemia have a higher risk of getting cancers of the throat
    - *dyskeratosis congenita* - this genetically linked syndrome can also cause aplastic anaemia, and carries a very high risk of mouth and throat cancer occurring at an early age
- paan (betel quid) - immigrants from Southeast Asia who use paan (betel quid) in the mouth should be aware that this habit has been strongly associated with an increased risk. Paan, via Hindi from Sanskrit *parṇa* 'feather, leaf' is a stimulating, psychoactive preparation of betel leaf combined with areca nut and/or cured tobacco. *Paan* is chewed and finally spitted or swallowed. Paan has many variations. Slaked lime paste is commonly added to bind the leaves. Some South Asian preparations include katha paste or mukhwas to freshen the breath. It is mostly consumed in Asia, and elsewhere in the world by some Asian emigrants, with or without tobacco, in an addictive and euphoria-inducing formulation with adverse effects (Wikipedia). A

Lancet Oncology publication claims that *paan masala* may cause tumours in different parts of the body and not just the oral cavity as previously thought (Sharma)
- maté - consumption of maté, a tea-like beverage habitually consumed by South Americans, has been associated with an increased risk of cancers of the mouth, throat, oesophagus, and larynx
- preserved or salted foods - consumption of certain preserved or salted foods during childhood is a risk factor for nasopharyngeal cancer.
- oral health - poor oral hygiene and missing teeth may be weak risk factors for cancers of the oral cavity
- radiation exposure - radiation to the head and neck, for noncancerous conditions or cancer, is a risk factor for laryngeal cancer

(Cancer Treatment Centers of America; Cancer Research UK; Mayo Clinic; National Cancer Institute).

Signs and Symptoms of Laryngeal Cancer

Most laryngeal cancers start on or near the vocal cords. Laryngeal cancer is often diagnosed in its early stages because even a very small tumour can stop the vocal cords from vibrating properly and cause your voice to change. Sometimes, the tumour may start in a part of the larynx that is not close to the vocal cords. Then the first sign may be difficulty swallowing or a lump in the throat or neck.

Possible symptoms of laryngeal cancer include:

- changes to the voice, such as hoarseness
- difficulty or pain when swallowing
- a sore throat or feeling that something is stuck in the throat
- a cough that doesn't go away
- an earache
- difficulty breathing or noisy breathing
- Other health problems can cause some of the same symptoms. Testing is needed to make a diagnosis.

(Canadian Cancer Society;

Diagnosis of Laryngeal Cancer

The doctor will examine the throat and feel the neck for lumps, swelling, or other problems. One or more of the following tests may be done:

- indirect laryngoscopy - the doctor uses a small mirror with a long handle to look at the throat and larynx. The doctor will check whether the vocal cords move normally when the person makes certain sounds
- direct laryngoscopy - the doctor uses a lighted tube (laryngoscope) to look at the throat and larynx. The lighted tube can be flexible or rigid:
    - flexible: The doctor puts a flexible tube through the nose into the throat under local anaesthesia.
    - rigid: The doctor puts a rigid tube through the mouth into the throat. A tool on the rigid tube can be used to collect tissue samples. It is usually done under general anaesthesia
- biopsy - the removal of a small piece of tissue to look for cancer cells is called a biopsy. Usually, tissue is removed with a rigid laryngoscope under general anaesthesia. A pathologist then looks at the tissue under a microscope to check for cancer cells. A biopsy is the only sure way to know if the abnormal area is cancer

- imaging tests - imaging tests use x-rays, magnetic fields, or radioactive substances to create pictures of the inside of your body. Imaging tests are not used to diagnose laryngeal or hypopharyngeal cancers, but they may be done for a number of reasons both before and after a cancer diagnosis

(MedicineNet.Com; American Cancer Society; Cancer Treatment Centers of America; Cancer Research UK).

Types of Laryngeal Cancer

The following types of laryngeal cancers occur:

- cancers that start in the skin like tissue (squamous cell cancer) - about 95 out of every 100 cancers of the larynx (95%) are this type. The cancer develops in the flat, skin like, squamous cells that cover the surface of the epiglottis, vocal cords and other parts of the larynx. Squamous cells are resistant to hot liquids and sharp foods and can heal quickly if damaged. But the more they are damaged, the more new cells have to be made. And the greater the chance that cells may gradually change into cancer cells
- cancers that start in gland cells (adenocarcinoma) - adenocarcinoma is uncommon compared to squamous cell laryngeal cancer. It starts in the adenomatous cells that are scattered around the surface of the larynx. Adenomatous cells are gland cells that produce mucus
- connective tissue cancers (sarcoma) - sarcomas are cancers that start in the body's connective tissues. These are the supporting tissues of the body, such as bone, muscle, and nerves. Cartilage is the supporting tissue of the larynx. Cancers that develop from cartilage are called chondrosarcomas. Sarcomas of the larynx are extremely rare
- other types of cancer found in the larynx - very rarely, other types of cancer occur in the larynx. It is possible to get lymphoma or plasmacytoma (a type of myeloma) in the larynx (Cancer Research UK; MacMillan Cancer Support).

Lowering the risk of Laryngeal Cancer

It is not possible to totally prevent the incidence of laryngeal cancer. Case-control studies, however, have shown up to an 80% reduced risk in people with the highest intakes of fruit and vegetables or fruit and vegetable fibre. In addition, eating a greater diversity of fruits and vegetables has been shown to reduce the risk of laryngeal cancer (Cancer Research UK).
Laryngeal cancer can be further prevented by avoiding the following risks:

- *tobacco use* - tobacco use is the greatest risk factor for laryngeal cancer, and for all other head and neck cancers. Most people who get laryngeal cancer have a history of smoking or other tobacco use or prolonged exposure. The risk of cancer increases with the frequency of tobacco use. Long-term exposure to second-hand smoke may also be a risk factor for these types of cancers, although studies are not yet conclusive

- *alcohol* - heavy drinkers are many times more likely to develop laryngeal cancer than are non-drinkers. Combined use of tobacco and alcohol increases the risk for these cancers multifold

- *human papilloma virus infection* - human papilloma viruses, or HPV, include about 100 similar viruses. Many HPVs cause warts, but some are involved in cancer. Most noteworthy, HPV is tied to the development of cervical cancer. More recently, HPV has been linked to oral cancer. HPV may also be a risk factor for some cancers of the hypopharynx. Estimates of the percentage of patients with laryngeal infected with the same HPVs range from 6 percent to 47 percent, but so far infection of this virus does not appear to be a direct factor in the development of laryngeal cancer (Cancer Treatment Centers of America).

Staging of Laryngeal Cancer

Staging is a way of describing where the cancer is located, if or where it has spread, and whether it is affecting the functions of other organs in the body. Doctors use diagnostic tests to determine the cancer's stage, so staging may not be complete until all of the tests are finished. Knowing the stage helps the doctor to decide what kind of treatment is best and can help predict a patient's prognosis (chance of recovery). There are different stage descriptions for different types of cancer.

One tool that doctors use to describe the stage is the **TNM** system. This system judges three factors: the tumour itself, the lymph nodes around the tumour, and if the tumour has spread to other parts of the body. The results are combined to determine the stage of cancer for each person. There are five stages: stage 0 (zero) and stages I through IV (one through four). The stage provides a common way of describing the cancer, so doctors can work together to plan the best treatments.

TNM is an abbreviation for tumour (**T**), node (**N**), and metastasis (**M**). Doctors look at these three factors to determine the stage of cancer:

- how large is the primary tumour and where is it located? **(Tumour, T)**
- has the tumour spread to the lymph nodes? **(Node, N)**
- has the cancer metastasised to other parts of the body? **(Metastasis, M)**

Tumour. Using the TNM system, the 'T' plus a letter or number (0 to 4) is used to describe the size and location of the tumour. Some stages are also divided into smaller groups that help describe the tumour in even more detail. Specific tumour stage information is listed below and has been divided into an outline of tumours of the larynx.

Tumours of the larynx

TX: the primary tumour cannot be evaluated
T0: **n**o evidence of a tumour is found
Tis: this is a stage called carcinoma (cancer) in situ. It is a very early cancer where cancer cells are found only in one layer of tissue

When describing a T1 to T4 tumours, doctors divide the larynx into three regions: the glottis, the supraglottis, and the subglottis

Node The 'N' in the TNM staging system stands for lymph nodes, the tiny, bean-shaped organs that help fight infection. Lymph nodes near the head and neck are called regional lymph nodes. Lymph nodes in other parts of the body are called distant lymph nodes. Since there are many nodes in the head and neck area, careful assessment of lymph nodes is an important part of staging.

NX: the regional lymph nodes cannot be evaluated
N0: there is no evidence of cancer in the regional nodes
N1: the cancer has spread to a single node on the same side as the primary tumour, and the cancer found in the node is 3 cm or smaller
N2: describes any of the following conditions:
N2a: the cancer has spread to a single lymph node on the same side as the primary tumour and is larger than 3 cm, but not larger than 6 cm
N2b: the cancer has spread to more than one lymph node on the same side as the primary tumour, and none measure larger than 6 cm
N2c: the cancer has spread to more than one lymph node on either side of the body, and none measure larger than 6 cm
N3: the cancer found in the lymph nodes is larger than 6 cm

Distant metastasis The 'M' in the TNM system indicates whether the cancer has spread to other parts of the body.
MX: distant metastasis cannot be evaluated
M0: the cancer has not spread to other parts of the body
M1: the cancer has spread to other parts of the body

Cancer Stage Grouping
Doctors assign the stage of the laryngeal cancer by combining the T, N, and M classifications.

Stage 0: this stage describes a carcinoma in situ (Tis) with no spread to lymph nodes (N0) or distant metastasis (M0)
Stage I: this stage describes a small tumour (T1) with no spread to lymph nodes (N0) or distant metastasis (M0)
Stage II: this stage describes a tumour that has spread to some nearby areas (T2) but has not spread to lymph nodes (N0) or to distant parts of the body (M0)
Stage III: this stage describes any larger tumour (T3) with no spread to regional lymph nodes (N0) or metastasis (M0), or a smaller tumour (T1, T2) that has spread to regional lymph nodes (N1) but has no sign of distant metastasis (M0)
Stage IVA: this stage describes any invasive tumour (T4a) that either has no lymph node involvement (N0) or that only has spread to a single same-sided lymph node (N1), but without distant metastasis (M0). It is also used to describe any tumour (any T) with more significant spread to the lymph nodes (N2) but no distant metastasis (M0)
Stage IVB: this stage describes any cancer (any T) with extensive spread to lymph nodes (N3) but no distant metastasis (M0). For laryngeal cancer, it is also used for a very advanced localized tumour (T4b), with or without lymph node involvement (any N), but no distant metastasis (M0)
Stage IVC: this stage indicates there is evidence of distant spread (any T, any N, M1)
(Cancer.Net; National Cancer Institute; Cancer Treatment Centers of America).

Prognosis (Outlook)
Throat cancers can be cured in 90% of patients if detected early. If the cancer has spread to surrounding tissues or lymph nodes in the neck, 50 - 60% of patients can be cured. If the

cancer has spread (metastasised) to parts of the body outside the head and neck, the cancer is not curable and treatment is aimed at prolonging and improving quality of life.

After treatment, patients generally need therapy to help with speech and swallowing. A small percentage of patients (5%) will not be able to swallow and will need to be fed through a feeding tube.
(National Cancer Institute; Medline Plus).

Treatment of Laryngeal Cancer
The treatment of laryngeal cancer is as follows:

Radiation therapy - external beam radiation therapy is a common form of treatment for laryngeal cancer. A machine is used to carefully aim a beam of radiation at the tumour. The radiation damages the cells in the path of the beam – normal cells as well as cancer cells. Small tumours may be cured by treating them with radiation only. For larger tumours, external radiation is often used together with chemotherapy.

Radiation therapy may also be combined with surgery to destroy microscopic cancer cells that may remain in the area after surgery. Radiation therapy also may be used for tumours that cannot be removed with surgery

Chemotherapy - For laryngeal cancer, chemotherapy is most commonly used together with radiation therapy for large tumours and tumours that have spread to the lymph nodes. Chemotherapy may be given as pills or by injection. Chemotherapy drugs interfere with the ability of cancer cells to grow and spread, but they also damage healthy cells. Although healthy cells can recover over time, patients may experience side effects from treatment like nausea, vomiting, loss of appetite, fatigue, hair loss and an increased risk of infection.

Surgery - a decision to have surgery depends on the size of the tumour and where it is. During the operation, all or part of the tumour and some healthy tissue around the tumour are removed. Surgery is done under general anaesthetic.

An operation to remove all or part of the larynx is called a laryngectomy. The surgeon may also remove nearby lymph nodes in the neck. Sometimes, the thyroid gland is also removed. For a partial laryngectomy, the surgeon removes the part of the larynx affected by the tumour. Usually one or both of the vocal cords are left in so that the patient can still speak. The voice may be different than it was before.

For a total laryngectomy, the surgeon removes the entire larynx. A tracheostomy is done at the same time to create an opening in the lower part of the neck for the patient to breathe through. Air enters and leaves the windpipe and the lungs through the hole (called a stoma). This opening is permanent. After a total laryngectomy, patients will have to learn to speak in a different way.

Vocal cord stripping - with this technique, a long surgical instrument is used to remove the outer layers of tissue on the vocal cords. This approach may be used for a biopsy, or to treat some stage 0 cancers confined to the vocal cords. Vocal cord stripping rarely impacts speech after the operation.

Cordectomy - in a cordectomy, part or all of the vocal cords are removed. This approach may be used to treat glottic cancer that is very small or located only on the surface tissues. Patients who receive a cordectomy may experience changes in speech. Removing part of a vocal cord may lead to a hoarse voice. If both vocal cords are removed, speech would no longer be possible.

Laser surgery - laser surgery uses an intense, narrow beam of light to remove cancerous tissue with little or no damage to surrounding healthy tissue. It is usually done under general anesthetic. Laser surgery may be used for very small laryngeal tumours. Laser surgery may not be available at all cancer centres or hospitals.

Biological therapy - biological therapies are drugs that have an anti-cancer effect but work differently from chemotherapy. Each drug works in a different way, but they all affect the way cancer cells grow or divide. A drug called cetuximab (Erbitux®), which is a monoclonal antibody, can be used for some people with cancer of the larynx.

Monoclonal antibodies are drugs that recognise and bind to specific proteins (receptors) that are found in particular cancer cells or in the bloodstream. Some cancer cells have receptors known as epidermal growth factor receptors (EGFRs). When growth factors attach to the receptor, the cancer cell is stimulated to grow and divide. The monoclonal antibodies lock onto the EGFR and may prevent the cancer cells from growing and dividing. They may also make the cancer cells more sensitive to the effects of radiotherapy.

Cetuximab has been recommended by NICE (National Institute for Health and Clinical Excellence) and the SMC (Scottish Medical Consortium) as a treatment for some people with a laryngeal cancer. It can be used with radiotherapy for people with laryngeal cancer that has spread into surrounding tissues (locally advanced cancer) who are unable to have chemotherapy. Cetuximab is given by drip (infusion) into a vein.

(Canadian Cancer Society; University of California San Francisco; Medscape Reference; MacMillan Cancer Support; Cancer Treatment Centers of America).

Mechanical Speech

Mechanical speech is a method of speech used after surgery for laryngeal cancer. An electrolarynx is held against the neck and produces a hum that vibrates up towards the mouth where one can articulate words. It does not require much learning to use this method and is often used while learning oesophageal speech (Honor Society of Nursing).

[Picture Credit: Electrolarynx]

An electronic larynx (electrolarynx) is a battery operated machine that produces sound for one to create a voice. There are many different makes and types, but they are usually about the size of a small electric razor. One holds the machine against the neck, or fit a small tube into the corner of the mouth. When the button is pressed on the

machine, it makes sound. By moving one's tongue and mouth one can form the sounds into words. This method of speech after laryngectomy may be best if:

- The person is not able to have a voice prosthesis (TEP) for medical reasons
- The patient did not have a voice prosthesis put in at the time of the laryngectomy but is waiting to have one put in later

To be able to use this method one needs training from a speech and language therapist and plenty of practice. The speech has a mechanical sound to it but most people can make themselves understood.

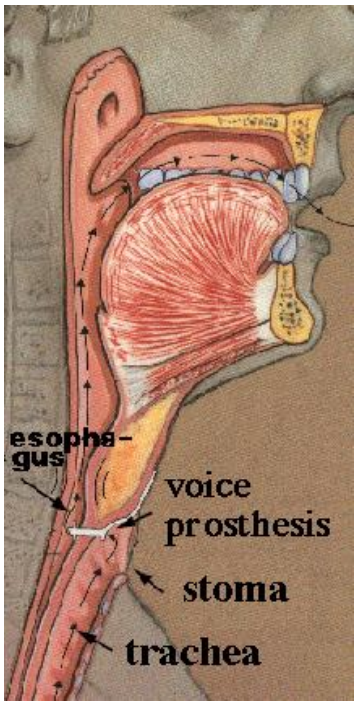
[Picture Credit: Using Electrolarynx]

Some of the machines have buttons to vary the pitch or tone of the sound made by the electronic larynx. This will make the voice sound more varied. A speech and language therapist will advise on the best type for every situation.
(Cancer Research UK).

Tracheo-oesophageal Speech

Tracheo-oesophageal speech is a method of speech that can be used after surgery for laryngeal cancer. This involves surgically making an opening between the oesophagus and trachea. Sound is made by covering the stoma and redirecting the air through the oesophagus where the sound vibrates off of the throat walls (Honor Society of Nursing).

One of the most effective techniques for speaking following a laryngectomy is tracheo-oesophageal speech (TE speech). To understand how TE speech works, one has to be familiar with the anatomy of the neck after laryngectomy. Briefly after a laryngectomy the end of the trachea (windpipe) is brought out to the front of the neck. This opening is called the stoma, and one breathes in and out of the stoma. No speech is possible as one exhales through the stoma, since air just travels out without causing any vibration or sound.



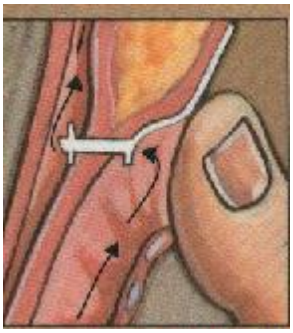
Just behind the trachea is the oesophagus, which is the tube through which food travels from the mouth to the stomach.

The principle in TE speech is that during exhalation, air is diverted into the oesophagus. The air eventually flows out the mouth. That air flow causes the oesophagus to vibrate, which produces a sound. By moving the lips and tongue, the sound is articulated into speech.

In order to divert air to the oesophagus during exhalation, a small opening called a fistula is created between the trachea and the oesophagus. A small valved tube is placed into the opening or fistula to keep it open and to prevent swallowed food and liquid from getting down the trachea. This tube is usually called a voice

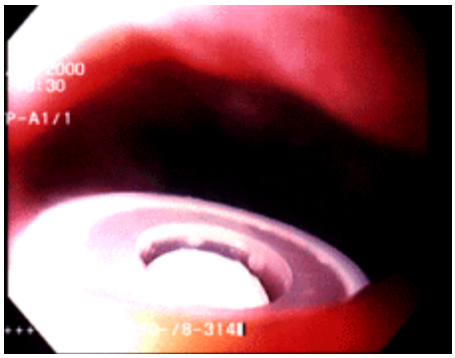
prosthesis.

The fistula can be created at the time of the original laryngectomy, or at a later time. It is a relatively minor operation.



The diagram shows a side view of the stoma and the voice prosthesis in position. Note that the prosthesis connects the trachea (windpipe) and the oesophagus. The prosthesis is constructed with a small valve on the end that goes into the oesophagus. This is done to prevent swallowed food from going into the trachea and causing lung problems.

In order to talk, the stoma must be covered with one's thumb during exhalation. This process is shown to the left.



Notice that when the thumb tightly covers the stoma, air will pass from the trachea and into the oesophagus. With practice, one can make this air vibrate the walls of the oesophagus. This produces a sound that is then modified by the lips and tongue through normal articulation to produce quite normal sounding speech.

The photo to the right was taken with a flexible fiberoptic scope at the upper portion of the oesophagus and shows the part of the TE prosthesis that extends into the oesophagus. This particular type of prosthesis is called an "indwelling prosthesis" and it can stay in for up to 6 months.

Advantages and Disadvantages of Tracheo-oesophageal Speech

Advantages

The sound quality with TO speech is very good, probably most closely resembling normal laryngeal speech. In contrast, speech using an electrolarynx has a very mechanical sound.

Since the air for the speech is coming from the lungs, one can speak for a fairly long time between breaks. With plain oesophageal speech, the air comes from the stomach and speech segments are short. There also is better control of the air flow with TE speech.

Disadvantages

Not everyone can do TO speech. In some cases the walls of the oesophagus are too tight to allow passage of air. In those cases, when one exhales and covers the stoma, air just can't escape. It is like trying to blow against a sealed tube. There is a test that a speech pathologist can do prior to placement of a TE fistula to see if the oesophagus will tolerate TE speech.

The voice prosthesis must be removed and cleaned periodically. This requires a moderate amount of dexterity, especially in putting it back in the right spot. However, there are now prostheses called "in-dwelling" that are designed to stay in for weeks or months at a time.

The stoma must be tightly covered during exhalation in order for air to get into the oesophagus. This requires good arm and hand movement, and this may be difficult after a

spinal cord injury. There are valves that can be placed over the stoma that divert air into the oesophagus, but they do not always work.

There can be food that leaks into the trachea.

The prosthesis can fall out and the hole will seal over in about 24 hours. If it does seal over, a second operation must usually be done to make a new hole. If the prosthesis falls into the trachea, it must be removed to prevent aspiration.
(Eastern Virginia Medical School).

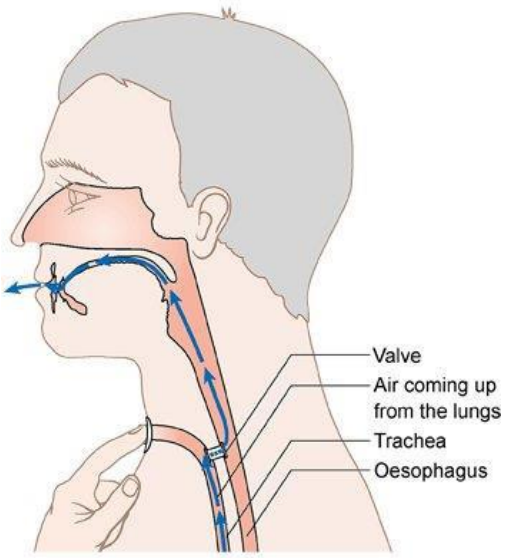


Diagram showing a voice valve
© CancerHelp UK

Voice Prosthesis (Tracheo oesophageal puncture – TEP)

Tracheo oesophageal puncture (TOP) is the most common way to restore speech after laryngectomy, but it is not suitable for everyone. A patient usually has TOP as part of the operation to have their larynx removed. One can also go back for a minor operation to have it done later. This is usually at least 8 weeks after the original surgery to remove the larynx.

In TOP, the surgeon makes a tiny hole called a fistula at the back of the stoma. The hole creates an opening between the windpipe and food pipe (oesophagus). The surgeon may put a tube (catheter) into the hole to keep it open or the/she may put a small valve (voice prosthesis) into the hole during the operation. If the patient does not have a catheter into the hole, he/she will need to have a feeding tube down the nose (nasogastric tube) for a while.

If there is a catheter into the puncture (hole), the patient may be able to have liquid food down the tube but once the area has healed and the patient is eating and drinking, the doctor takes the catheter out and will put a small, one way valve into the hole.

If the patient has the tracheo-oesophageal puncture some time after laryngectomy, the catheter will only need to be in place for a few days. The valve (voice prosthesis) can also be put in straight away.

The voice prosthesis is a valve that allows the patient to make sounds by pushing air from the lungs through the valve and up into the mouth. The person has to cover the stoma with the fingers so that the air goes through the valve and not out of the stoma. Once a person can use this type of voice prosthesis, he/she may be able to use other types of valves which are ‘hands free’. They automatically close the stoma when using the speaking valve. Hands free valves are not suitable for everyone.

Using a voice prosthesis takes practice. After a while, the muscles deep in the throat will grow stronger and vibrate more easily as the air passes through.

3 main types of valve are used:

- Blom-Singer valve
- Provox valve

- Groningen valve

Blom-Singer valves and some Provox valves are external valves. This means that they are meant to be taken out to be cleaned and many people look after these themselves. The valve must be kept clean. If it gets blocked, air can't pass through it easily and the patient will not be able to speak.

Groningen and some types of Provox valve are internal valves. They are left in place until they need changing – about every 6 months, or sooner if they are leaking. A specially trained therapist, doctor or nurse must change them.

Sometimes a person may need to switch from one type of valve to another if their needs change. Occasionally people have difficulty speaking with a speech valve in place. This is usually because the muscles in their pharynx go into spasm. The speech and language therapist will help to try and overcome the spasm. The surgeon may also suggest a treatment to inject some botulinis toxin (Botox) into the muscle to relax it. Sometimes the problem with speech is caused by swelling of the area around the valve caused by acid indigestion. The doctor or specialist nurse can prescribe anti indigestion medicines if someone has acid indigestion.
(Cancer Research UK).

Lifestyle Changes After a Diagnosis of Laryngeal Cancer
Lifestyle changes following an oesophageal cancer diagnosis can be helpful in a variety of important ways:

- strengthening the body so that one can withstand some of the rigors of treatment
- optimising the function of the immune system to aid in the fight against cancer
- improving one's emotional outlook, so one can enjoy life to the fullest, even during treatment for oesophageal cancer
- making healthful choices that will help to avoid other medical problems that could complicate health

General Guidelines
Stop smoking - smoking is a known risk factor for many cancers. It is never too late to stop smoking. Join CANSA's e-KickButt Programme or ask a doctor about programmes to help stop smoking.

Reduce the risk of infection - to decrease the risk of infection, avoid exposure to bacteria and viruses:

- try to avoid crowds, especially during cold and flu season
- ask a doctor about immunisation against the flu and pneumonia
- wash hands thoroughly and often. Hand washing is the most effective method of decreasing the chance of catching colds and flu. You may wish to carry hand sanitiser with you for occasions when washing is not convenient.
- follow a Nutritious Diet - Eating a healthful diet may help avoid other medical conditions linked to poor nutrition. Because cancer itself and some cancer treatment may have a dulling effect on one's appetite, it's important that one makes the most of the calories taken in. Strongly consider consulting a registered dietician (RD) to help learn more about the best kinds of foods to eat and how to eat other less healthful foods in moderation.

- rest when tired - The treatments for cancer can add to the fatigue patients may experience. Fatigue is the most frequently experienced symptom of cancer and cancer treatments. The fatigue can range from 'just feeling tired' to complete and utter exhaustion. It is important to allow the body time to rest. This will help the body have the strength to heal itself. Studies have shown a relationship between fatigue and an increased morbidity of cancer and cancer treatments as a result of fatigue's adverse effect on appetite, diminished quality of life, and loss of hope.
- seek support - The diagnosis of cancer is a life-defining event that is difficult to handle for anyone. Facing the uncertainty of a serious disease, feeling anxious about how one will feel during treatment, and worrying about the impact of both the diagnosis and treatment can take a devastating toll that no one should have to tackle on their own. Try to have access to the following:

    - family
    - friends
    - religious community
    - empathetic support groups for people with your type of cancer
    - professional support (social workers, psychologists, and/or psychiatrists who are trained to help support cancer patients and their families)

People who allow themselves to seek help while they are recovering from cancer can often maintain better emotional equilibrium, which will help them face the challenges of cancer and its treatment.
(Winchester Hospital; Life is Beautiful).

About Clinical Trials
Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

Types of Clinical Trials
Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

Prevention - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer.

Screening - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

Diagnostic - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

Quality of life or supportive care - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as "human subjects."

Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different "phase" in the clinical research process. The following phases are used for cancer treatment trials:

Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard

treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or “trial arms”: (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

Use of Placebos

The use of placebos as comparison or "control" interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as 'biospecimens') obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.
(National Cancer Institute).

Medical Disclaimer

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