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8 years study of pharyngocutaneous fistula following total laryngectomy at C. H. Baragwanath Hospital

Sabri, Issam Fetouri

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8 YEARS STUDY OF PHARYNGOCUTANEOUS FISTULA FOLLOWING TOTAL LARYNGECTOMY AT C.H.BARAGWANATH HOSPITAL

Candidate:

Dr Issam Sabri. Student No: 0419390X

Supervisor:

Professor P.C Modi, M.B.B.Ch (wits), D.C.H (SA), F.C.S(SA) , M Med (wits)

Otorhinolaryngology

A dissertation submitted in Partial fulfillment for the degree of Master of Medicine in Otorhinolaryngology

Faculty of Health Sciences, University of Witwatersrand

DECLARATION

I, Issam Sabri, declare that this dissertation is my own work. It is being submitted for the degree of Master of Medicine in Otorhinolaryngology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

25 / 09 / 2009

DEDICATION

I dedicate this work to my mum, who passed away during the preparation of this research; to my wife and son, whose loyalty and encouragement had enabled me to continue and eventually complete that which we set out to accomplish.

Abstract

Introduction

The bulk of the surgical literature about laryngeal cancer is concerned with cure rates or five-year survival rates. While this is important, the five year survival rate is only one measure of success of laryngeal cancer surgery. Whereas, postoperative morbidity and mortality are also very important.

Pharyngocutaneous fistula (PCF) is the most frequent complication in the early post operative period after total laryngectomy. It creates a communication between the pharynx and the cervical skin or less frequently with the stoma of the tracheostomy. The pharyngeal contents, usually saliva, flow through the fistula emerging from the cutaneous orifice.

This study aims to determine the incidence and the predisposing factors for the development of pharyngocutaneous fistula (PCF); and to review the management and outcome of such cases following total laryngectomy at Ear, Nose and Throat (ENT) department, Chris Hani Baragwanath Hospital.

Patients and methods

This is a retrospective study. The medical records of 30 patients who underwent total laryngectomy surgery for squamous cell carcinoma of the larynx with no local neck metastases between June 2000 and May 2008 were assessed.

All patients had similar (standard) preoperative and post operative care. I studied a number of factors that could influence pharyngocutaneous fistula formation such as age, smoking habit, alcohol consumption, tumour stage, preoperative tracheostomy, preoperative hemoglobin and associated systemic diseases (gastroesophageal reflux, chronic obstructive pulmonary disease, systemic high blood pressure and diabetes mellitus)

Results

Pharyngocutaneous fistula appeared in 20% (6/30 patients). Spontaneous closure with local wound care was noted in 5 patients (83.3%), whereas a surgical closure was necessary in one patient .

Conclusion

The results of our study concluded that pharyngocutaneous fistula remains a troublesome complication of the early post-operative period after total laryngectomy. There are many conflicting reports in the literature concerning the pharyngoctaneuos fistula predisposing factors, but our study data (table 1 page 22) of age, smoking habit, alcohol consumption, tumor stage, preoperative tracheostomy, preoperative hemoglobin and associated systemic diseases(gastroesophageal reflux, chronic pulmonary obstructive disease, systemic high blood pressure and diabetes mellitus) did not show any significant value.

Our experience confirmed that most pharyngocutaneous fistulas can be successfully treated conservatively.

Acknowledgements

I wish to express my gratitude to all the following:

PROFESSOR PC MODI, my supervisor and academic head, for his guidance support and encouragement throughout the preparation and execution of this study and for his invaluable criticism in the final preparation of this dissertation.

DR WASSILA JASSAT for providing advice and guidance on study design, statistical analysis and report writing.

To my family, here and in Libya, thank you for permitting me to take leave of you so that I have pursue my life's ambitions.

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LIST OF ABBREVIATIONS :

PCF	Pharyngocutaneous fistula
GORD	Gastroesophageal reflux disease
COPD	Chronic obstructive pulmonary disease
HT	Systemic blood hypertension
DM	Diabetes mellitus
TEP	Tracheoesophageal puncture
NPO	Nothing per os
LSCC	Laryngeal squamous cell carcinoma
NGT	Nasogastric tube

Introduction

A fistula is an abnormal communication between two epithelialized surfaces. In a pharyngo-cutaneous fistula the communication occurs between the pharyngeal mucosa and the skin of the neck due to failure in pharyngeal healing. This results in a salivary leak.

This is a devastating complication not only for the surgical management involved but also for the patient and his family. Its occurrence leads to increased morbidity, delay in adjuvant treatment, prolonged hospitalization and increased treatment costs [5.]

Anatomy of the larynx

The larynx is located at the upper part of the air passage (Fig 1). It is situated between the trachea and the root of the tongue; at the upper and forepart of the neck; where it presents a considerable projection in the mid-line. It forms the lower part of the anterior wall of the pharynx and is covered behind by the mucous lining of that cavity. On either side of it lie the great vessels of the neck. Its vertical extent corresponds to the fourth, fifth and sixth cervical vertebrae, but it is placed somewhat higher in females and in children.

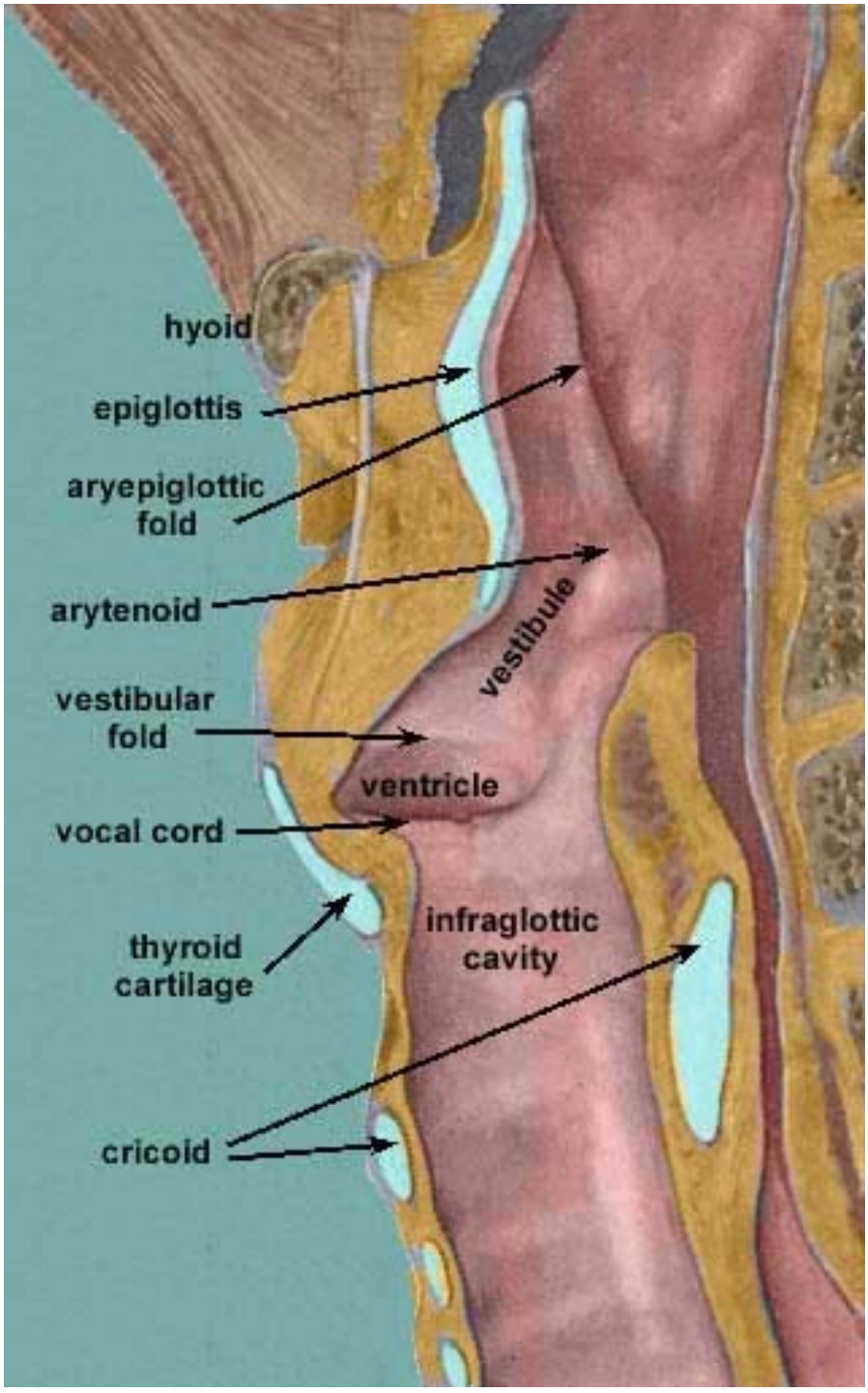

Fig 1: Location of the larynx

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The skeleton of the larynx consists of nine cartilages (Fig. 2) - three single and three paired -

Thyroid	2 Arytenoids
Cricoid	2 Corniculate
Epiglottis	2 Cuneiform

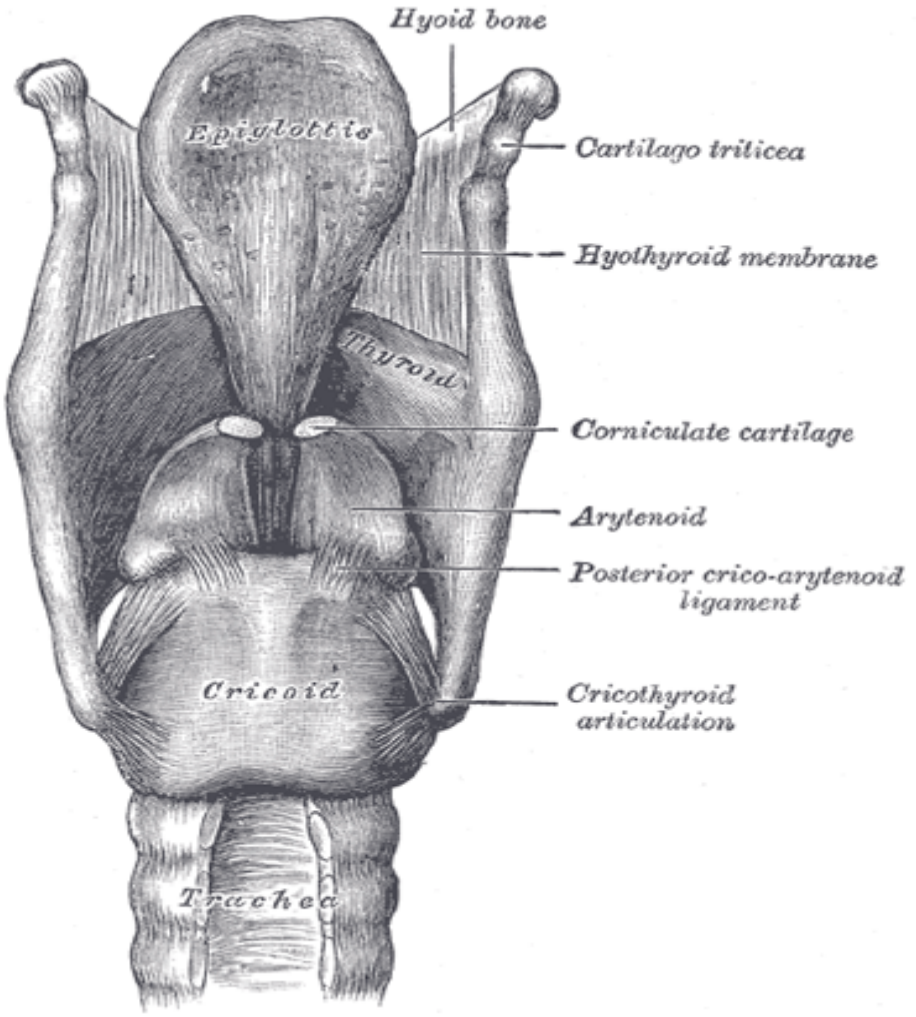

Fig 2: The laryngeal skeleton

(*Copyright* © Henry Gray (1825–1861). Anatomy of the Human Body.1918)

Laryngeal embryology

The larynx develops from the fourth and fifth branchial arches. At the third week of gestation, the respiratory primordium is derived from the primitive foregut to later form the lung bud and later the bronchial bud which will eventually develop into the tracheo-bronchial tree. At the fourth and fifth week of gestation the tracheo-oesophageal folds fuse to form the tracheo-oesophageal septum leading to the separation of the tracheal airway lumen from the esophageal digestive tract.

The laryngotracheal groove is the primitive opening of the larynx during development. This structure will develop into the primitive laryngeal aditus which are formed by three eminences. The hypobranchial eminence is the most cephalad of the structures and will later develop into the epiglottis. The other two eminences will form the arytenoid cartilages. The laryngeal lumen obliterates and later recanalizes by the tenth week of gestation.

Laryngeal function

The larynx has an array of functions including -

- Breathing passage
- Airway protection
- Clearance of secretion
- Vocalization

Reduction in the size of the laryngeal airway can produce symptoms of airway obstruction ranging from mild stridor, to increased work of breathing presenting with chest wall retraction, nasal flaring, tachypnea, apnea, cyanosis and even sudden death.

Laryngeal cancer

Laryngeal cancer is a serious disease. It is typically a disease of elderly smoking men. Even though laryngeal cancer is the most common head and neck malignancy, it comprises approximately only 1% of all malignancies[1] and 30 - 50% of head and neck carcinomas[2].

The overall prognosis of laryngeal squamous cell carcinoma (LSCC) is relatively good compared to head and neck cancers in general. However, the treatment options available, especially those for advanced disease cause severe impairment of the quality of life. This warrants a search for more conservative, yet equally effective treatment regimens. Further, methods for detecting these cancers at an earlier stage and for distinguishing the cancers with more aggressive behavior are being sought. . These are the cancers that have potentially the worst prognosis. Despite the general improvement in cancer care during the past decades, the survival of LSCC has not improved significantly [1, 2].

In spite of a multitude of published studies, our knowledge about the prognostic factors of LSCC has not markedly increased during the past decades [1, 2]. Even

today, the disease stage at the time of diagnosis and the anatomical subsite of the tumour are the only solid and practical prognostic factors and tools in choosing the treatment protocol for laryngeal squamous cell carcinoma (LSCC). A wide variety of histopathological factors have been studied as potential indicators of poor prognosis and, consequently, aggressive treatment, but with conflicting results [1, 2].

Many options are available for treatment of laryngeal cancer which include laser surgery [1], partial laryngectomy, radiation therapy, chemotherapy and total laryngectomy. Frequently patients undergo total laryngectomy after unsuccessful attempts at preserving the larynx with partial laryngectomy [3], failed radiation therapy or for advanced laryngeal cancer.

Review of literature

History of pharyngo-cutaneous fistula (PCF)

Total laryngectomy started in 1829 by Dr Albers who recorded successful extirpation of the larynx of a dog which lived for 9 days [4].

Billroth performed what is considered to be the first successful total laryngectomy on a human being in 1973. The patient was a 36 year old man who was thought to have a tumor on one vocal cord which was excised. Nine days later the entire larynx had to be removed because the growth had spread and infection developed. The patient died from local recurrence of the tumor in the neck, which included a worsening PCF.

Billroth was also the first person to report PCF as one of the complications of total laryngectomy [4.]

The procedure of total laryngectomy is still followed by surgical complications which may cause serious morbidity and even mortality such as severe infection with flap necrosis resulting in carotid blow out; or the development of PCF which is the most common complication.

Incidence of pharyngo-cutaneous fistula

The reported incidence of PCF in international literature, is extremely variable ranging from 3.6% to 65% [6,7,19,2].

Attributing factors of pharyngo-cutaneous fistula

Despite a large number of studies performed to find out the contributing factors in the development of PCF with the aim of reducing its incidence, there is still disagreement on factors that predispose to this complication.

Various contributing factors have been identified, including:-

a) Time of oral feeding

It is surprising what little information is available in the literature to support the time of initiation of the oral feeding. It is well known that a skin incision heals in a water tight fashion within 24 - 48h after surgery [7]. It seems reasonable to assume that the pharyngeal mucosa could do the same in a similar period. Under normal conditions saliva is swallowed at a rate of 1500 ml/24hours. Saliva is as potentially harmful mechanically as other swallowed liquids or soft food.

Initiating oral feeding within 48 hours of total laryngectomy without partial pharyngectomy; who have not had a previous surgical resection of the upper aerodigestive tract; and who have either not received previous therapeutic

irradiation to the head and neck region; does not increase the frequency of PCF [7].

Oral feeding especially with solid food encourages granulation tissue formation along the fistula tract and eventually results in more spontaneous closure of the fistula tract [8].

b) Gastroesophageal reflux disease(GORD)

Gastroesophageal reflux disease has recently been identified as an important factor in numerous inflammatory and neoplastic disorders of the upper aerodigestive tract. It is associated with contact ulcers and granulomas of the larynx, chronic laryngitis, post intubation laryngeal complications, laryngeal stenosis and even laryngeal cancers especially in non-smokers.

Seventy one percent of patients with laryngeal carcinoma had abnormal 24-hour pH studies using the double pH probe monitoring system[9]. This suggests that many patients undergoing laryngectomy also have gastroesophageal reflux. Prophylactic use of ranitidine (H2 receptor blocker) and metoclopramide (prokinetic) has decreased the incidence of pharyngo-cutaneous fistula and the mean length of hospital stay after total laryngectomy [10].

c) Age

Age has received increasing attention as a prospective factor for post operative complications. The suitability of surgical candidates based on chronological age has been a source of controversy. Traditionally, patients more than 60 years of age are predisposed to wound related complications including PCF formation [11].

d) Preoperative tracheostomy

Tracheostomy is frequently performed for more advanced tumors. These are usually due to airway obstruction at presentation. In emergency situations this is usually performed in a bacterially contaminated field; and this may contribute to post total laryngectomy PCF fistula formation [12].

e) Tumor stage and laryngeal site

The size of the primary tumor has no effect on PCF formation, although supraglottic tumors have significantly more fistulas than glottic tumors [13]. They attributed this to extension of supraglottic tumors either to the vallecula or to the pyriform fossa, consequently requiring excision of large part of pharyngeal mucosa which resulted in closure being performed under some tension.

f) Preoperative Hemoglobin

Low preoperative hemoglobin increases the incidence of PCF nine-fold [14]. This rise in the number is related simply to a decrease of the oxygen

carriage to the repair site by the heamoglobin poor blood, thus predisposing to poor wound healing.

g) Preoperative radiation

It is well known that irradiated tissue lacks good tissue circulation, is friable and must be handled more gently than non-irradiated tissue. In the acute phase; during the delivery of radiotherapy; cells that regularly or rapidly divided are killed leading to acute toxic effects such as dermatitis or mucositis. The second, or chronic, phase of radiotherapy injury results from the effects of irradiation on native tissue are endarteritis obliterans, excessive fibrosis, decrease of cellular replication and disruption of wound healing by tissue ischemia and impaired angiogenesis.

An increase in the number of PCF is related to the increase of the radiation field size, dose increment and a change from continuous to fractionated radiation therapy [15].

h) Malnutrition

The incidence of malnutrition has been reported in the literature between 30% to 50% in patients with head and neck cancers. Patients with more than 10% weight loss in the 6 months prior to surgery were at

greatest risk for the development of major post-operative complications [17].

i) suture material

There is a statistically significant difference in the formation of PCF between vicryl and catgut groups in favor of vicryl which has greater tensile strength, less inflammatory reaction and has a longer half-life [18] .

j) Positive surgical margins

Presence of infiltrated margins may explain the higher frequency of fistula formation as a result of deficient healing process occurring at the surgical wound, where the presence of the tumor cells may negatively influence the healing process and wound closure [19].

k) Vascular diseases related to smoking and alcohol drinking

This may play a huge role especially if there is clinical evidence of vascular disease. Various mechanisms may explain this association. Nicotine-induced vasoconstriction leads to limited perfusion and, together with carbon monoxide-induced cellular hypoxia, results in decreased tissue oxygen tension causing reduction in collagen deposition and tensile strength in the wound [30].

Detection of pharyngo-cutaneous fistula

This can be accomplished by careful post-operative monitoring of:

i) Temperature.

Fever in the early post operative period (first 48 hours) particularly when corrected for atelectasis and pneumonia is an excellent predictor of a fistula formation. Fistula developed in 71% of the patients with early post-operative fever >101.5 F (38.6 Ċ) compared with only 4% of those without fever [20] .

ii) Wound amylase concentration

Amylase is an enzyme present in small amounts in the serum (500 IU/λ) and in the saliva (70.000 IU/λ). Drain amylase >4000 IU/λ on day one post total laryngectomy is a predictor of PCF development [21].

iii) Radiologic assessment

A barium-swallow videoesophageogram is indicated in patients with signs and symptoms suggestive of an impending fistula (fever, wound erythema, wound swelling, or persistent elevated neck-drain output) to be an excellent predictor of a clinical fistula [22].

Management of pharyngo-cutaneous fistula

The management of PCF is a challenge for the surgeon and the patient alike. Options are as follows:

1. Conservative treatment

The conservative treatment of the PCF aims to preserve and restore the injured region. It is a complex, dynamic and systemic process, depending on the general health condition of the patient, and can be delayed by several intrinsic factors (age, preexisting medical diseases, radiotherapy, poor nutrition, low hemoglobin) which should be identified in order to promote the continuity of the treatment process [11, 12,13].

Early recognition of a fistula can prevent secondary wound complications and reduce the incidence of catastrophic complications. Areas suspicious for fluid collection should be aspirated and if purulence or salivary contamination is detected, exteriorization should be done immediately by opening the suture lines. The drainage will divert the fistula from critical structures such as the carotid sheath and posterior tracheal wall [20].

Temporary techniques can be used.

a) Silicon septal button is described as a temporary management of selected PCF which are not more than 1cm in size and the cases cannot be repaired in a reasonable period of time. There is however two limiting factors related to the use of this technique [23]

- High cost of the button

- Prevents spontaneous closure

Other potential complications include erosion of surrounding tissue and aspiration of the button if it is too small for the fistula opening.

b) Decrease salivation by injection of Botulinum Toxin (BTX)

Injecting BXT into the parotid and submandibular glands, if not resected with neck dissection, in both sides under ultrasonographic guidance was used in three patients with PCF gave good results [24].

2. Surgical management

Several articles in the literature described techniques that are used for surgical closure of the PCF. The wide variety of reconstructive procedures described indicates the lack of a single, reliable operative approach that can be used in all cases. This is due to the great differences in PCF presentation. However, the principle of PCF fistula closure is the same in all cases and relies on the simple fact that a fistula must be closed by two epithelial surfaces, one to provide an internal lining and the second for external cover.

PCF have been classified according to source of tissue used in reconstruction to three types [28].

- Type 1 fistula is that where both tissue surfaces can be provided locally.
- Type 2 fistula, one tissue surface can be provided locally and the other must be provided from a distance.

- Type 3 fistula, is a fistula that requires both surfaces from distance.

Surgical management is indicated in cases where conservative management fails and fistula persists, exposing the patient to continuous salivary leak with inherent risks of infection, aspiration, carotid artery exposure and even rupture.

The timing of surgical repair of a fistula is not clear in the literature, some suggested forty post-operative days [25]. Many options are available for reconstruction of PCF fistula which includes:

i) Primary closure

Primary closure of PCF is rarely possible but may be considered in small fistula in cases in which there is minimal surrounding soft tissue loss and the mucosa seems healthy and adequate for closure.

1. Loco-regional flaps

- Myocutaneous flaps

  The pectoralis major flap offers the benefit of an excellent vascular pedicle. The latissimus dorsi and the trapezius flaps represent available myocutaneous flaps with overlying skin fed by musculocutaneous perforating vessels. These flaps have been used

for oesophageopharyngeal reconstruction, but are much less advantageous than the versatile, durable pectoralis major.

- Muscle flaps

  Sternocleidomastoid muscle flap is also used for fistula closure which has advantages of workable mass, good coverage and single stage reconstruction.

2. Free flaps

- Radial forearm free flap in conjunction with the Montgomery salivary bypass tube revealed good results for reconstruction of defects of the hypopharynx and cervical oesophagus [26] . The Montgomery bypass tube stents the reconstruction and decreases the exposure of the anastomotic suture line to saliva.

- Dorsalis pedis flap is a suitable choice in the management of large pharyngocutaneous fistula [31]. Because the transferred tissue in this area is preferred to be adequately pliable and thin which affects the aesthetic and functional outcomes. On the other hand it leaves relatively less conspicuous scar on the foot which may better accepted by the patients because of its' less noticeable location.

Rationale for the Study

The information of this study will define and identify patients at risk for developing PCF post-total laryngectomy and assist in their management.

Aim

The overall aim of this study is to assess the current status of pharyngo-cutaneous fistula after total laryngectomy at the Department of Otolaryngology, Head and Neck Surgery, Chris Hani Baragwanath Hospital.

Specific Objectives

1. To describe the patients treated with total laryngectomy for carcinoma of the larynx with no local metastasis in the department.
2. To determine the incidence of pharyngo-cutaneous fistula post total laryngectomy.
3. To assess predisposing factors related to developing pharyngo-cutaneous fistula.
4. To evaluate the management and outcome of pharyngo-cutaneous fistula in this institution.

Methods

Ethics approval

This study was approved by the standards and ethics Committee of the University of the Witwatersrand (Ethics clearance number M090221).

Study setting

This retrospective study was conducted at the Otorhinolaryngology Department, at the chris Hani Baragwanath Hospital, which is an academic department affiliated to the University of the Witwatersrand. It is a tertiary referral center for patients suffering from ENT diseases.

Study population

The study includes all patients who underwent a total laryngectomy as part of their management for carcinoma of the larynx with no regional metastases.

Inclusion and exclusion criteria: All total laryngectomy patients that fulfilled the inclusion criteria of having a histologically-proven carcinoma with no local metastasis were included. The study excluded all patients who underwent total laryngectomy with additional surgical procedure like radical or functional neck dissection, partial laryngectomy and failed radiation therapy.

Study period

Data for the study was collected on all patients seen between June 2000 and May 2008.

Data collection

A list of all the names and numbers of the patients who met the inclusion criteria was obtained from the theatre records. The medical files were then recieved and each file was studied.

A data collection sheet was utilized for the purpose of extracting information from patient records (see Appendix A page 38). The following variables were extracted from the notes and transferred to the data sheet:

- Age
- Smoking habit
- Alcohol
- Pathologic primary tumor staging according to TNM classification
- Concurrent medical problems (COPD, Diabetes Mellitus, systemic blood hypertension, gastroesophageal reflux)
- Pre-operative tracheostomy
- Pre-operative hemoglobin

Data analysis and presentation

Statistical analysis included assessment of central trend and dispersion; absolute and relative frequencies; and Fisher's exact test to verify association between all categorical variables and the development of fistula. A probability (p) value of more than 0.05 is regarded as insignificant.

The following software applications were used manipulation, statistical analysis and presentation.

- Microsoft Access 2003 Database for data storage, retrieval and selection.
- Microsoft Excel 2003 spreadsheet for descriptive data analysis, summary statistics and comparison of sample means.
- SATA version 10 for analytical testing.

Results.

30 patients were identified from the registers of the operating theatre and ENT ward as patients who had undergone total laryngectomy surgery.

Incidence of PCF

Six of the thirty patients who underwent total laryngectomy developed a pharyngocutaneous fistula during the post-operative period achieved an incidence rate of 20%. The time of appearance of the pharyngocutaneous fistula varied between 3 and 10 days, mean 7.16 ± 3.25 days.

The vast majority of the fistulae (50%) were observed by 10th postoperative day.

Various factors were assessed to determine predisposing factors for developing PCF (Table 1).

Table 1 Distribution of patients with pharyngo-cutaneous fistula

Variables	Pharyngo-cutaneous fistula %		
	No fistula (24) n (%)	Fistula (6) n (%)	p value
Age (mean±SD) years	56.5±10.2	59±11.4	0.60
Age < 60 years ≥ 60 years	 16 (66.7%) 8 (33.3%)	 3 (50%) 3 (50%)	0.64
Smoking	22 (91.7%)	5 (83.3%)	0.50
Alcohol	20 (83.3%)	5 (83.3%)	1.0
Tumor Stage T2 T3 T4	 1 (4.2%) 11 (45.8%) 12 (50%)	 0 1 (16.7%) 5 (83.3%)	0.48
Tracheostomy	3 (12.5%)	2 (33.3%)	0.25
Preoperative Hb (mean±SD) gm/dl	13.6±2.0	13.4±1.6	0.78
Preoperative Hb ≤ 11.5 mg/dl > 11.5 mg/dl	 4 (16.7%) 20 (83.3%)	 1 (16.7%) 5 (83.3%)	0.25
GORD	1 (4.2%)	0	1
HT	6(25%)	1(16.7%)	1
DM	2 (8.3%)	0	1
COPD	1 (4.2%)	1 (16.7%)	0.27

Age

The mean value of the age in both groups, fistula 59 years and no fistula, was slightly different 2.5 years and the two groups were comparable (Fig 3).

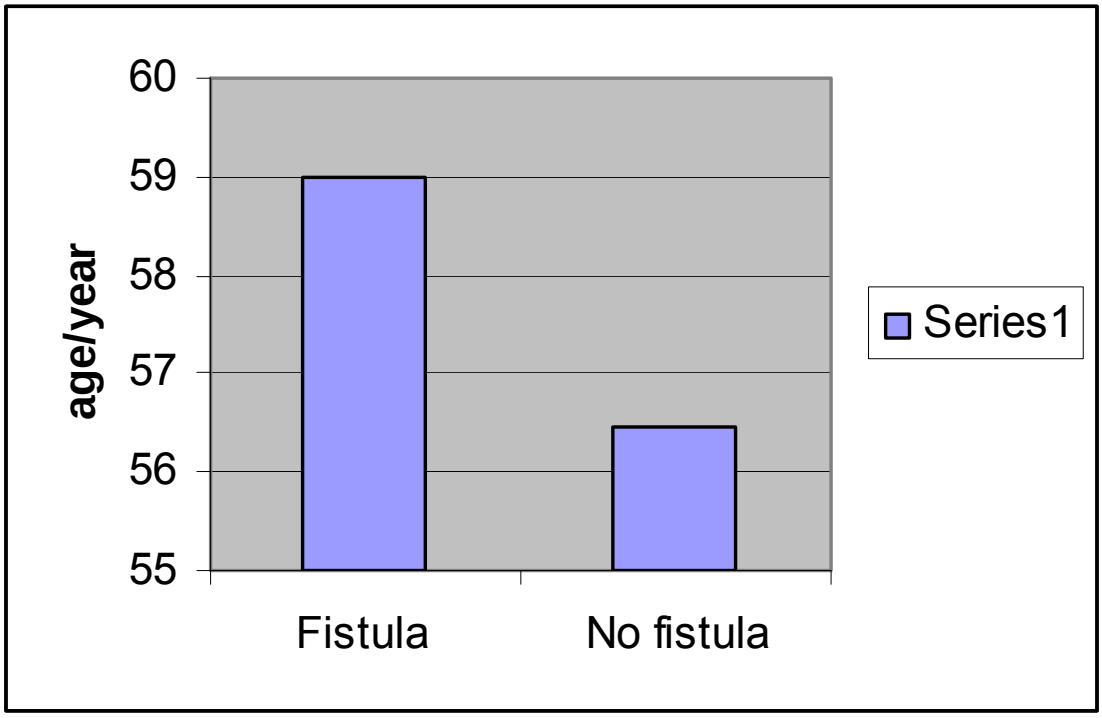

Fig 3: Patients mean age

The rate of development of a postoperative PCF according to the age groups of ≤60 and >60 years did not differ in a statistically significant manner and is demonstrated in table 1 page 22.

Smoking and alcohol habit

Majority of the patients were smokers and alcohol consumers (90% and 83.33%) respectively. PCF developed in only five patients in each group with no significant value recorded.

Tumor stage

These seems to be a greater observed tendency for pharyngocutaneous fistula development in relation to T4 suprglottic tumors, probably because more pharyngeal mucosa is excised as part of tumor margin.

Preoperative tracheostomy

Only 5 of 30 patients (16.66%) underwent emergency tracheostomy for the airway distress before the planned total laryngectomy, which did not show any significant value for developing PCF.

Preoperative hemoglobin

PCF developed more frequently in patients with hemoglobin value of > 11.5 gm/dl (83.33%), which revealed that low hemoglobin value < 11.5 gm/dl insignificant factor for developing PCF.

Medical associated conditions

In this study group, PCF occurred in one patient with systemic high blood pressure (14.28%), one patient with chronic obstructive disease (50%), while no fistula among the diabetes mellitus and the gastroesophageal reflux disease

patients. In this study no significant association noted with any pre-existing comorbidity and the development of PCF.

Description of total laryngectomy approach

All patients were meticulously prepared as for any major surgical procedures, including a thorough head and neck examination, preoperative endoscopic examination of upper respiratory and alimentary tracts, evaluation of all necessary hematological and biochemical values, radiographs of chest and neck with use of computed tomography or magnetic resonance imaging studies as needed. TNM classification was used according to American joint committee for staging of the tumor.

All surgical procedures were carried out by different surgeons with same technique. All of the patients received preoperative Augmentin 1.2gm. A transverse collar incision was used approximately two fingers breadth above the sternal notch extended, superiorly and laterally on both sides, anterior to the anterior border of the sternoclidomastoid muscle just above the hyoid bone.

A standard total laryngectomy was performed including the hyoid bone, isthmus, and lobe of the thyroid gland on the tumor side.

After removal of the specimen 15 patients received Nasogastic tube(NGT), while the other 15 patients received tracheo-esophageal puncture(TEP) by placing a right angled hemostat against the back of the trachea through the esophagus

and a horizontal incision was made over the hemostat 1-1.5 cm below the tracheal edge .

A size 16 french Foley's silicone lined catheter was inserted through the puncture site towards the stomach and secured by adhesive plaster. The pharyngeal mucosal defect then was repaired meticulously with vicryl absorbable sutures. The pharyngeal muscle was closed as a second layer. The closure was in a straight or T-fashion, whichever closure had the least tension.

Suction drains were used in all the patients; and removed when the drainage was less than 50 ml/day. No post-operative antibiotics were given unless the patient developed wound infection or any other infection requiring antibiotics.

All the patients were fed through the nasogastric tube (NGT) or the tracheo-esophageal puncture tube (TEP) for 7-10 days where routine barium swallow screen was done, if the swallow screen was negative i.e no pharyngeal leak, then oral feeding with clear fluids was started orally and gradually changed to normal food.

A standard criteria for discharging patients was followed. This includes that suction drains have been removed, that the patient has returned to a normal oral diet and that post operative recovery, which is defined as patient not requiring hospital care and having no need for intravenous medications is achieved.

In the patients who developed PCF, consideration was given to the post operative day on which it was diagnosed, its duration, the period of hospitalization, therapeutic approach and outcome.

Management and outcome

In this study, spontaneous PCF closure was achieved in five of the six patients (83.3%) within a month time in whom treated conservatively by instructing the patient not to swallow the saliva and to frequently use the oral suction, keeping the patient nothing per os (NPO), enteral feeding through the nasogastric tube (NGT) or through the tracheoesophageal puncture (TEP) which was already inserted intraoperatively, twice daily wound dressing with iodine and intravenous antibiotics injection.

The sixth patient in the series failed to respond to the conservative treatment for a month, after which he was taken to theatre, the PCF was identified, the mucosa debrided and a free fat graft from the subcutaneous tissue of the left lower abdomen inserted in to the pouch between the fistula and the neck skin. A barium swallow x-ray on the tenth post operative day revealed that the fistula was still leaking. Conservative management continued for further two months with serial barium swallow x-rays till the fistula had healed spontaneously.

The mean hospitalization days among the PCF patients was 36.5 compared with 19.5 among the patients who did not have fistula (Fig 5).

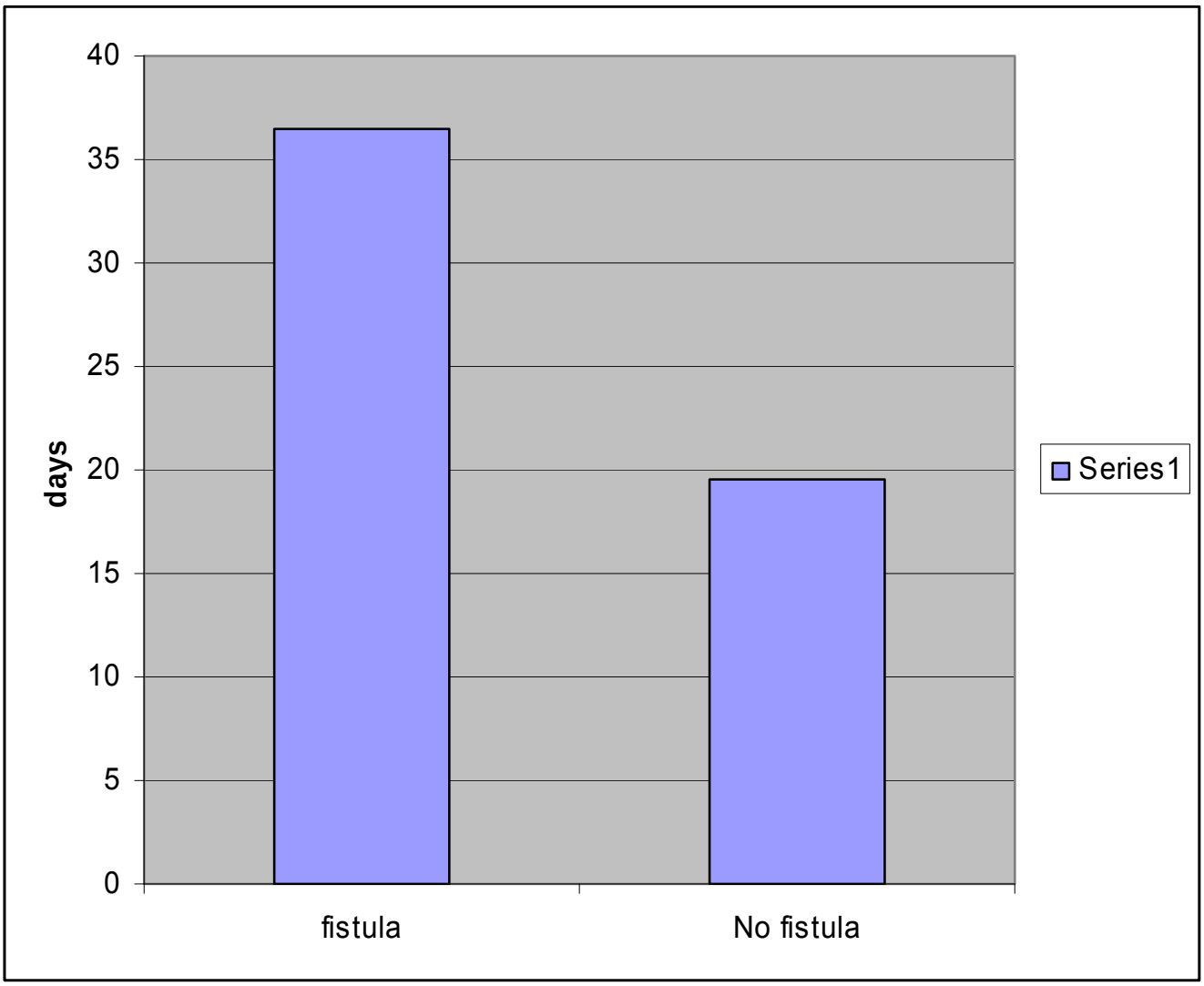

Fig 4: Mean hospital stay

Discussion

Over the last century a great deal of research has been carried out to determine the causes and the most efficacious treatment of post-total laryngectomy PCF. The aim of this project was to assess the current status of pharyngo-cutaneous fistula after total laryngectomy at the Department of Otolaryngology, Head and Neck Surgery at Chris Hani Baragwanath Hospital.

After total laryngectomy, the occurrence of PCF results in a delayed outcome and rarely in carotid artery rupture[15]. Generally PCF develops just above the tracheostoma, at the weakest point of the suture line of the pharyngeal mucosa. It is always associated with surrounding tissue necrosis. It may also occur high in the neck, at the level of the junction of the base of tongue and the pharyngeal mucosa.

The presence of saliva results in contiguous tissue infection and microvascular thrombosis with progressive tissue loss. The overlying skin becomes tender and dark red in color.

The incidence of PCF after total laryngectomy is variable in the literature and ranges between 3.6% and 65% [6,7,19,25], with an average time of appearance of 10

days after surgery. In this study PCF was diagnosed in 6 of 30 patients, achieving an incidence of 20%, which is within the range as mentioned in the literature [6,7,19,25] .

The occurrence of PCF was diagnosed on the 3rd to 10th day after the operation with mean of 7.16±3.25 days; and lasted from 18 to 70 days, which is consistent with the mean values as reported in the literature[11,14] .

Statistical analysis in a previous study showed a significant correlation between post-total laryngectomy PCF and advanced age[11]. However the results of this study show no correlation between increasing age and the development of PCF; where most of the fistulas developed in patients' of <60 years of age. This sentiment is echoed in other studies [8,19].

Life style factors such as smoking and alcohol consumption are significantly associated with blood vessel diseases and wound healing delay[27]. Although majority of the patients in my study were smokers and alcohol consumers, there was no relationship between these factors and PCF occurrence.

It is reported that there is a significant increase in the rate of PCF formation in large cancers (stage IV versus stage III)[18,29], which requires resection of part of the pharyngeal mucosa. This however was not found in this study.

Preoperative tracheostomy according to one study[12], could lead to an increase in fistula formation. This is probably due to surgical field contamination with bacteria; and the higher tumor stage. This study recorded five patients that had a preoperative tracheostomy, which did not seem to be statistically associated with fistula formation.

Low preoperative hemoglobin value in this study was not significantly associated with formation of PCF which confirms the results of the previous studies [10]. Other study has found significant rise in the number of PCF in patients with hemoglobin values less than 11.5 gm / dl [12].

Associated medical conditions such as systemic high blood pressure, diabetes mellitus (DM), gastroesophageal reflux disease (GORD) and chronic obstructive pulmonary disease (COPD) did not seem to have significant values in formation of PCF.

Even though much controversy still surrounds the occurrence of PCF, it is generally agreed that most fistulas respond well to conservative treatment. This has been reported in 60% to 86% of cases[13,16].

According to our study and the literature review[13,16], we concluded that observation period for one month after the primary surgical procedure is the best approach for the PCF.

Conclusion

This study revealed that the incidence of PCF in patients undergoing total laryngectomy for laryngeal cancer is 20%. This is in keeping with the internationally reported incidence[6,7,19,25]. This study further reaffirmed that PCF remains a troublesome complication in the early post-operative period after total laryngectomy.

In the presence of specific risk factors as mentioned in the literature[7,8,9,11,1214,15,17] PCF can be expected. Nevertheless its prevention remains very difficult.

In this study factors of age, smoking, tumor stage, preoperative tracheostomy, preoperative hemoglobin and comorbidities such as (gastroesophageal disease, diabetes mellitus, systemic high blood pressure and chronic obstructive pulmonary disease) did not show any correlation with the occurrence of the PCF after total laryngectomy.

(NB ; This study did not have any patients with a positive HIV result)

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Appendix A

Patient	Age	Smoking History	Alcohol History	Stage of Tumor	Previous Tracheostomy	Preoperative Hemoglobin gm/dl	GORD	HT	DM	COPD
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