

Risk Factors for Pharyngocutaneous Fistula After Total Laryngectomy: An 11-year Retrospective Cohort Study in Burkina Faso

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Research Article

Keywords: Pharyngocutaneous fistula, total laryngectomy, risk factors

Posted Date: July 2nd, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-10208746/v1>

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Additional Declarations: No competing interests reported.

Abstract

Introduction: Pharyngocutaneous fistula is a common and much-feared complication following total laryngectomy despite advances in surgical techniques and perioperative care. The aim of this study was to identify the factors associated with the occurrence of post-laryngectomy pharyngocutaneous fistula in a sub-Saharan context.

Materials and methods: This was a descriptive and analytical study, conducted at the Yalgado OUEDRAOGO University Hospital over an 11-year period (January 2011 to December 2021). Patients who had undergone a total laryngectomy and had a usable clinical record were included in the study. A univariate analysis was performed (Fisher's exact test, $p=0.05$).

Results: Thirty consecutive patients, of whom 14 (46.67%) developed a pharyngocutaneous fistula. The mean age was 54.13 years. The factors significantly associated with pharyngocutaneous fistula included surgical site infection ($p < 0.001$), age over 60 years ($p = 0.013$), a postoperative haemoglobin level <12 g/dl ($p = 0.036$), malnutrition ($p = 0.021$) and an operative time exceeding 4 hours ($p = 0.036$). Spontaneous closure was observed in 78.57% of cases.

Conclusion: Pharyngocutaneous fistula is a common complication following total laryngectomy. Prevention relies on infection control, correction of anaemia and malnutrition, and reducing operating time.

INTRODUCTION

Pharyngocutaneous fistula is an abnormal communication between the pharyngeal lumen and the cervical skin, resulting in leakage of saliva through the neck wound [2]. The pharyngocutaneous fistula is one of the most common post-operative complications following a total laryngectomy. It is potentially serious and occurs in the post-operative period following cancer surgery of the pharynx and larynx, with an incidence that varies across different case series [3]. Several patient-, tumors- and treatment-related factors have been implicated. The incidence of pharyngeal fistulas following total laryngectomy can range from 2.6 to 65.5 per cent [6, 10].

Pharyngocutaneous fistula leads to reduced quality of life, prolonged hospital stay, and increased healthcare costs, delayed oral feeding and postponement of adjuvant therapy (radiotherapy, chemotherapy) following surgery [9,20]. The diagnosis of a pharyngocutaneous fistula is primarily clinical. To date, few studies have investigated pharyngocutaneous fistula in sub-Saharan Africa.

However, a few studies have been carried out on this potentially serious condition in the Maghreb and in high-income countries. The aim of this study was to describe the risk factors and treatment modalities for pharyngocutaneous fistula following total laryngectomy in the Oto-rhino-laryngology and Head and Neck surgery department at teaching university hospital.

PATIENTS AND METHODS

This was a descriptive and analytical study involving retrospective data collection over a period of eleven (11) years in Head and Neck surgery department at Yalgado Ouédraogo university teaching hospital in Burkina Faso.

Patients who underwent a total laryngectomy and had a complete medical record were included in the study.

For statistical analysis, the various data were collected on a data collection form from patients' clinical records, consultation records, the surgical report register, the hospitalisation register and the pathological examination report registers. The data were entered and analysed using EpiInfo version 7.2.4. For the descriptive study, we calculated frequencies and percentages for qualitative variables, and means and ranges for

quantitative variables. For the analytical study, we divided our cohort into two groups included in the study who had undergone a total laryngectomy: the first group comprised patients who had a pharyngocutaneous fistula, and the second group comprised those who did not have a pharyngocutaneous fistula. A univariate analysis was carried out: A statistical comparison of risk factors between the two groups was carried out using Fisher's exact test. The significance threshold (p) was set at 0.05. Odds ratios were calculated with continuity correction (Haldane–Anscombe method). Confidence intervals were calculated at the 95% level. Because of the limited sample size (30), multivariate analysis was not performed.

Malnutrition was defined as BMI < 18.5 kg/m² and/or unintentional weight loss > 10%

Postoperative anaemia was defined as haemoglobin level < 12 g/dl

Surgical site infection was defined according to the CDC criteria.

Ethical considerations

The protocol for this study was conducted in accordance with the ethical principles set out in the Declaration of Helsinki. Prior to inclusion, all participants gave their informed consent after being fully informed of the study's objective. There are no conflicts of interest to report.

RESULTS

1-Incidence

We identified 30 cases of total laryngectomies, of which 14 patients developed a pharyngocutaneous fistula, representing an estimated frequency of 46.67%.

2-Epidemiological data

All patients were male, accounting for 100 per cent of the study population. The mean age of the patients in the series was 54.13 years $\pm$ 10.34, with ages ranging from 31 to 73 years.

3- Clinical and paraclinical data

Tobacco use was identified in 83.33% of patients. Mean tobacco exposure was 15 pack-years. Alcoholism was identified in 23 patients prior to total laryngectomy, representing 76.67% of cases. Primary tracheostomy was performed in 19 patients, representing 63.33%. Only one patient received pre-operative radiotherapy in our series. Malnutrition (BMI < 18.5 kg/m² and/or weight loss > 10%) was noted in four (04) patients. Postoperative anaemia, with a haemoglobin level < 12 g/dl, was identified in the complete blood count in 04 patients, representing 13.33% of cases.

Squamous cell carcinoma was the histological type observed in all patients. According to the TNM classification, the tumours were classified as T3–T4 in 29 cases (97 per cent) and N0 in 66 per cent of cases (Table 1). The mean operative was 6 hours. Surgical site infection was observed in 12 patients, representing 36.66% of cases. The main reason for consultation was cervical salivation in 14 patients, representing 100% of cases with a pharyngocutaneous fistula. The mean time to onset was 14 days following a total laryngectomy, with a range of 9 to 21 days in our series.

4- Treatment data

Antibiotics were administered to all our patients, initially on a probabilistic basis and subsequently adjusted according to the results of the antibiotic susceptibility testing.

In this study, all patients were placed on a proton pump inhibitor (omeprazole 20 mg/day) for 3 weeks postoperatively.

Local care consisted of a compression dressing, twice-daily local disinfection with antiseptics, and frequent tracheal and oral suctioning, which were carried out in all patients.

To ensure postoperative nutrition for laryngectomised patients:

- A nasogastric tube (NGT) was inserted in 29 patients.
- One patient underwent a feeding gastrostomy.

Surgical treatment using a musculocutaneous flap from the pectoralis major muscle was performed on one patient following the failure of medical treatment due to the large size of the pharyngocutaneous fistula.

5- Follow-up data

The clinical course was favourable in 11 patients with a pharyngocutaneous fistula, representing 78.57% of cases, with spontaneous closure. One death was recorded in a patient with a pharyngocutaneous

fistula, representing a mortality rate of 7.14%. The cause of death was haemorrhage due to the rupture of a large blood vessel.

Table 1
Risk factors for pharyngocutaneous fistula studied

Risk factors for pharyngocutaneous fistula studied			Number of patients (n = 30)
Epidemiological factors	Age	< 60 years	20
		> 60 years	10
	Gender	Male	30 (100%)
Comorbidities and medical history	Smoking		25 (83.33%)
Medical	Alcohol		23 (76.67%)
	Pre-operative radiotherapy		1 (3.33%)
Clinical factors	Malnutrition (BMI < 18.5 kg/m ²)		4 (13.33%)
	Mean time to onset		14 days
	Surgical site infection		12 (36.66%)
	Salivary leakage		14 (46.66%)
Biological factors	Pre-operative haemoglobin < 12 g/dl		4 (13.33%)
	Post-operative white blood cell count > 10,000/mm ³		14 (46.66%)
Tumour-related factors	Squamous cell carcinoma		30 (100%)
	TNM classification	T3–T4	29 (96.66%)
		N0	20 (66.66%)
	Surgical margins	Positive	1 (3.33%)
		Negative	29 (96.66%)
Treatment-related factors	Preoperative tracheotomy		19 (63.33%)
	Type of surgery	Total laryngectomy	29 (96.66%)
		Total pharyngolaryngectomy	1 (3.33%)
	Operating time	≥ 4 hours	17 (56.66%)
		< 4 hours	13 (43.34%)
	Lymph node dissection		30 (100%)
	Compression dressing		30 (100%)
	Pectoralis major flap		1 (3.33%)

Risk factors for pharyngocutaneous fistula studied			Number of patients (n = 30)
	Feeding method	Nasogastric tube	29 (96.66%)
		Gastrostomy	1 (3.33%)
	Antibiotics		30 (100%)
	Proton pump inhibitor		30 (100%)

6- Factors **associated** with **the development of a** pharyngocutaneous fistula

According to the univariate analysis, we found no correlation between smoking ($p = 0.423$), alcohol consumption ($p = 0.418$), locoregional spread ($p = 0.351$), lymph node dissection ($p = 0.466$), pre-operative tracheotomy ($p = 0.316$) and the occurrence of a pharyngocutaneous fistula. However, surgical site infection ($p < 0.001$), operative duration ($p = 0.036$), malnutrition ($p = 0.021$), age of 60 years or over ($p = 0.013$) and postoperative anaemia ($p = 0.036$) were statistically significant factors associated with pharyngocutaneous fistula (Table 2).

Table 2
Univariate analysis of risk factors for pharyngocutaneous fistula

Variables		Group 1: pharyngocutaneous fistula	Group 2: No pharyngocutaneous fistula	OR (95% CI)	p
Smoking	Yes	11	14	0.52 (0.08– 3.29)	0.423
	No	3	2		
Alcohol exposure	Yes	10	13	0.58(0.10– 3.24)	0.418
	No	4	3		
Preoperative tracheotomy	Yes	10	9	1.94(0.38– 9.78)	0.316
	No	4	7		
Locoregional spread	T4-T3	13	16	0.27(0.001– 5.49)	0.351
Age	< 60 years	6	14	9.33 (1.49– 58.3)	0.013
	≥ 60 years	8	2		
Duration of laryngectomy	≥ 4 hours	11	6	6.11 (1.19– 31.3)	0.036
	< 4 hours	3	10		
Malnutrition	Yes	4	0	18.67 (0.88– 394.6)	0.021
	No	10	16		
Anaemia (Hb < 12 g/dl)	Yes	4	0	18.7 (0.88– 394.6)	0.036
	No	10	16		
Surgical site infection	Yes	11	1	18.33 (2.01– 167.3)	< 0.001
	No	3	5		

OR: Odds Ratio

DISCUSSION

The incidence of pharyngocutaneous fistula varies considerably in the literature, ranging from 2.6 to 65.5 per cent [5, 6, 10].

In our study, the incidence of pharyngocutaneous fistula following total laryngectomy was 46.67 per cent. Indeed, the pharyngocutaneous fistula is the most common complication following total

laryngectomy in the secondary postoperative period.

Age over 60

In our series, being aged over 60 was a risk factor for the development of a pharyngocutaneous fistula ($p = 0.013$). Indeed, there is a statistically significant difference between patients who developed a pharyngocutaneous fistula and those who did not. However, this risk factor is not universally recognized by all authors. Indeed, Kedous [8] noted that patients under the age of 60 developed more pharyngocutaneous fistulas in their series. Similarly, Thiam [9] noted that age was not a risk factor for the occurrence of complications following total laryngectomy.

Ageing is associated with physiological changes, including a reduction in muscle mass, a decline in lung function and an increased susceptibility to infections, all of which prolong the recovery time in elderly laryngectomized patients [1, 2].

Malnutrition

Malnourished patients with a body mass index $< 18.5 \text{ kg/m}^2$ and/or weight loss $> 10\%$ were significantly more likely to have developed a pharyngocutaneous fistula. A statistically significant difference was observed between the two groups ($p = 0.021$). The same finding was reported by Busoni [3] and Paydarfar [10]. The incidence of malnutrition is extremely high in cancers of the upper aerodigestive tract. According to the literature, 35–70% of patients presented with severe malnutrition [2]. This is attributable to a reduction in oral intake (anorexia, dysphagia, odynophagia) and by increased protein catabolism associated with the disease. This state of pre-operative malnutrition, particularly in patients who have lost more than 10 per cent of their body weight in the six months prior to surgery, places them at high risk of developing major post-operative complications [10, 20].

Post-operative anaemia

Postoperative anaemia with a haemoglobin level below 12 g/dl was associated with the occurrence of pharyngocutaneous fistula in our study ($P = 0.036$). Our findings are consistent with those of several recent series [2, 6], which report that a haemoglobin level below 12 g/dl in the immediate postoperative period is likely to increase the incidence of pharyngocutaneous fistula. Correction is recommended where possible. All transfusion strategies must follow restrictive approaches based on international guidelines. Furthermore, significant intraoperative blood loss reflects extensive and complex tumor resection, which in itself constitutes a risk factor for pharyngeal fistula [10]. The temporal relationship between infection and fistula cannot be definitively established because of retrospective design.

Tumor extent

Statistical analysis shows no correlation between tumor extent and the occurrence of a pharyngocutaneous fistula. The same finding was reported in Thiam's study [9]. However, Kouassi [6] noted an association between tumor stage and the occurrence of a pharyngocutaneous fistula ($p = 0.03$). Extensive resection leaves less mucosa available to close the defect in the pharyngeal wall. The loosening of sutures placed under tension was the cause of this type of post-operative complication [2, 13].

Preoperative radiotherapy

Only one case of pre-operative radiotherapy was recorded in our series, which is insufficient to establish a link between radiotherapy and the occurrence of pharyngocutaneous fistula. However, other authors, such as Dedivitis [2] and Paydafar [10], have found a link between pre-operative radiotherapy and the occurrence of pharyngocutaneous fistula.

Indeed, the tissue's ability to heal is impaired by radiotherapy and contributes to the development of pharyngeal fistulas [20].

Preoperative tracheotomy

In the present study, statistical analysis showed no association between the occurrence of a pharyngocutaneous fistula and pre-operative tracheotomy ($P = 0.316$). This result is consistent with data from several series [6, 8]. However, primary tracheotomy was identified as a risk factor by other authors, such as Eleni [11] and Charfeddine [12]. Indeed, it constituted an undeniable source of infection and impaired wound healing. This may be explained by the fact that pre-operative tracheotomies may be colonized by bacteria other than the usual oropharyngeal flora [8].

Duration of the procedure

In this series, a procedure duration exceeding 4 hours was correlated with the occurrence of pharyngocutaneous fistula ($P = 0.036$). Indeed, the exact duration is not clearly defined in the literature [13, 14].

According to data from multivariate hospital analyses, a total laryngectomy lasting between 4 and 5 hours should be considered a risk marker, and beyond 6 hours, the risk of fistula increases significantly, regardless of other factors [20].

There is no universal ideal average duration, but any procedure exceeding the 75th percentile for duration within its category significantly increases the risk of infection.

Indeed, a prolonged duration of the procedure is thought to involve several mechanisms: increased exposure to bacteria, tissue desiccation and microvascular damage, intraoperative hypothermia, surgical

fatigue and increased tissue manipulation, and finally a reduction in the efficacy of antibiotic prophylaxis [4, 10]

Lymph node dissection

Lymph node dissection was performed in all patients in our series. No correlation was observed between lymph node clearance and the occurrence of a pharyngocutaneous fistula. This finding was consistent with the data reported by several authors in the literature [8, 10]. However, some authors, such as Virtaniemi [15], noted a statistically significant correlation. Indeed, cervical dissection, when lymph nodes are removed, requires large incisions which alter local blood supply and create dead spaces where secretions can accumulate. These factors may promote the development of pharyngocutaneous fistulas [17, 19].

Time to onset

The time to onset of a pharyngocutaneous fistula varies between the 7th and 11th day following total laryngectomy. It occurs mainly during the secondary postoperative period and reflects a defect in pharyngeal healing [2]. This same observation was made by other authors in the literature. [6, 9]. In this series, the mean time to onset was 14 days.

Indeed, in our practice, the swallowing test is carried out around the 14th day; this may explain the delay in diagnosis, in contrast to the data in the literature [10].

Surgical site infection

In our series, the development of a pharyngocutaneous fistula was preceded by suppuration of the surgical wound. Surgical site infection was strongly associated with the development of a pharyngocutaneous fistula (OR 18.33; 95% CI 2.01–167.3; $p < 0.001$). Although the temporal relationship could not be definitively established because of the retrospective design.

This finding is consistent with the literature, particularly the work of Dedivitis [2] and Paydarfar [10], who identify surgical site infection as a major factor. However, the findings of Thiam [9] did not show any association between post-operative infection and the development of a pharyngocutaneous fistula. Indeed, suppuration and necrosis of the soft tissues at the surgical site lead to the loosening of sutures (Fig. 1), which in turn causes the salivary fistula [2, 19].

Treatment

Conservative treatment combining local care and medical management of pharyngeal fistulas constitutes the main approach to managing this type of post-operative complication [2]. Broad-spectrum antibiotic therapy targeting both aerobic and anaerobic bacteria was routinely prescribed to all patients. This was then adjusted according to the results of the antibiotic susceptibility testing. Third-generation cephalosporin (ceftriaxone) was the main drug prescribed, sometimes combined with metronidazole in cases of local superinfection. The bacteria identified in our study were *Escherichia coli*, *Pseudomonas aeruginosa* and *Cronobacter sakazakii*. Studies by Dedivitis [2], Payfardar [10] and Coyle [4] do not

demonstrate the superiority of any single drug in the prevention of pharyngolaryngeal fistulas and emphasize the importance of routine anaerobic coverage.

Indeed, antibiotic prophylaxis administered at the time of surgery (30 minutes before induction of anaesthesia) is intended to reduce the incidence of surgical site infections following the procedure [13].

Patients who were malnourished following total laryngectomy were systematically placed on a high-protein, high-calorie diet. A nasogastric tube was used for enteral feeding in 96.66 per cent of cases.

Indeed, malnutrition must be managed and, where possible, corrected prior to surgery, if necessary, by inserting a nasogastric tube or performing a gastrostomy. In most cases, the diet will be high in protein and calories. It appears that the use of immunonutrients helps to reduce rates of postoperative infections [2, 19].

Seikaly [18] reported his experience of anti-reflux treatment, combining intravenous ranitidine and metoclopramide in an experimental group. He demonstrated that the rate of pharyngeal fistulas decreased by 26% in the control group and to 0 in the experimental group. In this study, a proton pump inhibitor (PPI) based on 20 mg of omeprazole per day was routinely administered to all patients following total laryngectomy for 30 days. Indeed, gastric hyperacidity, through the local inflammation it causes, may be responsible for impaired healing of the neo-pharynx sutures, leading to a pharyngeal fistula [20].

In this study, a cervical compression dressing was routinely applied to patients with a pharyngocutaneous fistula. This is because applying a cervical compression dressing helps to limit the area of detachment—a potential site of fluid collection—thereby preventing the development of a pharyngocutaneous fistula [2].

In this study, only one patient underwent a pectoralis major flap procedure. In the literature, the pectoralis major flap has been widely used in cancer surgery of the upper aerodigestive tract in several series [3, 6]. Indeed, it is a very useful flap for large pharyngocutaneous defects and can be easily combined with a skin-on- graft on the deep muscular layer, thereby simultaneously reconstructing cervical skin defects.

Post-total laryngectomy pharyngocutaneous fistula generally close spontaneously. Various studies report a rate of spontaneous closure of between 60 and 94 per cent when treatment is initiated [5, 10]. In our series, spontaneous closure with medical treatment alone was observed in 78.57 per cent of cases. Our findings are similar to those of other authors in the literature [6, 15], who reported rates of 80% and 89% respectively.

Limitations of the study

This study has certain limitations. The main limitation of this study is its retrospective single-center design, and the relatively small, which prevented sample size, which prevented multivariable analysis. However, this study provides one of a few available datasets sub-sahara Africa of pharyngocutaneous

fistulas following total laryngectomy. Therefore, these findings should be interpreted with caution. Furthermore, the absence of prevents the identification of factors independently associated with the occurrence of pharyngocutaneous fistula.

CONCLUSION

Pharyngocutaneous fistula remains a frequent complication following total laryngectomy in our setting. Surgical site infection, malnutrition, anemia, advanced age and prolonged operative time were significantly associated with its occurrence. Optimization of perioperative care could help reduce the burden of this complication in low-resource settings.

Declarations

Funding

No external funding was received for this study.

Availability of data and materials

Datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Committee of Yalgado Ouédraogo University Teaching Hospital, Ouagadougou, Burkina Faso. As this was a retrospective study based exclusively on anonymized medical records, the requirement for obtaining individual informed consent to participate, was waived by the ethics committee. The study was conducted in accordance with the Declaration of Helsinki (1975, revised in 2013).

Consent for publication

Written informed consent was obtained from the patient presented in figure 1 for publication of clinical image.

Competing interests

The authors declare no competing interests

Author Contribution

Author contributions: Conceptualization: Yameogo Adama¹, Goueta Aboubakar², Gyébré Yvette;
Methodology: Yameogo Adama; Writing - original draft preparation: Yameogo Adama Writing - review

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Figures



Figure 1

Image showing a pharyngocutaneous fistula following suture dehiscence after total laryngectomy.