Rehabilitation of Laryngectomised Patients Adapted *(ECPG)*

WHO Copyright page

Disclaimer

The present Egyptian CPG (ECPG) represents an adapted CPG with clear outlined methodology and the related references to each guideline were cited. The contributors of these adapted ECPGs have made considerable efforts to ensure that the information upon which they are based is accurate and up to date. The publishers will be pleased to make good any omissions or rectify any mistakes brought to their attention at the earliest opportunity.

Acknowledgements

Chief Editor: Reda Kamel[1]
General Secretary: Ahmed Ragab[2]
General Coordinator: Baleegh Hamdy[3]
Scientific Board: Ashraf Khaled,[4] Mahmoud Abdel Aziz,[5] Mohamed Ghonaim,[6] Tarek Ghanoum,[7] Mahmoud Youssef[8]
Phoniatrics Manager: Mahmoud Youssef[8]
Phoniatrics Executive Manager: Dalia Mostafa[9]
Assembly Board: Amal Saeed[10], Aya Sheikhany[9], Hemmat El-baz[11], Effat Zaky[12]
Grading Board (In alphabetical order)
Ahlam El Adawy[13], Aisha Fawzy[9], Asmaa El-Dessuky[14], Dalia Mostafa[9], Essam Aref[15], Hanan Anwar[14]
Reviewing Board: Elham Magdy[10], Eman Ezzat [14], Sabah Hassan[8], Ibrahim Khaled[16], Shaimaa Farouk[17]

[1]Otorhinolaryngology Department, Faculty of Medicine/ Cairo University, [2]Otorhinolaryngology Department, Faculty of Medicine/ Menoufia University, [3]Otorhinolaryngology Department, Faculty of Medicine/ Minia University, [4]Otorhinolaryngology Department, Faculty of Medicine/Beni-Suef University, [5]Otorhinolaryngology Department, Faculty of Medicine/ Tanta University, [6]Otorhinolaryngology Department, Faculty of Medicine/Mansoura University, [7]Audiovestibular Unit, Otorhinolaryngology Department, Faculty of Medicine/ Cairo University, [8]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Ain Shams University, [9]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Cairo University, [10]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Zagazig University, [11]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Mansoura University, [12]Phoniatrics Unit, Otorhinolaryngology Department/ Faculty of Medicine/ Minia University. [13]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Sohag University, [14]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Menoufia University, [15]Phoniatrics Unit, Otorhinolaryngology Department, Faculty of Medicine/ Assiut University, [16]Otorhinolaryngology Department, Faculty of Medicine/ Zagazig University. [1]7 Radiotherapy & Nuclear Medicine Department Zagazig university

Sincere thanks extend to the secretaries: Samar Hussein and Eman Ragab, as well as the editor: Mohamed Salah

Abbreviations

ASHA: American Speech-Language and Hearing Association.

CPG: Clinical Practical Guideline.

EBP: Evidence-based practice.

ECPG: Egyptian Clinical Practical Guideline.

GRADE: Grading of Recommendations Assessment, Development and Evaluation.

HME: Heat and Moisture Exchange.

TEP: Tracheoesophageal Puncture.

VFSS: Video-Fluoroscopic Swallow Study.

Executive Summary

1- The patient is presented with severe dysphonia, dysphagia and/ or stridor (conditional recommendation).
2- Patient interview and data collection are needed followed by detailed endoscopic, radiological and laboratory investigations (conditional recommendation).
3- If assessment revealed the presence of extensive malignant laryngeal mass, patient should be informed about the possible lines of intervention, including total laryngectomy (conditional recommendation).
4- Pre-operative assessment of voice and swallowing is done (conditional recommendation).
5- Total laryngectomy decision is taken, based on all pre-operative assessment lines and the surgery is done (strong recommendation).
6- The post-operative anatomical and physiological changes have to be discussed with the patient as well as the expected communication and swallowing problems after intervention (conditional recommendation).
7- Post-intervention detailed assessment is needed (conditional recommendation) including:
    - Patient interview and case history.
    - Baseline assessments of communication and swallowing are done & instrumental assessments may be needed for evaluation of the oro-pharyngeal swallow using video-Fluoroscopic swallowing Study (VFSS).
    - Questionnaires about quality of life may be administered.
8- Then the rehabilitation plan is tailored according to the patient conditions and preferences (strong recommendation):
    a. Voice and speech rehabilitation is done by any of the following methods:
        - Tracheo-esophageal puncture using speech valve e.g., Provox or Blom & Singer speech valves.
        - Esophageal speech (unaided) training sessions
        - Electro-larynx or external vibrator.
    b. Swallowing and smell rehabilitation may be needed according to the difficulty (conditional recommendation).
    c. Care of the neck stoma includes measures of protection against dust, dryness and droplet infection. The use of Heat and Moisture Exchanger (HME) system may help protection of the air way (conditional recommendation).

Introduction, purpose, scope and audience

Introduction
Treatment for cancer of the larynx, or voice box, will cause changes in the way patients' voice sound. Phoniatricians can help.

Scope:
The scope of the guideline provides a brief overview of the rehabilitation of total laryngectomy (e.g. current policy and practice) as well as the key issues that will be considered in the guideline that is related to adult patients having total laryngectomy. The guidelines should improve the clinical practice of the clinicians in assessing and treating those patients with the best evidence-based practice methods.

Target audience:
Phoniatricians, ENT surgeons, critical care physicians, radiotherapists, oncology physicians and nurses who are dealing with adults with total laryngectomy.

Methods

Methods of development:

Stakeholder Involvement: Individuals who were involved in the development process. Included the above-mentioned Phoniatrics Chief Manager, Phoniatrics Executive Manager, Assembly Board, Grading Board and Reviewing Board.

Information about target population experiences were **not applicable** for this topic.
Search Method
Electronic database searched:
Pubmed, Medline, Egyptian Knowledge Bank, Medscape, WebMD, Google Scholar

Keywords:
Laryngectomized patients, guideline, rehabilitation, voice

The adaptation cycle passed over: set-up phase, adaptation phase (Search and screen, assessment: currency, content, quality & /decision/selection) and finalization phase that included revision and external reviewing.

Time period searched: From 2002 to 2023.

Results:
Five guidelines were selected for assessment, treatment and rehabilitation of patients having extensive Cancer larynx which necessitates total laryngectomy,[1,2,3,4,5.] The selected guidelines were assessed by four experts in Phoniatrics and the ASHA (2015)[1]. Speech-Language Pathology Medical Review Guidelines had the highest scores as regards to the currency, contents and quality. It was graded by six expert phoniatricians and reviewed by three expert reviewers to improve quality, gather feedback on draft recommendations. The external review was done through a rating scale as well as open-ended questions.

Setting: Primary, secondary and tertiary care centers & hospitals, and related specialties.

Interpretation of strong and conditional recommendations for an intervention

Audience	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action; only a small proportion would not. Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Most individuals in this situation would want the suggested course of action, but many would not
Clinicians	Most individuals should receive the intervention. Adherence to the recommendation could be used as a quality criterion or performance indicator.	Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences.

WHO handbook for guideline development – 2nd ed.
Chapter 10, page 129

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to Decision frameworks (GRADE Working Group 2013) [6]

Grade	Definition
High ++++	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate +++	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low ++	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect
Very Low +	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Recommendations,

The following statements and flowchart were adapted from the Guidelines from (The ASHA, Speech-Language Pathology Medical Review Guidelines (2015) which received the highest scores as regards the currency, contents, and quality.

Recommendations statements:

Accepted statements	
Modified statements	
Added statements	

Clinical questions	Action of recommendation	Evidence quality	Strength of recommendation	Type of study	Reference
Background	Laryngectomy, a surgical removal of all or part of the larynx, is usually indicated to treat cancer of the larynx or vocal folds and adjacent tissues. The patient must learn a new method of communicating after a laryngectomy.	High	Strong Recommendation	Systematic review	7
Pre-operative Phoniatric Evaluation	The Phoniatrician is consulted prior to the surgical procedure to assess the individual's communication and learning skills and plan an appropriate and realistic approach for the patient to regain speech production post-operatively. Every patient should be informed about the expected communication and swallowing problems after intervention.	High	Conditional recommendation	Systematic review	8
Post-operative assessment	Continued phoniatric follow up is important in restoring voice and providing safe and effective swallow function following Laryngectomy. Baseline assessments of communication and swallowing are done & instrumental assessments may be needed for evaluation of the oropharyngeal swallow using (VFSS). The goals of postoperative assessment may help selection of the most appropriate rehabilitation program for every patient.	Low	Conditional recommendation	Observational study	9

Methods of voice restoration	Post-operative visits and duration of visits will vary in relation to the physical and emotional status of the patient, as well as the selected speech production program. Methods of restoration of voice may include: electro-larynx training, esophageal speech training, or tracheoesophageal prosthetic speech training, via the tracheoesophageal puncture (TEP). 1- An electrolarynx is a handheld device held against the throat region (or mouth with an oral adapter) to provide vibrations that allow speech sound to be heard. 2- TEP is a prosthetic device that is placed into a puncture or opening between the trachea and the Pharyngo-esophageal segment that is employed to generate tracheoesophageal speech, prevent aspiration, and maintain the integrity of the opening. 3- Esophageal speech is an un-aided learned method of speech that depends on inducing sound through vibration of air at the pharyngo-esophageal segment (creating a new glottis).	Moderate	Conditional recommendation	Prospective randomized trial & Observational study	10, 11
Swallowing rehabilitation	- Although laryngectomy patients should not aspirate unless their voice prosthesis is leaking, they may have difficulty swallowing solid foods or take significantly longer than others to finish meals. - Swallowing difficulty that may occur after chemo-radiotherapy to the oro/hypopharynx is multifactorial and difficult to treat. Xerostomia, fibrosis, reduced function of constrictors and loss of tongue base bulk, all play a part. Stenosis of the hypo-pharynx and neopharynx is common following treatment for laryngeal and pharyngeal cancer. - Management of swallowing problem depends on the nature of the difficulty.	High	Conditional recommendation	Systematic review	12
Smell & taste rehabilitation	Appetite can also be affected by a significant loss of ability to smell and taste after	Moderate	Conditional recommendation	Randomized controlled study	13

	laryngectomy. Olfactory rehabilitation utilizing the 'polite yawn' has been proposed to help correct this.				
Care of the stoma	- Respiration is altered significantly post-laryngectomy as the patient is now breathing through an open neck stoma bypassing the nasal passages and throat. - As a consequence of this anatomical change, the ability to filter dust, fumes, micro-organisms and to humidify inhaled air is lost. This can result in increased mucus production and crusting of dried secretions. - Patients with trachea-esophageal puncture should commence wearing heat and moisture exchange (HME) devices as soon as possible after laryngectomy, as this may limit exposure to humidity and air pollutant that may impair patient's health and enhance the efficacy of the speech valve. The importance of wearing HME has increased after the pandemic of Covid-19.	Low	Conditional recommendation	Observational study	14

Research needs

There is a need to conduct randomized controlled trials (RCTs) to determine the efficacy of different methods of rehabilitation of voice, smell and swallowing in patients having total laryngectomies.

Monitoring and evaluating the impact of the guideline

Monitoring/ Auditing Criteria:

To assess guideline implementation or adherence to recommendations. This is accomplished if the quality of life of patients with total laryngectomy is improved with no increase in the rate of complications.

Clinicians should be able to:

- Acquire full history from the patient/caregiver.
- Perform preoperative and postoperative assessment of voice, swallowing and smell functions and interpret the results.
- Perform and instruct patients about the methods of rehabilitation of voice, swallowing and smell functions after total laryngectomy.
- Choose the appropriate methods which are suitable for every patient conditions.
- Work in a team of related specialties for the best outcome of the patients.

All clinicians should be aware and informed to consider the following:

- It is crucial to perform frequent assessment visits to detect any problem and deal with it in order improve the quality of life of the patients.
- It is necessary to make sure that the patient is able to use and satisfied with the applied method of rehabilitation.
- Red Flags that need an urgent referral for Assessment/ rehabilitation must be taken into consideration.

Updating of the guideline

Updating Procedure:

Any recommendation of this guideline will be updated when new evidence that could potentially impact the current evidence base for this recommendation is identified. If no new reports or information are identified for a particular recommendation, the recommendation will be revalidated. The focus will be on recommendations supported by very-low- or low certainty evidence and where new recommendations or a change in the published recommendations may be needed.

References

1. ASHA, Speech-Language Pathology Medical Review Guidelines. 2015, 18.
2. Clarke, P., Radford, K., Coffey, M., & Stewart, M. (2016). Speech and swallow rehabilitation in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. The Journal of Laryngology & Otology, 130(S2), S176–S180.
3. Díaz de Cerio Canduela, P., Arán González, I., Barberá Durban, R., Sistiaga Suárez, A., Tobed Secall, M., & Parente Arias, P. L. (2019). Rehabilitation of the Laryngectomised Patient. Recommendations of the Spanish Society of Otolaryngology and Head and Neck Surgery. Acta Otorrinolaringologica (English Edition), 70(3), 169–174.
4. Papadas, T., Charokopos, N., Karamouzis, M. V., Pierakeas, C., Symeonidi, M., Economou, G., & Goumas, P. (2002). Rehabilitation after laryngectomy: A practical approach and guidelines for patients. Journal of Cancer Education, 17(1), 37–39.

5. Pfister, D. G., Laurie, S. A., Weinstein, G. S., Mendenhall, W. M., Adelstein, D. J., Ang, K., Wolf, G. T. (2006). American Society of Clinical Oncology clinical practice guideline for the use of larynx-preservation strategies in the treatment of laryngeal cancer. Journal of Clinical Oncology, 24(22), 3693–3704.
6. Mustafa R et al. (2013). The GRADE Approach is reproducible in assessing the quality of evidence of quantitative evidence. J Clin Epidemiol. 66(7):736-42.
7. Lagha, A., Chraiet, N., Labidi, S., Rifi, H., Ayadi, M., Krimi, S., Allani, B., Raies, H., Touati, S., Boussen, H., Kochbati, L., & Mezlini, A. (2013). Larynx preservation: What is the best non-surgical strategy? Critical Reviews in Oncology/Hematology, 88(2), 447–458.
8. Fitzgerald E, Perry A (2016), Pre-operative counselling for laryngectomy patients: a systematic review. J Laryngol Otol.130(1), 15-20
9. Coffey M, Tolley N, Howard D, Drinnan M, Hickson M. (2018) An Investigation of the Post-laryngectomy Swallow Using Videofluoroscopy and Fiberoptic Endoscopic Evaluation of Swallowing (FEES) Dysphagia, 33, (3), 369-379
10. Harms, K., Post, W. J., Van De Laan, K. T., Van Den Hoogen, F. J. A., Eerenstein, S. E. J., & Van Der Laan, B. F. A. M. (2011). A prospective randomized multicenter clinical trial of the Provox2 and Groningen Ultra Low Resistance voice prostheses in the rehabilitation of post-laryngectomy patients: A lifetime and preference study. Oral Oncology, 47(9), 895–899.
11. Liao J, (2016). An Acoustic Study of Vowels Produced by Alaryngeal Speakers in Taiwan American Journal of Speech-Language Pathology, 25, 481–492.
12. Mendez, A., Wihlidal, J., Eurich, D., Nichols, A., MacNeil, S., & Seikaly, H. (2022). Validity of functional patient-reported outcomes in head and neck oncology: A systematic review. Oral Oncology, 125, 105701.
13. Gürbüz, D., Kesimli, M. C., Bilgili, A. M., & Durmaz, H. Ö. (2022). Olfactory rehabilitation and olfactory bulb volume changes in patients after total laryngectomy: a prospective randomized study. Brazilian Journal of Otorhinolaryngology, 88(4), 607–612.
14. Boot I., Roth M., Skovgaard R, Kelley A., Tiedemann J., Smedby T. Esmann J. and Vrijhoef H. (2023). CO191 Effectiveness of New Generation Heat and Moisture Exchangers and Adhesives for Laryngectomized Patients in Portugal Value in Health,; 26 (12) S48-S48

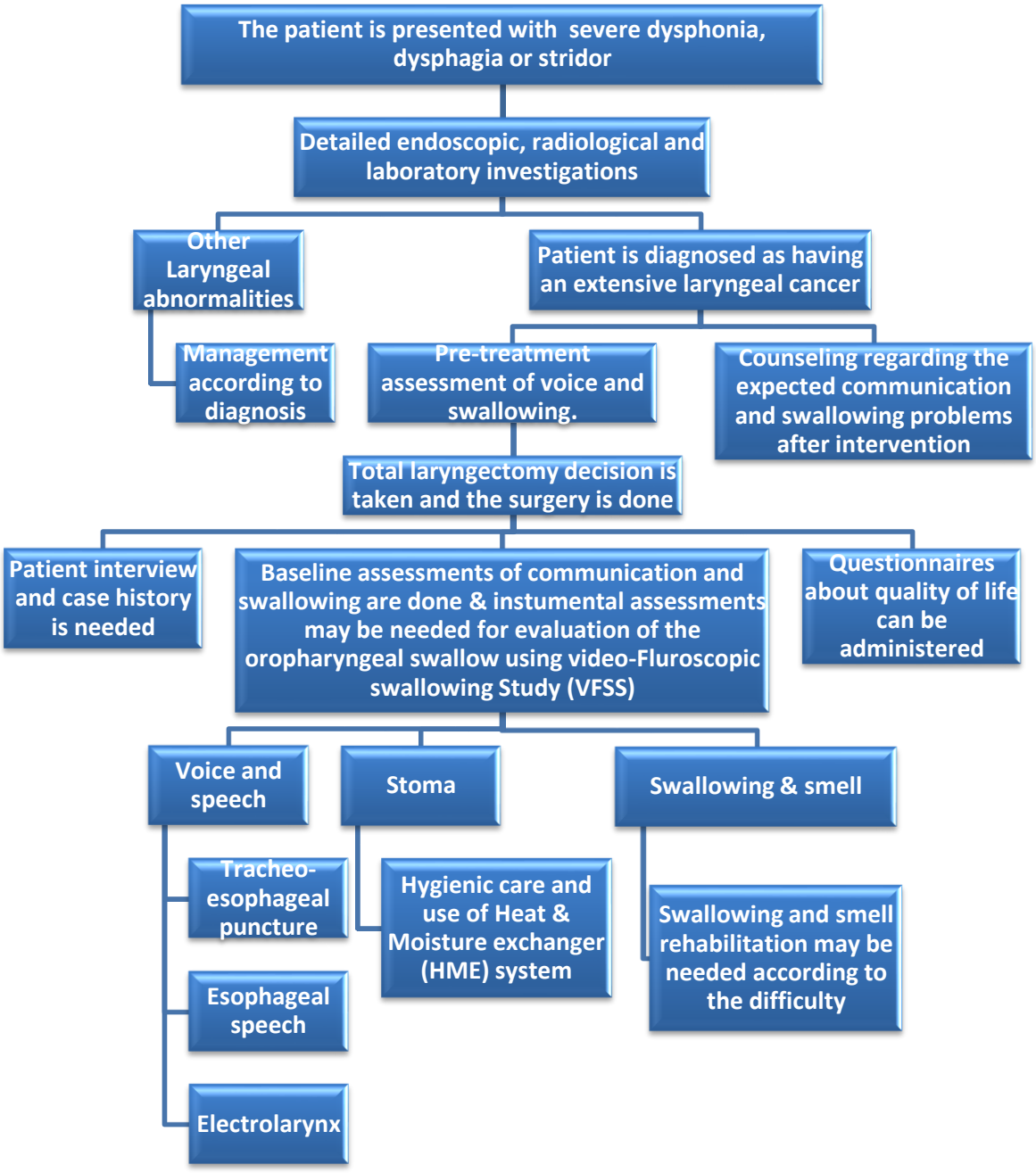
Annexes

Editorial Independence:

- This guideline was developed without any external funding.
- All the guideline development group members have declared that they do not have any competing interests.

Annex 1: Guideline Flowchart

Flow chart for rehabilitation of voice & swallowing after total laryngecomy



Annex 2:

Tables of appraisal of selected guidelines:

1- Currency (table 1)

Guideline name	Responsible organization	Date of publication	Expected review date
Speech-Language Pathology Medical Review Guidelines	American Speech-Language-Hearing Association (ASHA)	2015	Unknown
clinical practice guideline for the use of larynx-preservation strategies in the treatment of laryngeal cancer	American Society of Clinical Oncology	2006	Unknown
Speech and swallow rehabilitation in head and neck cancer	United Kingdom multidisciplinary guideline	2016	Unknown
Rehabilitation of the Laryngectomised Patient.	Spanish Society of Otolaryngology and Head and Neck Surgery	2019	Unknown
Rehabilitation after laryngectomy: A practical approach and guidelines for patients	ORL Department- Patrah University- Greece	2002	Unknown

2- Content (table 2)

	ASHA	American society of clininical oncology	Spanish society of otolaryngology	UK multidisciplinary guideline	practical approach and guidelines for patients
Credibility	6	9	9	9	7
Observability	9	8	6	6	6
Relevance	9	6	5	3	6
Relative advantage	8	6	5	3	3
Easy to install	8	6	3	6	5
Compatibility	8	6	3	3	3
Testability	8	6	6	6	3
Total Score	56	47	37	36	33

3- Quality (Table 3)

	ASHA	American society of clininical oncology	Spanish society of otolaryngology	UK multidisciplinary guideline	practical approach and guidelines for patients
Transparency	NR	A	C	C	C
Conflict of interests	NR	A	A	NR	NR
Development group	NR	A	C	C	NR
Systematic review	C	B	C	C	B
Grading of evidence	C	A	B	C	C
Recommendations	C	A	A	C	B
External review	NR	A	C	C	NR
Updating	B	NR	NR	NR	NR

Annex 3: The risks and benefits of added and/or modified statements

	Statement	Risk	Benefit
Pre-operative Phoniatric Evaluation	The Phoniatrician is consulted prior to the surgical procedure to assess the individual's communication and learning skills and plan an appropriate and realistic approach for the patient to regain speech production post-operatively. Every patient should be informed about the expected communication and swallowing problems after intervention.	The patient may become worried about the expected problems of the surgery, this may make him more reluctant in performing surgery	The physician and the patient are aware about all upcoming steps and can choose together the most appropriate approach of rehabilitation according to patient's condition.
Post-operative assessment	Continued phoniatric follow up is important in restoring voice and providing safe and effective swallow function following Laryngectomy. Baseline assessments of communication and swallowing are done & instrumental assessments may be needed for evaluation of the oropharyngeal swallow using (VFSS). The goals of postoperative assessment may help selection of the most appropriate rehabilitation program for every patient.	Many problems can't be dealt with if the patient is not exposed to continued assessment. This may affect the psychosocial well-being of the patient.	Early detection and management of problems is enabled with regular post-operative assessment.
Methods of voice restoration	Post-operative visits and duration of visits will vary in relation to the physical and emotional status of the patient, as well as the selected speech production program. Methods of restoration of voice may include: electro-larynx training, esophageal speech training, or tracheoesophageal prosthetic speech training, via the tracheoesophageal puncture (TEP). 1- An electrolarynx is a handheld device held against the throat region (or mouth with an oral adapter) to provide vibrations that allow speech sound to be heard. 2- TEP is a prosthetic device that is placed into a puncture or opening between the trachea and the Pharyngo-esophageal segment that is employed to generate tracheoesophageal	The patient may not be able to restore his voice after surgery due to lack of postoperative visits. Also failure of one method of voice rehabilitation may lead to disappointment and affection of the patient quality of life.	Variable methods of voice rehabilitation are discussed with the patient. This lead to better selection and early management of any failure during the rehabilitation process.

	speech, prevent aspiration, and maintain the integrity of the opening. 3- Esophageal speech is an un-aided learned method of speech that depends on inducing sound through vibration of air at the pharyngo-esophageal segment (creating a new glottis).		
Swallowing rehabilitation	- Although laryngectomy patients should not aspirate unless their voice prosthesis is leaking, they may have difficulty swallowing solid foods or take significantly longer than others to finish meals. - Swallowing difficulty that may occur after chemo-radiotherapy to the oro/hypopharynx is multifactorial and difficult to treat. Xerostomia, fibrosis, reduced function of constrictors and loss of tongue base bulk, all play a part. Stenosis of the hypo-pharynx and neopharynx is common following treatment for laryngeal and pharyngeal cancer. - Management of swallowing problem depends on the nature of the difficulty.	Lack of awareness of the patient about swallowing problems and methods of management may affect the health of the patient due to poor feeding.	Proper management of swallowing problems improves the health and quality of life of patients after total laryngectomy.
Smell & taste rehabilitation	Appetite can also be affected by a significant loss of ability to taste and smell after laryngectomy. Olfactory rehabilitation utilizing the 'polite yawn' has been proposed to help correct this.	Loss of smell after total laryngectomy may affect the appetite of the patient, especially if the patient does not know that he can regain smell ability with special rehabilitation program	Improving small after total laryngectomy is one of the important aspects of that lead to better and near normal life.
Care of the stoma	- Respiration is altered significantly post-laryngectomy as the patient is now breathing through an open neck stoma bypassing the nasal passages and throat. - As a consequence of this anatomical change, the ability to filter dust, fumes, micro-organisms and to humidify inhaled air is lost. This can result in increased mucus production and crusting of dried secretions.	Exposure to humidity and air pollutant through the stoma may impair patient's health and increases the risk of infection.	Care of the stoma and Use of HME may protect patient and enhance the filtering of the airway. This may also decrease the risk of respiratory tract infection

	- Patients with trachea-esophageal puncture should commence wearing heat and moisture exchange (HME) devices as soon as possible after laryngectomy, The importance of wearing HME has increased after the pandemic of Covid-19.		