ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
POSTGRADUATE PROGRAMS

PREVALENCE AND ASSOCIATED RISK FACTORS OF EARLY LOCAL COMPLICATIONS AFTER TOTAL LARYNGECTOMY IN LARYNGEAL CARCINOMA PATIENTS AT TIKUR ANBESSA HOSPITAL AND YEKATIT 12 HOSPITAL MEDICAL COLLEGE: A RETROSPECTIVE STUDY OVER 5 YEARS.

BY: WELELEW ZELALEM (MD, ORL-HNS RESIDENT)

A THESIS SUBMITTED TO THE DEPARTMENT OF OTORHINOLARYNGOLOGY, HEAD AND NECK SURGERY, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SPECIALTY CERTIFICATE IN OTORHINOLARYNGOLOGY, HEAD AND NECK SURGERY

FEBRUARY, 2025
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BY: WELELEW ZELALEM (MD, ORL-HNS RESIDENT)

ADVISORS

MESELE BOGALE (MD, ASSISTANT PROFESSOR OF ORL-HNS, HEAD AND NECK SURGEON)

MOHAMMEDSEFA ARUSI (MD, ASSISTANT PROFESSOR OF ORL-HNS)

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ACRONYMS/ABBREVIATIONS

CCRT ……..concurrent chemo-radiation
ORL-HNS**……** otorhinolaryngology head and neck surgery
PCF……pharyngocutaneous fistula
RT…….radiation therapy
RND……..radical neck dissection
TASH**……** Tikur Anbessa specialized hospital
TL …… total laryngectomy
TNM …… Tumor Node Metastasis

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ABSTRACT

Background: Laryngeal carcinoma is the most common site of malignancy in the head and neck worldwide. Total laryngectomy is the standard surgical treatment for management of locally advanced laryngeal and hypopharyngeal cancers. Complications after total laryngectomy have significant impact on morbidity and health care cost, leading to prolonged hospitalization, further operations, permanent sequelae, and sometimes a fatal outcome. Studies from various countries report that the prevalence of early postoperative complications after laryngectomy ranges from 9% to 25%. In Ethiopia, the prevalence and risk factors of early local complications in total laryngetomy patients is not yet studied.

Objective: To determine the prevalence and associated factors of early local complications in laryngeal cancer patient who had total laryngectomy at Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia, 2025.

Methods: A retrospective study design was conducted to determine the magnitude of early local complication and associated risk factors in laryngeal cancer patients for whom total laryngectomy was done at Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia from January 1 to 30 2025. All patients with a diagnosis of laryngeal cancer for who total laryngectomy was done at Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College from January 2019 to December 2024 were included. Data were collected using a structured checklist questionnaire by using Kobo tool box was imported to SPSS for analysis and interpretation. Descriptive statistics was used to describe baseline patient characteristics. To identify the independent effects of the factors logistic regression analysis was employed and those variables with a p value <0.05 was considered as a significant predictor factor for early local laryngectomy complications.

Result: A total of 43 patients met the inclusion criteria and were enrolled in the study. The mean age 58.52 years (SD = 12.21, range: 30–82 years). There were 41 males and 2 females with a ratio of 21 to 1. All patients 100% presented with voice change. A large majority of patients 93.0% reported shortness of breath while throat pain/discomfort and stridor present in 88.4% percent of patients each and the least was neck swelling in 16.3 %. The majority of patients 83.7 % were diagnosed at TNM Stage IV with smaller proportion 16.3 % were at Stage III disease. Nodal stage of the disease shows 74.42% N0, 13.95%, N1 and 11.63 % N2. Only smaller proportion (4.7%) had partial pharyngectomy. Preoperative tracheostomy was done in 79.1% of patients. The most commonly used neopharynx maturation was the vertical method (41.9%). Pharyngocutaneous fistula was observed in 20.9% of cases. Wound infection, bleeding and hematoma, mortality rate, chyle leak reported in 34.9%, 11.6%, 4.7%and 2.3% of cases respectively.

Conclusion: This study highlights that wound infection is the most prevalent postoperative complication following total laryngectomy, affecting nearly one-third of patients. Given the high prevalence of wound infections and pharyngocutaneous fistulas, enhanced perioperative care, strict infection control measures, and optimized surgical techniques are essential to improve patient outcomes. Further prospective studies are recommended to better understand the risk factors and develop targeted interventions to reduce postoperative complications in laryngeal cancer patients undergoing total laryngectomy in Ethiopia.

Key words: laryngeal cancer, total laryngectomy ,ealy laryngectomy complications

1. INTRODUCTION

1.1 Background

Laryngeal carcinoma is the most prevalent malignant tumor affecting the head and neck worldwide, with squamous cell carcinoma (SCC) being the most common histopathological type(1, 2). Globally, laryngeal cancer incidence and mortality rates are approximately seven times higher in men than in women**(2)**.Typically, affected individuals are men in their 50s or 60s with a history of smoking and alcohol consumption. Tobacco and alcohol use contribute to around 85% of laryngeal cancer cases, with smoking being the primary risk factor, while alcohol serves as both an independent and synergistic risk factor. Current smokers are estimated to have a 10- to 20-fold greater risk of developing laryngeal cancer compared to nonsmokers(3)

The primary goal of laryngeal cancer treatment is to ensure optimal survival while preserving function and maintaining quality of life.(4). Early-stage tumors (T1/T2) are generally managed with a larynx-preserving approach, either through surgery or radiation therapy, with proper patient selection playing a crucial role. (5). Conversely, for locally advanced tumors, treatment remains a subject of debate, with two major options: primary total laryngectomy (TL) followed by postoperative adjuvant radiation therapy (RT) or definitive concurrent chemoradiation (CCRT), with surgery reserved for salvage situations(6, 7) Recent large-scale studies have shown that surgical intervention offers a survival advantage for select patient groups. One study assessing survival outcomes for patients with T3 and T4a laryngeal tumors who underwent total laryngectomy found better survival rates compared to those who received chemoradiotherapy(8). Additionally, analyses using data from the National Cancer Database (NCDB) demonstrated a significant survival benefit for patients with T4a and stage IV laryngeal cancer who underwent total laryngectomy(9).

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Total laryngectomy is typically recommended for patients who are unsuitable for organ-preserving treatments such as radiation therapy or chemoradiotherapy. This includes individuals with extensive tumors that invade the cartilage, extralaryngeal structures, or the base of the tongue (T4a stage). It is also indicated for certain histopathologic subtypes that are resistant to radiotherapy, such as adenocarcinoma, soft tissue sarcoma, and chondrosarcoma. Other indications include large oropharyngeal tumors extending into the larynx, extensive thyroid cancers involving the larynx, and hypopharyngeal cancers. Additionally, salvage TL is performed when organ-preserving treatments fail due to persistent disease, severe aspiration risks, or chondroradionecrosis unresponsive to medical therapy(10).

Total laryngectomy entails the complete removal of laryngeal structures, including the epiglottis, hyoid bone, and a portion of the upper trachea, requiring the creation of a permanent tracheostomy and reconstruction of the pharynx. This procedure is life-altering, necessitating adjustments to communication and breathing, which can lead to significant psychological and functional challenges. Postoperatively, patients often experience depression, social isolation, and body image issues. Therefore, comprehensive preoperative counseling and postoperative support, including assistance from a clinical nurse specialist, are essential(11, 12).

Total laryngectomy is associated with significant postoperative complications that increase morbidity, extend hospital stays, raise healthcare costs, and, in some cases, lead to fatal outcomes. Risk factors for these complications include advanced age, poor nutritional status, and comorbidities linked to chronic tobacco and alcohol use(13). Postoperative complications are generally categorized as minor (manageable through conservative treatment) or major (requiring extended hospitalization, additional surgery, or intensive care admission)(14).

Pharyngocutaneous fistula (PCF) is the most common postoperative complication, characterized by an abnormal connection between the pharynx and the cervical skin, resulting in saliva leakage and increased infection risk. PCF can significantly prolong hospitalization, elevate healthcare costs, and delay adjuvant treatments such as

radiotherapy, ultimately affecting prognosis and quality of life(15)The reported incidence of PCF has declined over the years, from 5-65% in earlier decades to approximately 9-25% in the past decade (14). In severe cases, PCF can lead to salivary dissection, carotid artery rupture, sepsis, mediastinitis, pneumonia, and death(16).

Hematoma is another frequent complication, occurring in approximately 1% of neck dissections and 4% of major head and neck surgeries. Hematomas can elevate skin flaps, cause airway compression, and increase the risk of wound infections if not promptly addressed(17). Additional postoperative complications include wound infections, neopharyngeal stenosis, and chyle leaks, all of which can negatively impact recovery and long-term functional outcomes (12).

1.2. Statement of the Problem

Laryngeal carcinoma is the most prevalent malignant tumor of the head and neck worldwide. In 2019, it accounted for approximately 209,149 new cases and 123,356 deaths globally(18).Advanced laryngeal cancers, frequently presenting with upper airway obstruction, are particularly common in Sub-Saharan Africa, often requiring urgent surgical intervention(4).

In Ethiopia, a substantial proportion of head and neck cancer patients (84.9%) seek medical attention late, typically between six months and two years after the onset of symptoms. Consequently, most cases (74.1%) present with advanced T-stage disease (T3/T4), and 88.1% are diagnosed at stage III or IV. (19) . This delayed diagnosis contributes to poor treatment outcomes and increases the likelihood of requiring total laryngectomy.

While total laryngectomy is an effective treatment for advanced laryngeal cancer, it is associated with significant postoperative complications, including PCF, wound infections, chyle leaks, and difficulties with airway and swallowing function. These complications can lead to prolonged hospitalization, higher healthcare costs, and, in severe cases,

permanent disability or death (13). Contributing factors to these complications include preoperative tracheostomy, radical neck dissection, extensive surgical procedures, and flap reconstruction. The most common early complications of TL include bleeding, hematoma, wound infections, chyle leaks, and PCF(10).

Despite its significance, the history and practice of total laryngectomy in Ethiopia remain largely undocumented due to a lack of published studies on the subject. To the best of the investigator's knowledge, this study represents the first research conducted on total laryngectomy and early postoperative complications in Ethiopia.

1.3. Significance of Study

The waiting time for chemoradiotherapy at Tikur Anbesa Hospital Oncology Center is considerably prolonged, with over 42% of patients facing delays ranging from 3 to 12 months, and 12% waiting more than a year for treatment(20) . Given that the majority of patients present at an advanced stage, these extended delays in laryngeal preservation treatment contribute to further disease progression. As a result, many patients ultimately require TL as the primary treatment option. Complications following TL have a substantial impact on morbidity and healthcare costs, often leading to prolonged hospitalization, additional surgical interventions, permanent functional impairments, and, in some cases, fatal outcomes. Early identification and timely management of these complications are crucial in improving patient outcomes and reducing healthcare burdens(21).

In Ethiopia, the practice of TL has gained traction in recent years. However, there is a lack of clear documentation on its adoption, surgical volume, prevalence, and associated risk factors for early postoperative complications. Furthermore, there is no published data identifying key areas for improvement in surgical outcomes.

This study aims to address these critical knowledge gaps by examining the current state of TL practice and evaluating the prevalence, risk factors, and patterns of early postoperative complications at Tikur Anbesa Hospital and Yekatit Hospital Medical College over the past five years. Identifying predisposing risk factors will enable better preoperative risk assessment, early complication management, and overall improvement in patient care.

2. LITRATURE REVIEW

A retrospective study conducted at Tata Memorial Hospital, India (2017), examined patients who underwent laryngectomy between 2012 and 2013. Out of 169 patients, 93.5% were male, and 6.5% were female, with an average age of 57 years. The study reported complications in 43.5% of cases, with 18.8% experiencing major complications. Infections requiring extended antibiotic treatment were observed in 15.8% of patients. Pharyngocutaneous fistulas (PCFs) developed in 22.4% of cases, with 42.1% of PCF occurrences seen in patients who had previously undergone radiotherapy (RT). However, no significant correlation was found between PCF development and prior RT. The postoperative mortality rate was 1.7%, with three deaths reported—two resulting from major PCFs and blowouts, and one due to stomach tube necrosis following a gastric pull-up(22) .

A retrospective study conducted at Johns Hopkins Medical Institutions in 2014 analyzed 59 patients who underwent total laryngectomy between 2001 and 2012. The average patient age was 63 years, with a gender distribution of 81% male and 19% female. Pharyngocutaneous fistulas (PCFs) developed in 34% of cases. Univariate analysis revealed that postoperative hemoglobin levels below 12.5 g/dL were significantly linked to PCF occurrence (OR 9.1, $p = 0.04$). Additionally, patients with a prior tracheostomy had a notably higher incidence of PCFs (55% vs. 23%, OR 4.1, $p = 0.02$)(23).

A 2022 meta-analysis of 58 studies, involving 9,845 patients, examined risk factors for pharyngocutaneous fistula (PCF) following laryngectomy. The overall PCF incidence was 21.69%. Increased risk of PCF was associated with factors such as age under 60, anemia, hypoproteinemia, diabetes mellitus, smoking, alcohol use, and comorbidities like coronary artery disease and chronic obstructive pulmonary disease. Additionally, disease-related factors, including tumor extension beyond the glottis, were linked to PCF development. Surgery-related factors such as previous tracheostomy, salvage versus primary surgery, and extended total laryngectomy were also significantly correlated with PCF occurrence(24).

A meta-analysis of 63 studies investigated risk factors for PCF following total laryngectomy. Factors such as age, sex, smoking, alcohol consumption, T3 versus T4 staging, and histological grade were not significant predictors. However, a preoperative hemoglobin level below 12.5 g/dL, blood transfusion, prior radiotherapy or chemoradiotherapy, tumors located in the supraglottic or hypopharyngeal regions, advanced tumor staging, positive surgical margins, and neck dissection were associated with an increased risk of PCF(25).

A meta-analysis of 24 retrospective studies (1979–2021) analyzed the incidence of fistulas based on different mucosal closure techniques. In primary laryngectomy, PCF rates were 19.9% for T-shaped closure, 16.1% for vertical closure, and 16.4% for horizontal closure. For salvage laryngectomy, the rates were 35.1% for T-shaped closure, 36.1% for vertical closure, and 17.9% for horizontal closure. Horizontal closure was significantly linked to a lower risk of PCF compared to vertical closure (OR 0.31, $p < 0.05$)(26). A retrospective analysis of 77 patients who underwent laryngectomy with horizontal closure reported a PCF rate of less than 2%, reinforcing the technique as a safer approach with better postoperative outcomes.(27).

A retrospective chart review examined 30 patients who underwent total laryngectomy for histologically confirmed laryngeal carcinoma between December 2000 and December 2012 in Sokoto, Nigeria. Among them, 23 (76.7%) were male and 7 (23.3%) were female, resulting in a male-to-female ratio of 3.3:1. The patients' ages ranged from 20 to 75 years, with a mean age of 50.1 years. Postoperative complications were observed in 20 patients (66.7%). The most common complications were wound infection and pharyngocutaneous fistula, each occurring in 4 cases (20%). Other complications included carotid blowout hemorrhage in 3 patients (15%). Identified predisposing factors included middle age, cigarette smoking, co-existing medical conditions, and clinically or histologically high-grade cancer(28).

A retrospective study was conducted in the Otorhinolaryngology Head and Neck Surgery Department at Specialties Hospital in Rabat, Morocco, from January 2006 to December 2013. The study included 136 male patients who underwent total laryngectomy, with a mean age of 58 ± 10 years. Six patients had diabetes mellitus, and flap reconstruction was performed in three cases. The overall incidence of pharyngocutaneous fistula (PCF) was

27.8%. In univariate analysis, factors significantly associated with PCF development included age (P=0.028), hemoglobin levels below 12 g/L (P=0.026), and prior tracheotomy (P=0.028). However, multivariate analysis identified prior tracheotomy (P=0.028) and low preoperative hemoglobin levels (P=0.026) as the strongest predictors of PCF occurrence. Tumor location, extra-laryngeal extension, pharyngeal closure technique, and the use of a flap were not significant in univariate analysis.(15).

A retrospective study was conducted to assess the prevalence of wound infections following total laryngectomy and to identify associated risk factors. The study took place in the Department of Otorhinolaryngology at Hospital University University of Oviedo, Spain, spanning from January 1998 to January 2008.The study included 129 patients diagnosed with primary hypopharyngeal and laryngeal cancer who underwent total laryngectomy. Of these, 126 were men and three were women, with mean ages of 63 years (SD 11.7) and 53.5 years (SD 13.5), respectively. Smoking was highly prevalent, with 98% of patients being smokers, and 66% (85 patients) also regularly consumed alcohol. Postoperatively, wound infections were observed in 44% (57 patients). The findings indicated a significantly higher infection rate among patients with hypopharyngeal tumors (65% vs. 31%; $p < .001$). However, no significant association was found between wound infections and other clinical or pathological factors, including comorbidities, substance use, tumor classification (T or N stage), or the number and type of neck dissections. Nonetheless, patients who underwent radical neck dissection exhibited a higher incidence of infection.(29).

A retrospective study reviewed 226 consecutive neck dissections performed on 201 patients who underwent therapeutic neck dissection, including at least levels II–IV, between 2010 and 2020 at the University of Missouri School of Medicine in Columbia, Missouri, U.S.A. The study focused on cases with a final pathological diagnosis of mucosal squamous cell carcinoma (SCC) of the head and neck or papillary thyroid carcinoma (PTC). Elective neck dissections without clinical evidence of lymphadenopathy and those that did not encompass at least levels II–IV were excluded. Among the 226 neck dissections, 65 (29%) were performed for PTC, while 161 (71%) were for SCC. Patients with SCC were categorized based on tumor subsite: 40% had laryngeal involvement, 53% had tumors in the oral cavity or oropharynx, and 7% had hypopharyngeal tumors. Regarding laterality, 124 (55%) procedures were performed on the left side and 102 (45%)

on the right. Postoperative chyle leak was observed in 15 cases (6.6%), with eight occurring in PTC patients and seven in those with SCC. The incidence of chyle leak was significantly higher in PTC cases (12.3%) compared to SCC cases (4.3%) ($p = 0.029$).(30).

A prospective, single-center study conducted over 8 years at the Department of Otolaryngology-Head and Neck Surgery, School of Medicine, Kyungpook National University, Daegu, Korea, examined the incidence, clinical features, and treatment of chyle leak. Between 2007 and 2014, a total of 472 neck dissections involving the level IV compartment were included. The overall incidence of chyle fistula was 4.7% (22 out of 472 cases), with a 3.0% incidence following right neck dissection and a 6.2% incidence after left neck dissection.(31).

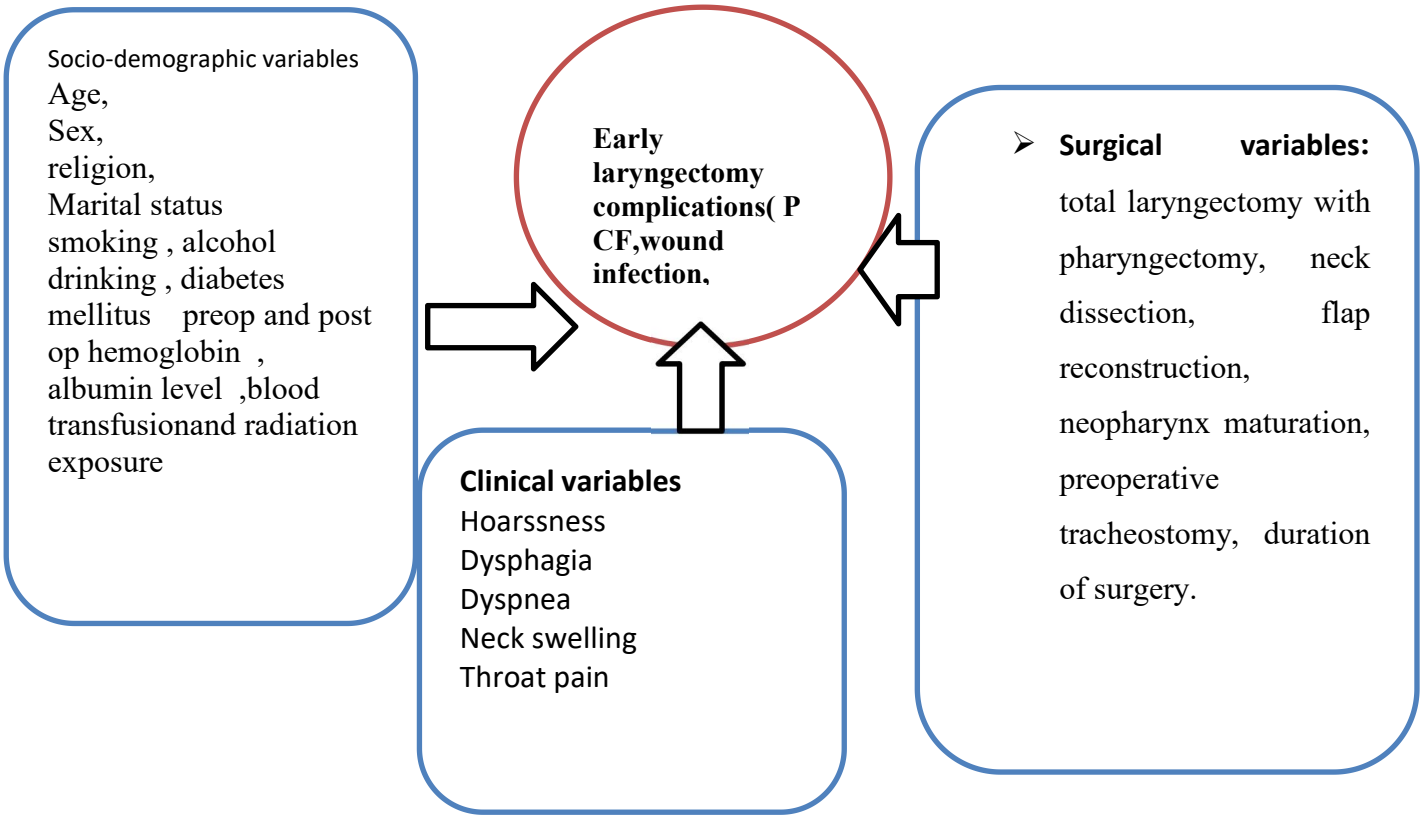
A retrospective cohort study conducted at Hallym University Kangdong Sacred Heart Hospital from January 2006 to June 2010 assessed risk factors for wound infection. Medical records were analyzed to identify factors and microbiological causes. The data collected included age, sex, smoking and alcohol history, comorbidities, tumor site, TNM stage, ASA score, NNIS risk index, preoperative albumin level, BMI, blood loss, blood transfusion, surgery duration, preoperative chemotherapy and radiotherapy, hospitalization duration before surgery, causative microorganisms, and antibiotic use. The study population had a mean age of 59.02 ± 13.09 years, with 290 (78.4%) males. The overall surgical site infection (SSI) rate was 19.7% (73/370). Multivariate analysis revealed that male sex (OR 4.281; $p = 0.004$), cardiovascular disease (OR 1.941; $p = 0.020$), significant blood loss during surgery (OR 4.213; $p = 0.001$), and surgery lasting longer than 6 hours (OR 4.213; $p = 0.002$) were significantly associated with increased SSI risk (32).

A retrospective study conducted at a tertiary center in Southwestern Nigeria from 2007 to 2016 examined factors contributing to pharyngocutaneous fistula (PCF) after total laryngectomy. The study included 42 patients with a male-to-female ratio of 7.4:1 and a mean age of 52.3 ± 2.1 years. All patients had stage 3 (83.3%) or stage 4 (16.7%) laryngeal cancer. The incidence of PCF was 11.9%. Significant risk factors for fistula formation included prior radiotherapy and diabetes. Age, gender, neck dissection, tumor site, and emergency tracheostomy were not associated with fistula development. All fistulas closed spontaneously, except for one patient who required surgical closure. (33).

A retrospective cohort study conducted in Tehran, Iran, between 2011 and 2019, involving 85 patients who underwent laryngectomy, found no significant links between pharyngocutaneous fistula (PCF) and factors such as gender, previous radiation therapy (RT), or the technique used for closure. However, PCF occurred more frequently in patients with anemia, with a rate of 15.2%. These studies underscore various risk factors for PCF and other surgical complications after laryngectomy, highlighting the role of preoperative hemoglobin levels, prior RT, surgical methods, and existing comorbid conditions in influencing postoperative outcomes.(34).

A prospective study conducted over a period of 2 years (April 2006 to March 2008) at Government ENT Hospital, Koti, Hyderabad. A total number of 30 male patients with an age range between 23 and 70 years, who were subjected to total laryngectomy and who subsequently developed complications were included in the study. All the 30 patients presented with hoarseness of voice, in addition 26 of them had stridor, five of them had neck nodes and five had dysphagia. Wound infection and dehiscence was found in 7 cases (23%), pharyngocutaneous fistulae again in 7 cases (23%). This was followed by recurrence of disease in 4 cases (13%). Hematoma, pharyngocutaneous fistula due to postoperative radiotherapy, pharyngeal stenosis and stomal stenosis in 2 patients each (6.6%). One case of abscess (3.3%) was noted. There was one death (35)

Conceptual frame work



3. OBJECTIVE

3.1. General Objective

To determine the prevalence and associated risk factors of early complications in laryngeal cancer patient for whom total laryngectomy was done at Tikur Anbesa Specialized Hospital and Yekatit 12 Hospital Medical College from January 2019 to December 2024.

3.2. Specific Objective

- To determine the prevalence of early local complications post total laryngectomy.
- Identify risk factors for early local laryngectomy complications.

4. METHODS

4.1. Study Design

A retrospective study design was conducted to determine the prevalence of early local laryngectomy complication and associated risk factors in laryngeal cancer patients for whom total laryngectomy was done from January 2019 to December 2024 at TASH and Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia.

4.2. Study Area and period

The study was conducted at otorhinolaryngology head and neck surgery department of Tikur Anbessa Specialized Hospital (TASH) and its affiliated hospital, Yekatit 12 hospital medical college, starting from January 1 to 30 2025. TASH is a tertiary hospital located in Addis Ababa which is a capital city of the country. It is the largest & oldest public hospital of the country providing high level of clinical care for millions of people and training to health science students from different parts of the country and from the Horn of Africa. The hospital is the leading in otorhinolaryngology head and neck surgery training and care in the country, providing tertiary specialist care. .

4.3. Source Population

The study included all patients who underwent total laryngectomy for the diagnosis of laryngeal cancer in the Department of Otolaryngology Head and Neck Surgery at Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College from January 2019 to December 2024.

4.4. Study Population

All patients with a diagnosis of laryngeal cancer for whom total laryngectomy was done at Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College from January 2019 to December 2024.

4.5. Inclusion Criteria

All patients diagnosed with laryngeal cancer who underwent total laryngectomy between January 2019 and December 2024.

4.6. Exclusion Criteria

- Patients whose medical charts or electronic medical records were lost or lacked essential dependent variable data.
- Patients who underwent partial laryngectomy.

4.7. Sampling

4.7.1 Sample Size Determination

The source population consisted of 48 patients, as recorded in the operating room registration logbook at TASH and Yekatit 12 Hospital Medical College over the five-year period. The sample size was determined using the Small Population Formula (Finite Population Correction):

$$n = \frac{N \cdot Z^2 \cdot p \cdot (1-p)}{(E^2 \cdot (N-1)) + (Z^2 \cdot p \cdot (1-p))}$$

Where:

n= sample size
N= population size
z= Z-score ((1.96 for 95% confidence level)
P= expected proportion of the population with the event of outcome (prevalence) –the prevalence of early local post laryngectomy complication patients in a similar set up was not known
50% prevalence was taken
E = margin of error (e.g., 5% = 0.05)

The calculated sample size was 43 patients. However, since the total population was small (fewer than 100), a census approach was used, including all eligible patients.

4.7.2 Sampling Technique

This study included all consecutive patients diagnosed with laryngeal cancer who underwent total laryngectomy between January 2019 and December 2024 at TASH and Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia.

4.7.3. Data Collection tools and Technique

Data collection was conducted by junior residents after orientation and training was given by the principal investigator. Data was collected using a structured checklist containing closed and open ended questions specifically designed for the study by using kobo tool box . The tool was prepared by reviewing related literatures done in other areas**.** The data was collected from the medical chart or electronic medical record of each participant by a trained health professional, under close supervision and facilitation by the principal investigator. Each day, the collected data was checked for accuracy and completeness.

4.8. Variables

4.8.1. Independent Variables

- **Socio-demographic variables:** Age, Sex, religion, Marital status,
- **Clinical variables and stage of tumor :** hoarseness/ voice change , throat pain /discomfort , dyspnea ,dysphagia, Neck swelling, Stridor, , TNM stage ,T stage , N stage
- **Behavioral variables and comorbidities :** smoking , alcohol drinking , diabetes mellitus preop and post op hemoglobin , albumin level ,blood transfusionand radiation exposure
- **Surgical variables:** total laryngectomy with pharyngectomy, neck dissection, flap reconstruction, neopharynx maturation, preoperative tracheostomy, duration of surgery.

4.8.2. Dependent Variables

Early laryngectomy complications (wound infections, pharyngocutaneous fistulas, bleeding, chyle leak, carotid blowout and death.

4.9. Operational Definitions

Early local laryngectomy complications: Complications that occur locally at the surgical site (the larynx and surrounding regions) within the first 30 days postoperatively, including wound infections, pharyngocutaneous fistulas, bleeding, chyle leak carotid blowout.

Carotid blowout: spontaneous rupture or bleeding from the carotid artery or its branches, is characterized by acute, uncontrollable bleeding from the site of the artery, which can lead to hypovolemic shock or death if not managed immediately.

PCF: is an abnormal and pathologic communication between the pharyngeal cavity and the skin surface of the neck, which is characterized by saliva, food, or fluid leakage through the neck wound, leading to a persistent opening or drainage site on the skin.

Wound infection: the presence of localized signs such as erythema, edema, increased tenderness, and purulent discharge from the incision site.

4.10 Data process and analysis

Data was first checked manually by principal investigator for completeness and consistency during data collection and rechecked again before data entry. The data was collected using Kobo Toolbox and the collected data was exported to SPSS version 25 for analysis and interpretation. Descriptive statistics was used to describe baseline patient's characteristics.. Phi coefficient was done for all independent variables with outcome variable and variables that are associated with outcome variable at p-value <0.25 was entered into binary logistic regression model to control possible confounders. Fisher's Exact Test was done for covariate with any cell that had less than 5 observations.

The adequacy of the final model was assessed using the Hosmer and Lemeshow goodness of fit test and the final model fitted the data well (p-value = 0.66)

Adjusted odds ratio (AOR) with 95% confidence interval (CI) was calculated to determine the presence and strength of association among predictors and outcome variables. P-value < 0.05 was used to consider significant variables.

4.11 Data quality management

Kobo toolbox software was used to collect data. Brief training for the data collectors about the process of data collection was given before the process of data collection. Close supervision was maintained during data collection and filled checklists were double-checked daily for consistency and completeness by the data collectors and principal investigator.

4.12. Ethical Consideration

Before beginning data collection, ethical clearance was secured from Institutional Health Research Ethics Review Committee (IHRERC). Letter of permission was obtained from Addis Ababa University, College of Health and Medical Sciences, School of Medicine, department of otolaryngology head and neck surgery and from institutional Review Board (IRB) of Yekatit 12 Hospital medical college. The study was executed without individual informed consent because the data was retrospectively obtained from routine care documentation. Confidentiality of the information was maintained with a deidentified database which excluded patient identifiers.

4.13. Dissemination of the Results

After completion of analysis and preparation of final research thesis, findings will be presented to the department of otolaryngology head and neck surgery, Addis Ababa University College of health sciences. Then final printed copy of the paper will be distributed to Addis Ababa University College of health sciences, department of otolaryngology head and neck surgery as well as to publication sites to serve as a baseline document for feature studies on total laryngectomy patients.

5. RESULTS

5.1 Socio Demographic Status

A total number of 48 patients had total laryngectomy in the study period for a diagnosis of laryngeal cancer in Tikur Anbesa Hospital and Yekatit 12 Hospital Medical College, of which only 43 cases had complete information and were included in the study. This constituted 89.5% of the cases. From the 43 patients 25 were done at yekatit 12 hospital medical college which was 58.1 %. The age range from the study was 30– 82 years, with a mean age of 58.52 years (12.21 SD) and about 51.2 % of patients are under age 60. There were 41 males and 2 females which constitute 95.3% male and the rest 4.7% are females with a ratio of 21 to 1. Around 32.6 from Oromia region and 27.9 from Addis Ababa

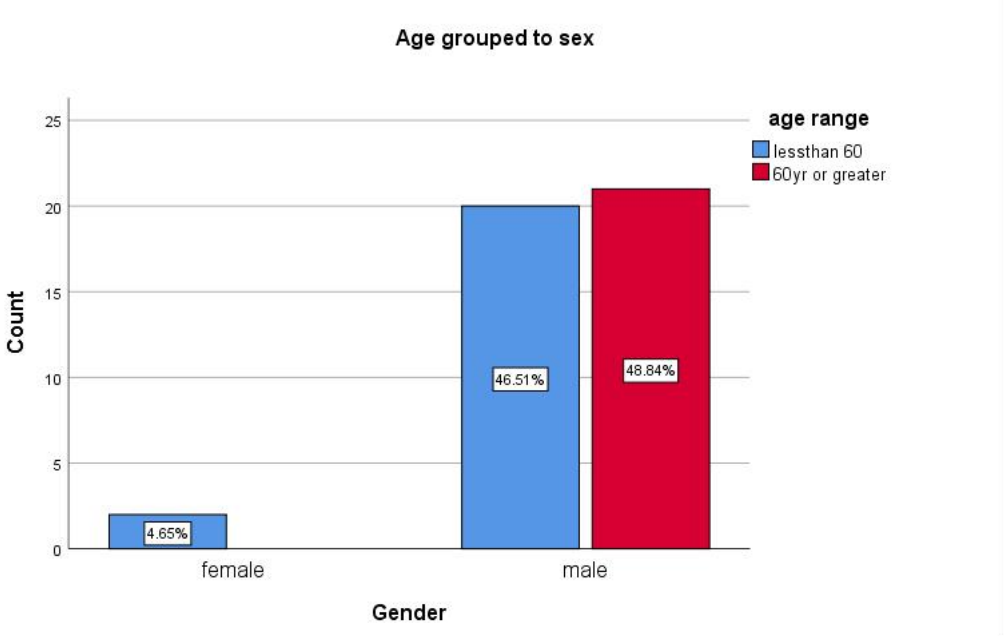


Figure 1: age group categorized in to male and female

5.2 Clinical presentation of patients

Among the patients included in the study, a variety of symptoms were observed. All patients 100% presented with voice change. A large majority of patients 93.0% (40) reported shortness of breath while throat pain/discomfort and stridor present in 88.4% (38) percent of patients each. The least reported symptoms were difficulty swallowing in 39.5% (17) and neck swelling in 16.3 %(7) of our patients.

Table 1: The clinical presentation of patients

Presenting symptoms	Frequency	Percent
Throat pan/discomfort	38	88.4%
Voice change	43	100%
Shortness of breath	40	93.0%
Dysphagia	17	39.5%
Neck swelling	7	16.3%
Stridor	38	88.4%

5.3 Tumor stage and site

The majority of patients 83.7 %(36) were diagnosed at Stage IV with smaller proportion 16.3 %(7) were at Stage III disease. Regarding T stage, 81.4 %(35) of cases were T4 and 18.6 %(8) were T3. N stage of the disease shows 74.42% (32) N0, 13.95% (6) N1 and 11.63 %(5) N2 (figure 2). Concerning the extent of the tumor at diagnosis 95.3 %(41) were limited the larynx.

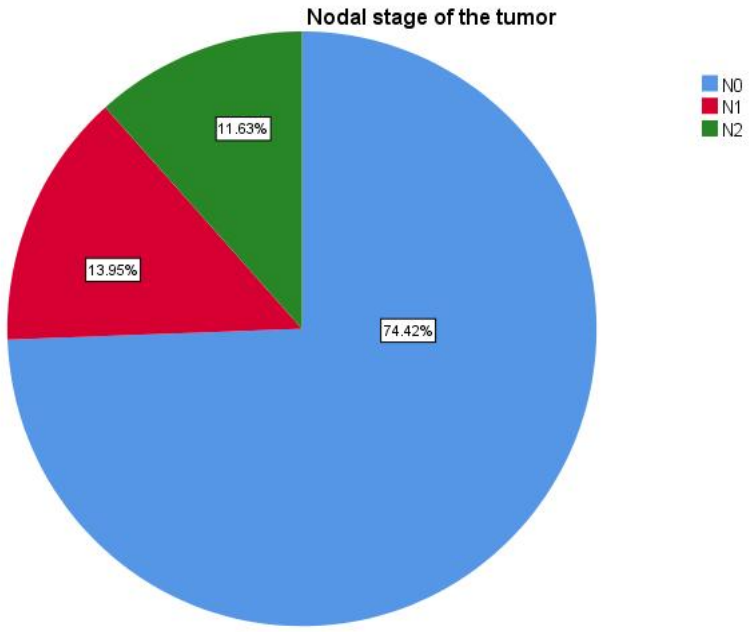


Figure 2: N stage of the tumor

Table 2: Stage and site of the tumor

		Frequency	Percent
TNM stage	Stage III	7	16.3%
	Stage IV	36	83.7%
T stage	T3	8	18.6%
	T4	35	81.4%
Tumor site	Confined to larynx	41	95.3%
	Extension to pyriform sinus	2	4.7%

5.4 Surgical variables

The majority of patients (95.3%) underwent total laryngectomy, while a smaller proportion (4.7%) had partial pharyngectomy. The vast majority of patients (97.7%) underwent neck dissection, with only 2.3% not having the procedure. Preoperative tracheostomy was performed in 79.1% of patients. The most commonly used neopharynx maturation is, vertical (41.9%) followed by horizontal (20.95and T-shape (9.3%). Duration of surgery is less than 10 hours in 60.5% of patients.

Table 3: Type of surgeries done in our patients

Variable	Response	Frequency	Percent
Type of surgery	Total laryngectomy only	41	95.3%
	Partial pharyngectomy	2	4.7%
Neck dissection	Yes	42	97.7%
	No	1	2.3%
Preop tracheostomy	Yes	34	79.1%
	No	9	20.9%
Neopharynx maturation	Horizontal	9	20.95%
	Vertical	18	41.9%
	T shape	4	9.3%
	Not documented	12	27.9%
Duration of surgery	Less than 10 hrs	26	60.5%
	Greater than 10 hrs	12	27.9%
	Not known	5	11.6%

5.5 Behavioral variables and comorbidities:

In this study, various behavioral and comorbid factors were assessed among the participants (table 4). A history of smoking was reported in 37.2% of patients. Similarly, 44.2% of participants had a history of alcohol consumption. Regarding metabolic conditions, diabetes mellitus was present in only 2.3% of the study population. Preoperative hemoglobin levels were predominantly within the normal range, with 93% of patients having levels above 12.5 g/dl, while 7% had levels below this threshold. Postoperatively, hemoglobin levels declined, with 41.9% of patients maintaining levels above 12.5 g/dl and 58.1% falling below this level. Intraoperative blood transfusion was required in 51.2% of cases, whereas 48.8% did not necessitate transfusion. Additionally, 2.3 %(1) of patients had undergone preoperative radiation therapy to the neck.

Table 4: Behavioral variables and comorbidities

Variable	Response	Frequency	Percent
Smoking history	Yes	16	37.2%
	No	27	62.8%
Alcohol history	Yes	19	44.2%
	No	24	55.8%
Diabetes mellitus	Yes	1	2.3%
	No	41	97.7%
Preop hemoglobin	>12.5 g/dl	40	93%
	<12.5 g/dl	3	7%
post op hemoglobin	>12.5g/dl	18	41.9%
	<12.5g/dl	25	58.1%
Intraop blood transfusion	Yes	22	51.2%
	No	21	48.8%
Pre-Op radiation to the neck	Yes	1	2.3%
	No	42	97.7%

5.6 Postoperative Complications

The incidence of postoperative complications was analyzed among the study cases (figure 3). Wound infection was the most common complication, occurring in 34.9% of patients, while 65.1% did not experience any signs of infection. PCF was observed in 20.9% of cases. Bleeding and hematoma were reported in 11.6% of patients, with 88.4% experiencing no such complications. Mortality was recorded in 4.7% of cases, while 95.3% of patients survived the postoperative period. Additionally, a chyle leak was identified in 2.3% of our patients.

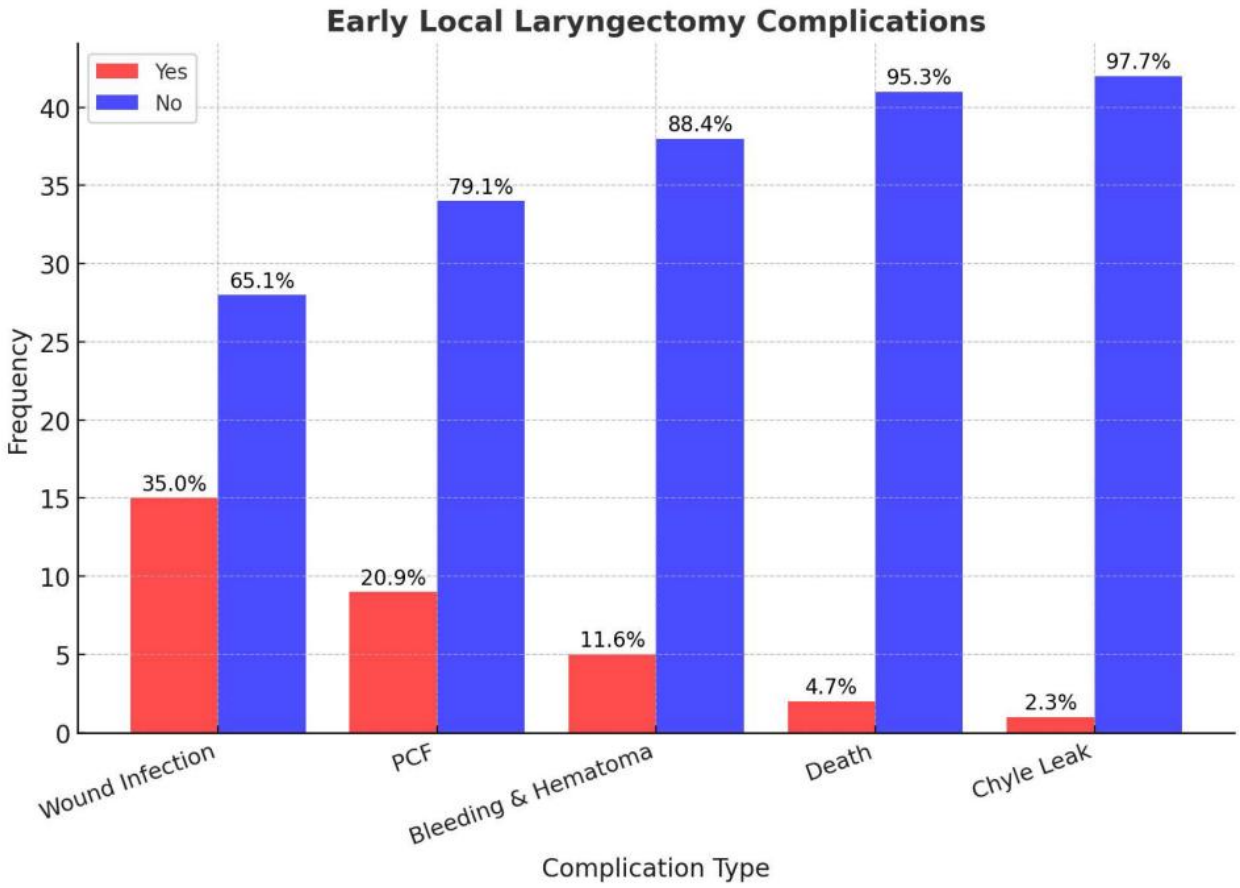


Figure 3: Frequency and percent of early local post laryngectomy complications

5.7 Factors associated with complications

5.7.1 Wound infection

In this study factors which could possibly affect the occurrence of complications (PCF and wound infection)were assessed through Binary logistic regression analysis methods. Univariate analysis at 25% level of significance was conducted tumor site, N stage of the tumor, type of surgery, PCF , bleeding and hematoma formation ,regional flap reconstruction ,duration of surgery and post op hemoglobin were found to be associated with wound infection (Table 5). Then Fisher Exact Test was done for tumor site and type of surgery since both has less than 5 cells on contingency table. The p value for both covariates was .116, which is not significant. On the multivariable logistic regression, after

adjusting for other covariates, none of the covariates were significantly associated with wound infection.

Table 5: The bivariate and multivariate association factors associated with wound infection

Factors		Wound infection		Phi coefficient	P-value	AOR	P-value
		Yes	No				
Bleeding	Yes	4	1	0.343	0.024	0.146 (CI, 0.008-2.596)	0.19
	No	11	27				
PCF	Yes	9	0	0.703	0.00	0.00	0.999
	No	6	28				
N stage of tumor	N0	7	25	0.466	0.002	.192 (CI 0.021-1.723)	0.14
	N1 and N2	8	3				
Post op Hgb	<12.5g/dl	11	14	-0.225	0.139	0.435(CI0.046-4.14	0.469
	>12.5g/dl	4	14				
Duration of surgery	<10hrs	7	20	0.244	0.109	3.208(CI0.55-28.99)	0.299
	>10 hrs	8	8				

5.7.2 Pharyngocutaneous fistula

Univariate analyses at 25% level of significance was conducted tumor site, N stage of the tumor, type of surgery, wound infection, smoking and preop Hgb were found to be associated with PCF development(table 6). Then Fisher Exact Test was done for tumor site and type of surgery since both has less than 5 cells on contingency table. The p value for both covariates was 0.040, which is significant. On the multivariable logistic regression, after adjusting for other covariates, none of the covariates were significantly associated with wound infection.

Table 6: The bivariate and multivariate association risk factors associated with PCF

Factors		PCF		Phi coefficient	P-value	AOR	P-value
		Yes	No				
Wound infection	Yes	9	6	0.703	0.00	0.00	0.998
	No	0	28				
N stage of tumor	N0	4	28	0.353	0.02	0.75	0.797
	N1andN2	5	6				
Type of surgery	Laryngectomy only	7	34	0.429	0.005	0.00	0.999
	With pharyngectomy	2	0				
Tumor site	Confined to larynx	7	34	0.429	0.005	0.00	0.999
	Extension to pyriform sinus	2	0				
Preop Hgb	<12.5g/dl	2	1	-308	0.043	1.242	1.00
	>12.5g/dl	7	33				
Smoking	Yes	9	19	.377	0.047	has cell 0	_
	No	0	8				

6. DISCUSSION

The goal of this study was to determine the prevalence and associated risk factors of early local complications post total laryngectomy which was done at Tikur Anbesa and Yekatit 12 hospital. For all patients total laryngectomy was done for the diagnosis of laryngeal cancer. The sociodemographic characteristics, clinical presentation, rate and risk factors of early complications were assessed from the chart of the patients. The male predominance in this study was similar to earlier study done at Tata Memorial Hospital, Mumbai, Maharashtra, India (Pantvaidya, Raina et al. 2017)which has male to female ratio 14 to 1 and a study done at Specialties Hospital in Rabat, Morocco (Nitassi, Belayachi et al. 2016)all of 136 patient were males . From our study, the mean age of 58.52 years (12.21 SD)) was similar to a study done at Specialties Hospital in Rabat, Morocco (Nitassi, Belayachi et al. 2016) with mean age was 58.

From our study, the most common presentations were voice change which present in all of our patient, shortness of breath (93%) and stridor (88.4) which are common presentations in most advanced laryngeal carcinoma patients. The least reported symptom was neck swelling (16.3%). A similar study in India (Reddy, Reddy et al.2012) all of the 30 (100%) had hoarseness 86.6 %(26) had stridor, 16.6 %(5) had neck swelling and dysphagia.

As an indication for total laryngectomy all of our patients were advanced TNM stage { stage III (16.%)and IV(83.7%}which is similar to a study done in Nigeria(Ogunkeyede, Adeyemo et al. 2020) which had had pathological diagnosis of stage 3 (83.3%) and stage 4 (16.7%) laryngeal cancer.

The findings of this study provide valuable insights into the postoperative complications following total laryngectomy, with a particular focus on pharyngocutaneous fistula (PCF), wound infection, bleeding, hematoma, chyle leak, and mortality. Wound infection was the most frequent postoperative complication in our study, occurring in 34.9% of patients. This is comparable to the study conducted in Spain, where 44% of patients developed a wound infection. A 12-year observation in Sokoto, Nigeria shows significantly lower incidence 20% (Aliyu and Riseh 2015). These findings highlight the need for stringent

infection control measures and optimization of preoperative conditions to minimize SSIs in laryngectomy patients.

The incidence of PCF in our study was 20.9%, which falls within the range reported in the literature, including the meta-analysis conducted in 2022 (Rao, Arora et al. 2022) that found an incidence of 21.69% (95% CI [0.19; 0.24]). It also aligns closely with findings from Johns Hopkins Medical Institutions (Benson, Hirata et al. 2015) 34% and Tata Memorial Hospital, Mumbai, Maharashtra, India (22.4%) (Pantvaidya, Raina et al. 2017). Postoperative bleeding and hematoma were observed in 11.6% of our patients.is consistent with seen in different studies 10% Nigeria (Aliyu and Riseh 2015)and 6.6% India , (Reddy, Reddy et al.2012)

Chyle leak was identified in 2.3% of patients in our study, which is within the range reported in the literature. The incidence of chyle leak varies widely, with studies reporting rates between 4.7% Kyungpook National University, Daegu, Korea(Ahn, Sohn et al. 2015) and 6.6% at University of Missouri, united states (Baker, Tassone et al. 2023) depending on the extent of neck dissection.

Postoperative mortality was recorded in 4.7% of patients, which is slightly higher than the 1.7% mortality rate observed at Tata Memorial Hospital, Mumbai, Maharashtra, India (Pantvaidya, Raina et al. 2017). One of the cases was associated with uncontrolled bleeding from the surgical site and one due to medical cause acute renal failure.

In our study there is no significant association between PCF and risk factors assessed age, hemoglobin level, TNM stage of the tumor, N stage, preoperative tracheostomy, wound infection, extent of surgery.. A study in Ibadan, Nigeria (Ogunkeyede, Adeyemo et al. 2020) shows factors related to fistula formation were prior radiotherapy treatment and diabetes. Age, gender, neck dissection procedures, site of primary tumor and emergency tracheostomy (p-0.29) did not contribute to fistula formation.

In our study there is no significant association between wound infection and risk factors assessed age, smoking, Tumor site duration of surgery , blood transfusion hemoglobin level, TNM stage of the tumor, , preoperative tracheostomy, PCF, extent of surgery. A

study in South Korea identified significant risk factors for SSIs, including male sex (OR 4.281; p=0.004), cardiovascular disease (OR 1.941; p=0.020), excessive blood loss during surgery (OR 4.213; p=0.001), and surgeries lasting longer than six hours (OR 4.213; p=0.002).

This may be due to small sample size that has significant impact on power of the study.

7. STRENGTH AND LIMITATIONS OF THE STUDY

The strength of this study is one of the first studies conducted both in TASH and Ethiopia.

One significant drawback of this study is that it is retrospective in nature, which means that detailed preoperative patient responses are not available.

The other limitation is the small number of sample size in our study which may not be representative of the big picture of the condition.

8. CONCLUSION

Total laryngectomy remains the gold standard treatment for advanced laryngeal carcinoma, particularly for patients with stage IV disease. The male predominance and the fact that most patients undergoing the procedure are in their fifth and sixth decades of life were consistent with existing patterns of this disease. In terms of postoperative complications, wound infection was the most common, occurring in 34.9% of patients, followed by pharyngocutaneous fistula in 20.9%, bleeding and hematoma in 11.6%, and an overall mortality rate of 4.7%.

The N stage of the tumor, PCF, bleeding, hematoma formation, and the use of regional flap reconstruction were all found to have significant associations with wound infection. Similarly, tumor site, N stage, and the type of surgery performed also showed relationships with the development of PCF. However, despite these associations, no statistically significant correlation was found between these factors and either wound infection or PCF development.

These findings underscore the complexity of postoperative outcomes in total laryngectomy, suggesting that while certain factors appear to be related to complications, no single factor is a definitive predictor. Future studies with larger sample sizes and prospective designs are necessary to identify additional strategies to improve postoperative outcomes and reduce complication rates.

9. RECOMMENDATION

For the department of otolaryngology head and neck surgery

Maintaining accurate and comprehensive records of all findings and ensuring proper chart keeping is strongly advised.

A strict infection control program with screening, asepsis, antibiotics, and surveillance reduces surgical site infections.

For minister of health

Since laryngeal cancer is prevalent condition it is advised to give public health education regarding clinical presentation of laryngeal cancer so that early diagnosis and management would be possible.

For researchers,

To conduct prospective study with larger sample size to better addresses risks and prevalence of complications.

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11. ANNEX 1: Questionnaire

Part 1 Socio demographic factors of respondent

	Hospital	**1TASH** **2 Yekatit 12 HMC**
Sr. No	**Questions**	**Choice Answers**
1	IC	1. ……
2	Gender	2. Male 3. Female
3	Age of the patient	in years:_____
4	Marital status	1. Single 2. Married 3. Divorced 4. Widowed
5	Religion	1. Orthodox 2. Protestant 3. Muslim 4. Other,
6	Region the patient comes from	_____

Part II:**Clinical variables and stage and site of tumor**

7	Hoarseness/ voice change	1, yes 2, no
8	Throat pain /discomfort	1, yes 2, no
9	Dyspnea	1. yes 2, no
10	Dysphagia	1 yes 2, no
11	Neck swelling	1 yes 2, no
12	Stridor	1 yes 2, no
13	Tumor site	1 confined to the larynx 2 extension to the pyriform sinus
14	TNM stage	1,I 2, II 3,III 4,IV

15	T stage	1, T1 2,T2 3,T3 4,T4
16	N stage	1 ,No 2, N1 3,N2 4 N3

PART III Behavioral variables and comorbidity :

17	Smoking history	1 yes 2,no
18	Alcohol drinking	1 yes 2,no
19	Diabetes mellitus	1 yes 2,no
20	Pre op hemoglobin	1,> 12.5 g/dl 2<12.5 g/dl
21	post op hemoglobin	1,> 12.5 g/dl 2<12.5 g/dl
22	Albumin level	1, >3.5g/dl 2,<3.5g/dl 3 Not known
23	Intraop blood transfusion	1,yes 2, no
24	Pre-Op radiation to the neck	1,yes 2, no
25	If yes to question no 24 Duration between RT and surgery	1, Less than 6 month 2,Greater than 6 month

Part IV Type of surgery and complications:

26	Type of surgery	1 laryngectomy only 2, Total laryngectomy with pharyngectomy 3 salvage laryngectomy
27	Neck dissection	1 yes 2,no
28	Flap reconstruction	1yes 2 ,no
29	**If yes to question no 28** Type of flap	1,PMMC flap 2 deltopectorial flap
30	Duration of surgery:	1<10 hrs

		2>10 hrs 3 not known
31	Preoperative tracheostomy:	1 yes 2,no
32	Neopharynx maturation:	1, vertical 2, T-shape 3,horizontal 4 not documented
33	Surgical margin:	1 negative 2 positive
34	Did the patient developed pharyngocutaneous fistula?	1, no 2 yes
35	If yes to question no 34 management of PCF	1 conservative 2 surgical closure
36	If surgical closure was, flap used?	1 primary repair 2 regional flap used
37	Was surgical intervention successful for question no 36?	1 yes 2 no
38	If conservative management time to heal :	1 <4 weeks 2, > 4 weeks
39	Bleeding and Hematoma	1 yes 2 no
40	If yes to question no 39 was surgical intervention required?	1 yes 2 no
41	chyle leak	1 yes 2 no
42	If yes to question no 41 was surgical intervention required?	1 yes 2 no
43	Wound infection	1 yes 2 no
44	Carotid blowout:	1 yes 2 no
45	death :	1 yes 2 no
46	If yes to question no 45 ,cause of death :	1 bleeding 2 Surgical site infection 3 Other cause

Approval Sheets

I hereby certify that I have read and evaluate this thesis entitled by “prevalence and associated risk factors of early local complications after total laryngectomy in laryngeal carcinoma patients at Tikur anbessa hospital and Yekatit 12 hospital medical college: a retrospective study over 5 years.Addiss Ababa, Ethiopia, 2025.

Principal investigator: Dr Welelaw Zelalem (ORL-HNS resident)

Dr Mesele Bogale	_____	_____
	Signature	Date
Dr Mohammedsefa Arusi	_____	_____
Advisors	Signature	Date
	_____	_____
_____		
Examiners’ name	Signature	Date