

Elective vs. emergency tracheotomy complications in advanced hypopharyngeal cancer

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Abstract. Squamous cell carcinoma of the hypopharyngeal region is a rare, aggressive disease with a poor prognosis and a high mortality rate, and represents up to 95% of all hypopharyngeal tumors. Patients with upper aerodigestive tract tumors can develop airway compromise before or during chemoradiotherapy. The present study aims to investigate the complication differences between elective tracheostomy and emergency-setting tracheostomy for patients with advanced hypopharyngeal squamous cell. The study group included 36 patients and analyzed the number and type of complications, functional outcomes and comparison of the laboratory testing in all the patients at 3 specific points (before tracheotomy, during the radiation therapy and at least 3 months after completion of radiation therapy). In addition, univariate analysis was performed in order to evaluate the prognosis of local control rates. The type and number of complications between elective and emergency-setting tracheostomy varied, but all the complications were resolved, and no hypoxic complications secondary to displacement of the tracheostomy tube or death cases related to the tracheostomy occurred. A total of 20/36 patients presented with complications, with 73% (16 patients) from the emergency tracheostomy cohort and 36% (4 patients) from the elective tracheostomy group. More than half of the elective tracheostomy (6/11 patients) responded favorably to the treatment, with a higher frequency than the patients with emergency tracheostomy (5/22 patients). The present study did not encounter significant statistical

differences ($P>0.05$) of the treatment end-result regarding the type of tracheostomy performed, but the prediction analysis found for the patients aged under 60 years old, elective tracheostomy was associated with a higher chance of favorable treatment end result.

Introduction

Hypopharyngeal cancer is considered to have the worst prognosis of all head and neck squamous cell cancers, it is an aggressive form of cancer with extensive submucosal lymphatic spread that associates poor prognosis (1,2). Hypopharyngeal cancer is difficult to treat as patients are often diagnosed during the advanced stages of the disease, as they lack specific symptoms and present usually when the surrounding regions are involved such as larynx, esophagus and they present bulky neck masses (2). Furthermore, there is a significant submucosal lymphatic extension that is difficult to appreciate through clinical evaluation and imaging and that can only be seen on histopathological report (1). In addition, up to 40% of patients are diagnosed with regional metastasis and 50% of patients are in the primary stages of advanced forms (3), leading to a high mortality rate of up to 30% in the first year of diagnosis, and a low 5-year survival rate of 25% in Europeans (1).

The main factors that predispose hypopharyngeal cancer are alcohol and tobacco intake, and the synergy of these two habits has been proven to be the main etiological factor in head and neck cancers (4). In addition, genetic predisposition (Plummer-Vinson Syndrome, also termed Paterson Brown Kelly Syndrome) (5-7), diet and low socioeconomic status are other factors that have been associated with the development of hypopharyngeal cancer (1,4,8-10).

The treatment in advanced stages, despite the recent advances in minimal access surgery, shows limited promise in hypopharyngeal cancer and lacks a gold standard treatment for advanced stages of this pathology (11). In advanced hypopharyngeal cancer the treatment options include traditional radical surgery (laryngo-pharyngectomy) followed by radiation therapy, or a non-surgical option, using chemo-radiation therapy and palliative care (11). Advances in molecular research have improved the knowledge of oncogenes and

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mechanisms of tumor spread but at present, are limited to pre-clinical testing (12). The majority of studies assessing surgery are non-randomized trials, and radiochemotherapy studies for the head and neck region include patients with a variety of primary sites, with the hypopharyngeal area being only represented by a small subset of patients (13-16). For patients unfit for curative treatment, with recurrent and/or metastatic head and neck cancer (in hypopharyngeal cancer up to 25% of patients newly diagnosed) the recommended treatment is best supportive care, using specialized palliative care providers (17). This type of treatment is usually reserved for patients unfit for major surgery, for which chemotherapy is not a feasible option due to comorbidities and radiation therapy as a single method of treatment is inefficient and expected to cause major toxicities (17). The decision to opt for supportive care instead of curative treatment is challenging, and usually made by the multidisciplinary head and neck team after careful consideration of all the possible treatment options and patient evaluation (17).

Primary organ preservation-therapy is associated with various degrees of speech and swallowing dysfunctions, which are aspects that are important in the assessment of laryngeal function. Primary organ preservation-therapy can also lead to the need of temporary tracheostomy due to mucositis, late xerostomia or progression in severity of dysphagia. The need for tracheostomy can occur due to airway compromise leading to laryngeal incompetence, chronic aspiration due to pooling of secretions or saliva, persistent bulky edema and radiation toxicity after treatment (18).

The objectives of the present study are to compare and analyze the influence of the tracheostomy type, to assess whether there are any specific complications linked to each procedure and finally, to find out if there are any predictive factors of end-treatment evolution regarding the tracheostomy procedure.

Materials and methods

Study design. The present non-randomized epidemiological study was performed on patients with advanced stage hypopharyngeal carcinoma confirmed through tumoral biopsy and histopathologic examination, and treated for hypopharyngeal cancer in the Department of Ear, Nose, Throat, Head and Neck Surgery, 'Carol Davila' Central University Emergency Military Hospital, (Bucharest, Romania). Patients from the retrospective arm of the study were treated from January 2018 to July 2022, and patients from the prospective arm were treated from August 2022 to March 2023. The exclusion criteria used were major psychiatric pathologies and disagreement for data usage and publication. The present study was authorized by The Ethics Committee of Titu Maiorescu Doctoral School of Medicine, Titu Maiorescu University (Bucharest, Romania; approval no. 15/2022) and by The Ethics Committee of 'Carol Davila' Central University Emergency Military Hospital (Bucharest, Romania; approval no. 538/2022). All the patients from the study provided written informed consent for data usage and publication, and oral consent to participate in the present study was obtained from the prospectively recruited patients.

The cohort (n=36) was divided into two groups, according to the tracheostomy type: i) Emergency tracheostomy group

(n=25), including patients who presented with acute respiratory distress; and ii) elective tracheostomy group (n=11), including patients who presented with chronic aspiration from the hypopharynx, persistent or growing edema during radiation therapy or tumor extension from the hypopharynx to the laryngeal region without airway compromise. A total of six patients were primary surgically treated with total laryngectomy with partial/total pharyngectomy and neck node dissection, primary closure and adjuvant radiotherapy. For two patients from the surgically treated arm, additional chemotherapy for relapse treatment was needed. The surgically treated patient cohort (n=6) was also split according to the tracheostomy type with five patients in the elective group (tracheostomy was made in the surgical procedure) and one patient that presented with acute respiratory distress prior to the surgery and needed emergency tracheostomy.

All the patients included in the present study were diagnosed with advanced stage hypopharyngeal carcinoma (Table I). In the present study, the laboratory testing performed on the patients included a complete blood count, assessment of the coagulation profile [prothrombin time/international normalized ratio (PT/INR) and activated partial thromboplastin time (aPTT)], erythrocyte sedimentation rate and serum levels of glucose, urea, creatinine, bilirubin, alanine aminotransferase, aspartate aminotransferase, sodium, potassium, serum amylase and C-reactive protein. The present study evaluated each patient at three timepoints including before tracheotomy, during therapy and at the end of the treatment (at least 3 months after completion of radiation therapy). The minimum follow-up period for patients was 6 months.

Treatment options. Radiation therapy was administered for all the patients included in the study, according to standardized protocols using intensity-modulated radiation therapy or volumetric modulated arc-therapy conformal radiation therapy at a total dose of 70-72 Gray (Gy) in 33-35 fractions to the primary tumoral location and clinically positive neck disease, at a dose of 56-63 Gy for intermediate target volumes and at a dose of 50-56 Gy to negative cervical lymph nodes at risk for occult metastatic disease-low-risk target volumes (1). Chemotherapy regimens used platinum-based drugs and were routinely used either concomitant to radiation therapy, or prior to it, as neoadjuvant chemotherapy used for bioselection in organ preservation treatment in order to determine subsequent treatment, definitive chemoradiotherapy for the responders, and for the non-responders surgical treatment followed by adjuvant radiation therapy (1,18).

A standard technique was used for the tracheostomy procedures, whereby a vertical skin crease incision was made, the muscles were separated from the middle cervical line and the thyroid isthmus was divided, clamped and sutured. A small tracheal hole was created at the third or fourth tracheal ring. Silk suture was used through the ring in order to facilitate the tube change (19). The tracheostomy tube was changed on the 3rd postoperative day to another sterling silver cannula and, after a minimum period of 1 week, the type of cannula was changed to a plastic one. The patients received constant humidification in the inspired air (including head and moisture exchangers and stoma bibs), mucolytics,

Table I. Associative distribution of patients according to treatment response, tracheostomy type and monitoring status.

Monitoring status	Treatment end-result	Total (%)	Elective tracheostomy, n=11	Emergency tracheostomy, n=25
In medical surveillance, n=3	Favorable	11 (31)	6	5
	Not favorable	15 (42)	4	11
	Stationary	8 (22)	1	7
Lost from evidence, n=2	X	2 (5)	-	2

X, not known. Favorable, complete response or remission; Stationary, partial response or partial remission; Not favorable, disease progression.

adequate hydration by either mouth, enteral or intravenous hydration, and regular tracheobronchial suction during the early postoperative period. Heat and moisture exchangers were set to 30 mg/l absolute humidity, 34°C and 100% relative humidity (20,21). This procedure was administered by the Ear Nose Throat Department nursing staff, who were trained in tracheostomy care. Patients were admitted to the intensive care unit postoperatively only if the general health of the patient required it or if ventilatory support was needed.

Patient comorbidity evaluation. The comorbidity burden on patients was evaluated using the Adult Comorbidity Evaluation 27 (ACE-27) (22) and the Karnofski Performance Status Scale (KPSS) (23). The Tumor Nodal Metastases (TNM) staging developed by the Union for International Cancer Control (UICC) and the American Joint Committee on Cancer staging system (7th and 8th edition) were used to stage tumors at the time of diagnosis (24).

Statistical analysis. According to the small sample size and to the type of variable, statistical analysis was performed to find significant difference between patients with elective vs. emergency tracheostomy. Qualitative variables, nominal or dichotomic (such as AJCC stage, social and economic status-SES, complications, type of complications, treatment, evolution) were described in rxc contingency tables, as absolute and relative frequencies; their association with type of tracheostomy was tested by Fisher's Exact Test or Mann-Whitney U test. The patient's age, at different time points, were described using range, central tendency indicators (mean and median) and dispersion (standard deviation-SD), for total and at subgroup levels. To seek the difference between groups of tracheostomy, after data normality distribution checking, unpaired Student's T test was applied; morbidity scores (ACE-27 and KPSS) were compared between tracheostomy groups with non-parametric Mann-Whitney U test. $P < 0.05$ was considered to indicate a statistically significant difference. Data analysis was performed using SPSS (version 27; IBM Corp) (25).

Results

The first step in the statistical protocol was to analyze whether the tracheostomy type groups were comparable according to attributes including socio-demographic characteristics, lifestyle and clinical status of patients. This comparison was necessary in order to show that an identified possible

association between end-treatment response or complication patterns is due only to intervention type and no other characteristics of the patients. In the cohort, the age of patients at diagnosis varied between 46 and 84 years old, with a mean age of 66 and a standard deviation of 8 years. The mean age of patients requiring emergency tracheostomy was 62 ± 6 years, with a variation between 51 and 71 years old. This was not significantly different from the total of patients who were surgically treated (63 ± 4.4 years). Almost all the patients 97% (35/36) were men and only one woman was included in the cohort, who underwent elective tracheostomy. Using an unpaired Student's t-test, no significant statistical differences were identified regarding age between the elective and emergency tracheostomy groups (Table II; $P > 0.05$).

A total of 75% of the patients (27 patients) included in the present study were retired, 17% (6 patients) were employed and 8% (3 patients) were unemployed (Table III). Lower socioeconomic status (such as retirement and unemployment) comprises a big part of the study group (up to 83% of patients) and significantly influences the profile of the patient diagnosed with hypopharyngeal cancer due to several factors. Poor living conditions often expose individuals to environmental carcinogens, limited opportunities for physical activity and access to nutritious foods weaken of the long term the health of the individual. Occupational habits (smoking, chronic drinking), more frequent in lower socioeconomic groups, increase directly the cancer risk. Additionally, the jobs with higher exposure to pollutants and hazardous substances are usually associated with lower economic status. These factors combined contribute to a higher risk of developing hypopharyngeal cancer in lower socioeconomic population (26).

Alcohol intake was confirmed statistically as a significant lifestyle risk ($P = 0.013$; Fischer's Exact test), with 10/22 patients in the emergency tracheostomy group confirming that the habit led to the requirement for an emergency tracheostomy and no participants of the elective tracheostomy group. However, smoking was not found as a statistically significant lifestyle risk in out ($P > 0.05$; Fischer's Exact test), although 16/22 patients from the emergency and 5/11 patients from the elective tracheostomy group presented with this habit.

For the majority of patients in the emergency tracheostomy group, the location of the primary tumor was hypopharyngeal with laryngeal involvement (22/25 patients), followed by hypopharynx (2/25), leaving one patient with hypopharyngeal, laryngeal and esophageal involvement at the time of diagnosis. The laryngeal involvement required an emergency

Table II. Age at various time points between study groups according to the tracheostomy type.

A, Elective			
Tracheostomy type	Age at surgery	Age at tracheostomy	Age on visit
N	5	11	11
Minimum, years	59	52	55
Maximum, years	70	70	82
Mean, years	62.60	61.64	67.64
SD, years	4.827	5.714	8.225
Median, years	60.00	62.00	66.00
B, Emergency			
Tracheostomy type	Age at surgery	Age at tracheostomy	Age on visit
N	1	25	25
Minimum, years	65	51	52
Maximum, years	65	71	73
Mean, years	65.00	62.08	64.72
SD, years	-	6.164	6.328
Median, years	65.00	64.00	67.00
C, Total patients			
Tracheostomy type	Age at surgery	Age at tracheostomy	Age on visit
N	6	36	53
Minimum, years	59	51	46
Maximum, years	70	71	84
Mean, years	63.00	61.94	65.94
SD, years	4.427	5.952	8.298
Median, years	62.50	63.50	67.00
SD, standard deviation.			

tracheostomy due to acute respiratory distress. The patient group that received elective tracheostomy presented chronic aspiration of saliva and secretions from the hypopharynx, persistent or growing edema during radiation therapy, and tumor extension from the hypopharynx to the laryngeal region without airway compromise. In the elective tracheostomy group the majority of the patients (7/11 patients) had hypopharyngeal tumors with laryngeal involvement, three patients had hypopharyngeal locations and one patient had pharyngeal extension (oropharynx and hypopharynx). One of the main limitations of the study was the lack of early-detected cases as all the patients were diagnosed from advanced stages (Table IV), and treatment options are limited by the stage of the disease, comorbidity burden, age and patient option. A total of 97.2% of the patients (35/36 patients) presented lymph

Table III. Associative distribution of patients according to their SES and tracheostomy type.

	Tracheostomy types		
SES of patients	Elective	Emergency	Total
UE			
Frequency	-	3	3
% of SES group	-	100	100
% of tracheostomy ^a	-	12	8
R			
Frequency	11	16	27
% of SES group	41	59	100
% of tracheostomy	100	64	75
E			
Frequency	-	6	6
% of SES group	-	100	100
% of tracheostomy	-	24	17
Total			
Frequency	11	25	36
% of SES group	31	69	100
% of tracheostomy	100	100	100

^aPercentage of tracheostomies, related to the number of cases. E, employed; R, retired; U, unemployed; SES, socioeconomic status. % rows analyze the percentage of cases for each socio-economic status and percentage of tracheostomy group.

Table IV. Patient classification by stage and tracheostomy.

AJCC stage	Emergency tracheostomy (n=22)	Elective tracheostomy (n=11)	Total (n=33)
III	0	1	1
IV A	16	5	21
IV B	2	5	7
IV C	4	0	4
P-value	0.024 ^a		

^aFischer's exact test.

node metastasis at the time of diagnosis, which represents a sign of poor prognosis due to local and regional extension of the disease.

The scales used for comorbidity evaluation, KPSS and ACE-27, showed that the emergency and elective tracheostomy groups were homogenous, with no significant statistical difference in both comorbidity evaluations (Table V; Mann-Whitney U tests; ACE-27, $P=0.76$; KPSS, $P=0.056$), and was the same across the 2 tracheostomy subgroups (elective, emergency). ACE-27 score varies between 0 and 9, with a median value of 2. In the present study a significant difference between the values on tracheostomy type was not found. KPSS score varied between 30 and 80, with a mean value of 60 and the

Table V. Comorbidity evaluation using ACE-27 and KPSS.

Tracheostomy type	ACE-27	KPSS
Elective		
N	11	11
Minimum	1	50
Maximum	9	80
Mean	3.36	63.64
SD	2.873	14.334
Mode	2.00	50.00
Emergency		
N	25	25
Minimum	0	30
Maximum	9	80
Mean	2.52	57.20
SD	2.58	11.733
Mode	2.00	60.00
Total		
N	36	36
Minimum	0	30
Maximum	9	80
Mean	2.81	60.00
Mode	2.00	60.00
P-value	0.076 ^a	0.056 ^a

^aNot significant. ACE-27, Adult Comorbidity Evaluation 27; KPSS, Karnofski Performance Status Scale; SD, standard deviation

values were similar for both cohorts (63.64 vs. 57.2, elective vs. emergency).

The present study recorded 21 complications in patients that were tracheostomized, with most found in patients that underwent emergency tracheostomy (17 vs. 4/36, emergency vs. elective tracheostomy). The incident rate was 37% in elective tracheostomy and 68% in emergency tracheostomy. For 13 patients there were no incidents associated with tracheostomy (Table VI). The study group was further refined (n=33), eliminating patients with insufficient data regarding the complications or the end-result of the treatment in order to better assess the association between the type of tracheostomy and the complications. The differences between the two groups were statistically significant in all the complications encountered except the blocked tracheostomy tube ($P>0.05$; Fischer's Exact test). In the emergency tracheostomy group, the most frequent type of complication encountered was scar tissue requiring revision, followed closely by bleeding complications. In the elective tracheostomy group the scar tissue and bleeding are present at a much lower frequency than the emergency setting tracheostomy (Table VII). In the present study complications such as preoperative hemorrhage, pneumothorax, chest infection, subcutaneous emphysema, tracheocutaneous fistula or collapsed windpipe that increase the morbidity and mortality of patients were not identified.

The prediction analysis identified ages <60 years as a favorable prediction factor for elective tracheostomy ($P=0.015$;

Table VI. Complications associated with tracheostomy.

Complications of tracheostomy	Elective tracheostomy	Emergency tracheostomy
Preoperative	0	0
Hemorrhage	0	0
Pneumothorax	0	0
Early postoperative	4	17
Chest infection	0	0
Bleeding	2	11
Infected tracheostomy	1	4
Displaced tracheostomy	1	2
Subcutaneous emphysema	0	0
Late postoperative	3	13
Tracheocutaneous fistula	0	0
Scar tissue requiring revision	2	12
Blocked tracheostomy tube	1	1
Collapsed windpipe	0	0

Please note that the sum of complications is different than the frequency number of patients because some of patients had two or more complications on a single visit.

Fischer's Exact test; Table VIII). For emergency tracheostomy, the discovered factor was not relevant ($P=0.441$; Fischer's Exact test; data not shown). In the statistical analysis, the only event considered favorable was the favorable end-result treatment, while the stationary and not favorable end-results were considered not favorable. Thanks to the lack of significant differences between the study cohorts, including age and comorbidities, the two groups formed were homogenous and allowed statistical analysis to be performed in order to find prediction factors.

Discussion

The present study did not investigate disease-free survival or overall survival due to the high mortality associated with hypopharyngeal cancer, as patients typically experience rapid disease progression and/or mortality. This study did not aim to compare treatment efficiency, but to explore potential associations between tracheostomy type and complication rates. Additionally, this study sought to determine whether performing tracheostomies in an elective manner could be beneficial. A significant number of complications including bleeding, scar tissue, infected tracheostomy, displaced or blocked tracheostomy tube were encountered in the present study for patients that underwent tracheostomy, which was in line with the literature (tracheal stenosis, bleeding and displaced tracheostomy tube) (27-29), but no hypoxic events or deaths were recorded associated with tracheostomy. Both types of tracheostomies had the same type of adverse events but with a much higher frequency for the emergency tracheostomy cohort. One of the early causes of mortality after tracheostomy is accidental decannulation and blockage of the tracheal tube, which, in the present study was found to be associated

Table VII. Rate of complications associated with tracheostomy between the two groups.

Complications associated with tracheostomy	Elective tracheostomy (n=11)	Emergency tracheostomy (n=22)	Total (n=33)	P-value
Yes	4	16	20	0.044 ^a
No	7	6	13	

^aFischer's exact test.

Table VIII. Prediction analysis of age impact on evolution following elective tracheostomy.

Age at tracheostomy	F evolution		F or S evolution	
	NF + S	F	NF	F + S
>60 years	5	1	4	2
≤60 years	0	5	0	5
Total	5	6	4	7
P-value	0.015 ^a		0.06 ^a	

^aFischer's exact test. NF, not favorable; S, stationary; F, favorable.

with patients with increased neck thickness, a conclusion also supported by other authors (30,31). Also, tracheostomy tube obstruction with dried secretions and mucous plugs due to poor tracheostomy care were also common complications found in the present study group (31).

In the present study the complication rate was higher for patients that underwent emergency tracheostomy that presented with respiratory arrest. However, increased morbidity or tracheal stenosis was not encountered in the long-term follow-up (31). Other studies found that factors such as body mass index and smoking status (32) were related to tube displacement, and preoperative radiotherapy was a risk factor for tracheostomy-related complications and were more likely to lead to other serious complications (33,34). Levy *et al* (35) identified age, hospital length of stay and several comorbidities (such as cardiac and liver disease) to be significant risk factors of in-hospital mortality in patients admitted with primary tracheostomy complications. Another study conducted by Saroul *et al* (36) highlighted the importance of assessing the nutritional status and inflammatory status of patients, with a prognostic value in head and neck cancers, alongside TNM staging system.

The present study had several limitations. Firstly, the study group was made up of a small cohort from a single tertiary hospital. Furthermore, hypopharyngeal cancer is a rare form of head and neck cancer with a poor prognosis, which impacts the number of follow-ups and data collected. Another limit of the study is the timeline, including as the Covid-19 pandemic negatively impacted the mobility and accessibility of medical centers and patient follow-up. Finally, the size of the study group limited the statistical analysis to solely univariate analysis for prediction factors.

In conclusion, the results of the present study did not find any difference between the end results in patients with emergency or elective tracheostomy. Emergency tracheostomy was associated with a higher rate of the same complications found in the elective tracheostomy study group. However, the prediction analysis results indicated that patients younger than 60 years old in the elective tracheostomy group were associated with more favorable outcomes.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Author's contributions

AGVC and DC conceptualized the study; AGVC curated the data; MAC performed the formal analysis; AGVC carried out the investigation; AGVC and MAC confirm the authenticity of all the raw data. MAC performed the study methodology; AGVC and MAC obtained the resources; MAC obtained the software; DC supervised and validated the study; AGVC visualized the study; AGVC and MAC and wrote the original draft; and AGVC and DC reviewed and edited the manuscript. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The present study was authorized by The Ethics Committee of Titu Maiorescu Doctoral School of Medicine, Titu Maiorescu University of Bucharest (Bucharest, Romania; approval no. 15/2022) and by the Ethics Committee of 'Carol Davila' Central University Emergency Military Hospital (Bucharest, Romania; approval no. 538/2022). All patients provided written informed consent for data usage and publication, and oral consent to participate in the present study was obtained from the prospectively recruited patients.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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