بسم الله الرحمن الرحيم

المجلس القومي السوداني للتخصصات الطبية
SUDAN MEDICAL SPECIALIZATION BOARD

Research Proposal

On

Clinical Presentation, Staging, Management, and Associated Factors of Laryngeal Carcinoma: A Retrospective Multicenter Record-Based Cross-Sectional Study

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Submitted for partial fulfilment of the requirements for the degree of. clinical MD in ORL, H&NS.

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Introduction:

Cancer of the larynx is ranked as the fourteenth most common cancer worldwide, and it is the most common cancer in the head and neck [1].

Laryngeal carcinoma, a malignancy originating from the squamous epithelium of the larynx, is categorized into three regions: supraglottic, glottic, and subglottic. Studies, such as those by Ciolofan et al., have identified squamous cell carcinoma as the most common histopathological finding, often with moderate or well-differentiated characteristics (2). Cancer can develop in any part of the larynx, and the majority can originate in the glottis, where the cure rate is affected by the location of the tumor and tumor staging [1].

Key risk factors include smoking, alcohol consumption, gastroesophageal reflux, chemical exposure, and HPV infections (2)

Aetiology of laryngeal cancer includes; tobacco and alcohol are the most important etiological factors and most likely have a synergistic effect and also Human Papilloma Virus. Work-related exposure to substances such as nickel may also play a role in aetiology. There is no hereditary risk for squamous epithelial carcinoma in the larynx and smoking is the most important risk factor for laryngeal cancer [1]

It is the neoplasm with the largest male to female ratio in most populations. Thus, inadequate data is found in women. The male to female sex ratio for laryngeal cancer is about 10:1. In females, we need to consider other habits in Sudan like the types of foods, smoking used for other purposes (Dokhan for smoothening complexion) and some other materials used for cleaning (clorex, etc) (1)

Common symptoms include hoarseness, throat pain, dysphagia, otalgia, coughing, dyspnoea, and haemoptysis. In some cases, cervical lymphadenopathy may be the only clinical manifestation, necessitating advanced diagnostic tools such as laryngoscopy, CT scans, and MRIs for accurate diagnosis. Most patients are diagnosed at advanced stages (III or IV), limiting treatment options and affecting prognosis. Five-year survival rates vary, with 80% for glottic cancers and 50% for supraglottic cancers. (2)

Specific treatment depends on the location, type, and stage of the tumors. Treatment may involve surgery, radiotherapy, or chemotherapy, alone or in combination.

Justification:

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Laryngeal cancer is one of the most debilitating tumors in which early diagnosis remains best predictor for prognosis. It is present in Sudanese population yet there is very limited literature regarding incidence, risk factors and management plans and outcomes.

Literature Review:

Laryngeal carcinoma, a malignancy originating from the squamous epithelium of the larynx, is categorized into three regions: supraglottic, glottic, and subglottic. Studies, such as those by Ciolofan et al., have identified squamous cell carcinoma as the most common histopathological finding, often with moderate or well-differentiated characteristics. (2)

Laryngeal cancer is a multifactorial disease, associated with a variety of lifestyle factors, environmental factors, and smoking is the predominant risk factor for laryngeal cancer [1].

It is the neoplasm with the largest male-to-female ratio in most populations. Thus, inadequate data is found in women. The male-to-female sex ratio for laryngeal cancer is about 10:1 [3]. Trends over time in mortality were unremarkable for women, as most published data reported in men [4]. Among the few investigations providing data on women was a case-control study from the United States, including 56 females with a relative risk of 28.2 for smokers of >20 cigarettes/day compared with nonsmokers [5]. No data is found up to date related to African and Arab women [6].

Variations in laryngeal cancer incidence rates have been generally related to changes in tobacco and alcohol consumption. However, other relevant factors may be present among women [3]. Among these, diet may have a role in laryngeal carcinogenesis. Poor diet in fruits and fresh vegetables is associated with an increased laryngeal cancer risk [7]

In terms of population attributable risk, tobacco smoking accounted for 78% of laryngeal cancer, alcohol drinking for 34%, and the combination of the two factors together accounts for 82%. Low vegetable intake was estimated as a risk in 30% and for the combination of alcohol, tobacco, and low vegetables diet were estimated as a risk in 85% of the cases of laryngeal cancer [8,9,10].

The question is to identify the predisposing factors of laryngeal carcinomas in Sudan.

Data collected from Mardi Waluyo Hospital reveal that the majority of laryngeal carcinoma cases involve differentiated moderately squamous cell carcinoma. While there is a slight difference in the incidence of well differentiated squamous carcinoma, the findings cell is consistent with global trends. However, these results differ from those observed in Kenya, where most cases were reported as well-differentiated squamous carcinoma. (2)

This study identified 39 cases of laryngeal carcinoma over the past five years, with an average incidence of eight cases per year. Smoking emerged as the most significant risk factor for laryngeal carcinoma, followed by male gender dominance and advanced age, which were also key contributing factors. Residential areas with a predominantly farming population had higher incidences of laryngeal carcinoma. In contrast, alcohol consumption

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and exposure to industrial pollution appeared to have minimal influence on the disease□s occurrence. (2)

Diagnosis was made by different methods which includes, CT/MRI Neck, Flexible loop laryngoscopy and direct micro laryngoscopy.

Most patients are diagnosed at advanced stages (III or IV), limiting treatment options and affecting prognosis. Five-year survival rates vary, with 80% for glottic cancers and 50% for supraglottic cancers. Based on the guidelines provided by the American Joint Committee on Cancer (AJCC), 8th edition 2018, the classification and staging of malignant laryngeal tumors are categorized as follows:

1. Supraglottic: Includes the posterior surface of the epiglottis located near the hyoid bone, aryepiglottic folds, arytenoids, the epiglottis below the hyoid, false vocal cords, and ventricles.

2. Glottis: Encompasses the true vocal cords, anterior commissure, and posterior commissure.

3. Subglottic: Includes the subglottic walls.

Staging Summary:

Overall stage	TNM combination
Stage 0	Tis N0 M0
Stage I	T1 N0 M0
Stage II	T2 N0 M0
Stage III	T3 N0 M0, or T1□T3 N1 M0
Stage IVA	T4a N0□N2 M0, or T1□T3 N2 M0
Stage IVB	T4b any N M0, or any T N3 M0
Stage IVC	Any T, any N, M1

Management of laryngeal cancer treatment options includes radiotherapy, chemotherapy, and surgical intervention. The choice of treatment depends on the tumor stage, location, and overall health of the patient. (2)

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Objectives

General

To describe the clinical presentation, risk factor profile and management plan of laryngeal carcinoma among patients treated at three oncology centers in Sudan between January 2023 and January 2026.

Specific

1. To describe the socio-demographic characteristics (age, sex, occupation, residence) of patients with laryngeal carcinoma.
2. To determine the frequency of documented risk factors (smoking, toombak use, alcohol use, GERD, HPV).
3. To describe the presenting symptoms and signs, tumor site and stage at diagnosis.
4. To determine the association between documented risk factors and (a) tumor site and (b) stage at presentation (early vs advanced).
5. To describe the treatment modalities used and the documented treatment outcomes.

Research methodology

1. Study Design:
A retrospective, multicenter, descriptive cross-sectional study based on review of hospital records. All data are extracted once from existing records, and associations are examined among cases of laryngeal carcinoma only.

2. Study Area:
Three oncology centers in Sudan:
-Shendi Oncology Center (River Nile State)
-Turki Oncology Center (Kassala)
- Marawi Oncological Center (Northern State).

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3. Study Period:
Records of patients diagnosed between 1 January 2023 and 31 January 2026 will be reviewed. Data collection will take one month, and analysis will be conducted over the following two months.

4. Study Population:
Source population: all patients with laryngeal carcinoma registered at the three centers during the study period.
Study population: the source population that meets the criteria below:
4.1. Inclusion Criteria:
1. Histopathologically confirmed primary laryngeal carcinoma
2. Patients aged 20 to 80 years
3. Complete medical records available
4. Sudanese nationality

7. Exclusion Criteria:
1. Non-Sudanese patients
2. Secondary laryngeal carcinoma or metastasis to the larynx
3. Records without a histopathology report or without a TNM stage
4. Benign laryngeal lesions

5. Sampling:
5.1 Sample Size and Sampling Technique
No sample size calculation is required. All eligible records during the study period will be included (complete enumeration). Based on [cite source: previous report of 39 cases over 5 years], about 40 to 60 cases are expected. The small number limits the precision of estimates and the analytic options, and this is acknowledged as a limitation.

8. Data Collection Tool:
A structured data extraction sheet, pre-tested on 5 records (not included in the final analysis) and revised as needed. including:

- A. **Socio-demographic:** age (grouped 18-40, 41-60, over 60), sex, occupation (categories to be defined, for example, farmer, laborer, teacher, metalworker, other), residence (rural/urban), center.
- B. Risk Factors:
    - Cigarette smoking: never, former, current; duration in years; cigarettes per day (pack-years calculated)
    - Toombak use: never, former, current
    - Alcohol use: yes/no/not documented
    - History of GERD: yes/no/not documented
    - HPV status: positive/negative/not tested
- C. Clinical Presentation: Hoarseness, throat pain, dysphagia, otalgia, cough, dyspnea, hemoptysis, cervical lymphadenopathy, duration of symptoms before diagnosis (in months, then grouped).
- D. Diagnostic Workup: IDL finding (site: supraglottic, glottis, subglottic), CT/MRI Neck, Flexible laryngoscopy, Direct micro laryngoscopy
- E. Staging: TNM per AJCC 8th edition 2018 - (reference table given at the top). For analysis, stages will be grouped as early (I-II) and advanced (III-IV).

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- F. Management Plan:
    - Treatment modality: surgery, radiotherapy, chemotherapy, combined modality, palliative or supportive care only, no treatment documented
    - Treatment completion: completed, interrupted, not completed
    - Documented response at end of treatment: complete, partial, none/progression
    - Recurrence: yes/no

9. Data Collection Procedure:
The data will be extracted from patient files, oncology registry books and histopathology reports at each center using the extraction sheet. Patient identity (name, file number, phone) will be replaced with a study code before analysis.

10. Study Variables:
- Dependent: Laryngeal carcinoma site, stage, management outcome
- Independent: Age, gender, smoking, tobacco, alcohol, GERD, HPV, occupation

11. Data Analysis:
Data will be entered and analyzed using SPSS

- **Descriptive:** frequencies and percentages for categorical variables; mean (SD) or median (IQR) for continuous variables, depending on distribution.
- **Analytical:** association of each exposure with tumor site and with stage (early vs advanced) using the chi-square test, or Fisher's exact test when expected cell counts are below 5. Categories will be collapsed where counts are small. A p-value below 0.05 is considered statistically significant.
- If the final number of cases allows, an exploratory logistic regression with at most 1 or 2 variables may be reported with odds ratios and 95% confidence intervals.

12. Ethical Considerations:
- Ethical approval from the Sudan Medical Specialization Board (SMSB) IRB
- Permission from the administrative authorities of oncology centers
- Confidentiality: no names recorded, files identified by study code, the code key kept separately from the data, data stored on a password-protected device accessible only to the research team and used only for this study.

13. Limitations

- Retrospective records may be incomplete, especially for HPV, GERD and alcohol use.
- Results come from three centers and cannot be generalized to all of Sudan.
- Patients who died or defaulted early may be missing from complete records, which may underestimate advanced disease.
- Small sample size limits statistical power and rules out multivariable analysis.
- Associations are among cases only and cannot show risk of developing laryngeal cancer.

- **References**

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Questionnaire for cases: Laryngeal carcinoma clinical presentation, associated factors, staging

And management plan

1_ Age:

20_40y **41_60y** **61_80y**

2_ Gender: female male

3_ Occupation:

teacher farmer labourer miner

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metalworker others

4_ Residence: Rural Urban

5_ history of smoking:

Yes No

***Duration if present**

6_Alcohol consumption:

Yes No

7_ Tobacco usage:

Yes No

8_ Infection with HPV:

Yes No

9_ History of GERD:

Yes No

10_ IDL finding:

Site of Tumor: Supraglottic, glottic, subglottic

11_ Presence of Lymph nodes: how many, which level

12_ presence of Metastasis: Yes No

13- Stage of tumor:

Stage I

Stage II

Stage III

Stage VI

14- clinical presentation:

hoarseness of voice, globus sensation, dysphagia, referred ear pain, neck mass, stridor.

15_ Did the patient need tracheostomy!?

Yes No

16_ Management plan:

Surgical: Conservative laryngeal surgery, non-conservative surgery

Chemoradiotherapy.

17_ Outcome of treatment:

1. **On follow up**
2. **Cured**
3. **Died**

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