Tracheoesophageal Voice Rehabilitation after Total laryngectomy: Primary Versus Secondary Tracheoesophageal Puncture Ibrahim Ahmed Khaled*, Alaa El-Din Mohammed El-Feky, Tarek Abd-Elmoaty Omran, Khaled Abd-Elshakour Mohammed, Amal Said Quriba, Ali Mohammed Awad

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ASTRACT

Background: Voice prosthesis is the current standard for post laryngectomy rehabilitation. Several clinical factors can affect the functional outcomes of voice prosthesis. Various complications are recorded with voice prosthesis. **Objective:** This study aimed to compare the results of primary and secondary provox insertion in patients with advanced laryngeal carcinoma undergoing total laryngectomy.

Patients and Methods: Randomized-controlled clinical study included 24 patients with provox voice prosthesis rehabilitation 12 had primary tracheoesophageal puncture and 12 had secondary tracheoesophageal puncture. All patients were evaluated for successful voice restoration and complications rates.

Results: Short-term success rate was 92% in the primary group and 83% in the secondary group. Long-term success rate was 83% in the primary group and 75% in the secondary group. Success rates were higher in the primary group but without statistically significant difference. Complications rate in the primary group was 58.3% and in the secondary group 66.6%. Complications rate was higher in the secondary group but without statistically significant difference. Complications rate and good voice results, which improve with time. Primary provox insertion had better success rates and fewer complications. Periprosthetic leak is the most common complication.

Keywords: Total laryngectomy, Voice rehabilitation, Tracheoesophageal puncture, Provox prosthesis.

INTRODUCTION

Laryngeal cancer represents the second most tumor of the region of head and neck and upper aerodigestive tract following carcinoma of the oral cavity with a predominant histological type of squamous cell carcinoma $^{(1, 2)}$.

Total laryngectomy (TL) is the best surgical approach in advanced laryngeal cancer. It is an aggressive surgery compromising many vital functions of the patients including speech communication with an adverse impact on patients' physical, functional and psychological health resulting in a decreased quality of life. Restoration of speech is an integral part of rehabilitation of laryngectomees and can be achieved by esophageal speech, artificial larynx, or surgical creation of tracheoesophageal fistula to insert voice prosthesis ⁽³⁾. Tracheoesophageal puncture (TEP) and voice prosthesis insertion allows the patient to speak through tracheoesophageal speech. When the stoma is occluded it causes shunting of the expired air through the one way valve into the esophagus. The expired air causes vibrations of the upper esophageal and neopharyngeal segment with production of voice ⁽⁴⁾.

Prosthetic voice rehabilitation has numerous advantages including immediate voice production, higher success rate, and the ability to produce fluent, intelligible and natural sounding voice in contrast to other speech rehabilitation methods so that TEP with prosthetic voice rehabilitation is considered the gold standard for post TL voice rehabilitation ⁽⁵⁾. TEP) can be made at the time of total laryngectomy (primary

TEP) or late afterwards (secondary TEP). Primary TEP has the advantages of avoiding a second operation with immediate postoperative voice acquisition but it is associated with increased risk of surgical complications such as pharyngocutaneous fistula (PCF), stomal stenosis, and local infection around prosthesis. Secondary TEP ensure proper wound and tracheostomal healing with better patient satisfaction after being aphonic for certain duration ⁽⁶⁾. This study aimed to compare the results of primary and secondary provox insertion in patients with advanced laryngeal carcinoma undergoing total laryngectomy.

PATIENTS AND METHODS

This randomized-controlled clinical study was carried out in ORL-HNS Department, Zagazig University from 2017 to 2020. Sample size was designed to be 24 cases, (**Group A**) or primary group: (12) cases with advanced laryngeal carcinoma operated by total laryngectomy and provox insertion at the same operation. (**Group B**) or secondary group: (12) cases actually operated by total laryngectomy and provox insertion is made as a separate operation.

Inclusion criteria in the primary group: Patients with advanced laryngeal carcinoma T3 & T4 laryngeal lesions, fit for surgery, and intact (T0) party tracheoesophageal wall.

Inclusion criteria in the secondary group: Patients motivated for TEP, patent stoma, adequate pulmonary support, good visual acuity and good manual dexterity.



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Exclusion criteria in the primary group: Partly affected tracheoesophageal wall, patients with excessive or low tracheal resection, and excessive pharyngeal resection.

Exclusion criteria in the secondary group: Patients with rigid neck, following radiotherapy, Patients with dysphagia & proved to have pharyngeal stenosis by Barium swallow, recurrent disease and inadequate depth and diameter of the stoma.

General Exclusion Criteria: Patients with arthritis of fingers, deformed fingers, tremors and impaired vision, manual workers, patients unfit for surgery and patients who are not interested for TEP insertion.

Ethical approval:

An approval of the study was obtained from Zagazig University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

Preoperative Assessments:

History: Group (A): Detailed history with stress on laryngeal manifestations. History of radiotherapy or chemotherapy. History of chronic diseases eg chronic chest disease or DM. Comprehensive evaluation and motivation of the patient and of the relatives who were involved in patient's care. This is done with counseling and interaction with other patients. **Group** (B): History of radiotherapy or chemotherapy. History of dysphagia. Comprehensive evaluation and motivation of the patient and his relatives.

Clinical examination: Group (A): Full ENT examination especially endoscopic examination of larynx and pharynx. Examination of the neck contour for planning for the possible contour of the stoma. Group (B): Tracheostoma assessment (Figure 1) (to exclude perichondritis, infection, granulations & stenosis). Assessment of neck contour & stoma occlusion ability. Assessment of recurrence.

Investigations: Group (A): Radiological evaluation with CT neck with contrast, biopsy from laryngeal lesion to confirm malignancy, metastatic workup, pelviabdominal ultrasound, chest X-ray and CT if needed, CT brain if needed, bone scan or skeletal survey and routine laboratory investigations. **Group** (B): Barium swallow for patients complaining of dysphagia and routine laboratory investigations.

Patients who will fulfill selection criteria will be divided into two matched groups:

Group A: operated with total laryngectomy and primary provox insertion. **Group B:** operated with total laryngectomy and secondary provox insertion (3 months after operation).

The duration of follow up: 6 months post operatively. **Postoperative assessment for both groups:**

Clinical assessment of tracheal stoma and neck contour. Direct examination and visualization of the speech valve (Figure 2). Postoperative clinical assessment of wound healing, local area around the prosthesis, leakage, infection, fistula formation and stability of the prosthesis. Short-term success rate, which is defined as the immediate postoperative acquisition of intelligible speech and long-term success rate, which is defined as using TE voice consistently as the primary mode of communication were assdssed.



Figure (1): Preoperative examination of tracheal stoma.



Figure (2): (A) Postoperative view of speech valve (Primary TEP).



Figure (2): (B) Postoperative view of speech valve (Secondary TEP).

Statistical Analysis

The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version **20**. Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as mean \pm SD (Standard deviation) and/or median and range.

All statistical comparisons were two tailed with significance Level of P-value ≤ 0.05 indicates significant, p <0.001 indicates highly significant difference while, P > 0.05 indicates non-significant difference.

RESULTS

The aim of this randomized-control study which was conducted in ORL-HNS Department, Zagazig University through 2017-2020 was to assess results of primary provox insertion in relation to secondary provox insertion. There were 12 patients (50%) with primary provox insertion (group A) with age ranged from 28 to 63 years and 12 patients (50%) with secondary provox insertion (group B) with age ranged from 57 to 71 years. All patients were males as laryngeal cancer is more common in males. In the present study, among 24 patients in both groups 21 patients were able to speak using voice prosthesis with total short-term success rate of 87.5%. Short-term success rate in the primary group was 92% as 11 patients acquired intelligible speech using their TEP prosthesis for phonation, while short-term success rate in the secondary group was 83% as 10 patients were able to phonate using TEP prosthesis. Short-term success rate was higher in the primary group but without significant statistical difference (Table 1).

In the present study, two patients did not use TE speech as the main method of verbal communication after acquisition of intelligible speech in the postoperative period, one patient in each group. Longterm success rate in the primary group was 83% as 10 patients used TE speech consistently, while long-term success rate in the secondary group was 75% as 9 patients used TE speech as the mean method of verbal communication. Long-term success rate was higher in the primary group but without significant statistical difference (Table2). The overall complications were recorded in 15 cases (62.5%), 7 cases in the primary group (58.3%) and 8 cases in the secondary group (66.6%). Complications rate was higher in the secondary group but without statistically significant difference (Table 3).

Short-term success rate									
	Primary group		Secondary group		Total		P- value		
Success	11	92%	10	83%	21	87.5%	0.546		
Failure	1	8%	2	17%	3	12.5%			
Total	12	100%	12	100%	24	100%			

 Table (2): Showing long-term success rate

Long-term success rate									
	Primary group		Secondary group		Total		p- value		
Success	10	83%	9	75%	19	79%	0.623		
Failure	2	17%	3	25%	5	21%			
Total	12	100	12	100	24	100			
		%		%		%			

 Table (3): Showing the overall complications of provox insertion

	Primary group			ondary roup	Total	
Complication	7	58.3%	8	66.6%	15	62.5
No Complication	5	41.7%	4	33.3%	9	37.5%
Total	12	100%	12	100%	24	100%

DISCUSSION

The use of a prosthetic valve has become an important method for rehabilitation after total laryngectomy TEP is an acceptable method of voice restoration, with better acquisition in speech intelligibility and fluency. Primary TEP can be performed at the same time of laryngectomy and secondary TEP at a later stage ⁽⁷⁾.

In our present study success rates was higher in the primary group but without statistical significance. Our results are comparable to the results of other investigators using different types of prostheses as Provox prosthesis used by Hilger and Schouwenburg ⁽⁸⁾. Cheng *et al.* ⁽⁹⁾ study reported statistically significant difference in rate of success between 1ry and 2ry provox insertion with P-value = 0.03 being more in primary provox insertion. In contrary, Cruz et al. (10), reported success rate of 73.7% in the secondary group and 67.2 % in the primary group being higher in the secondary group but statistically insignificant. Although the tendency toward higher success rates for primary TEP may be explained by the smaller number of patients who underwent secondary TEP, it is possible that immediate rehabilitation with earlier voice restoration exerts a positive psychological impact, and imparts a more intense motivation for oral communication ⁽³⁾.

Alternatively, the central command and plasticity of the esophageal musculature of patients after secondary TEP may be deficient because the prolonged absence of the larynx eliminated the need for an airway protection mechanism. In addition, these patients commonly develop other adaptive speech mechanisms, such as pharyngeal phonation, that can disturb subsequent vocal rehabilitation with TEP and voice prosthesis ⁽¹¹⁾.

The present study revealed no statistically significant difference between 1ry and 2ry provox insertion as regards surgical complications and prosthesis related complications with P-value > .05, which goes in run with **Cheng** *et al.* ⁽⁹⁾ study in which there was no significant difference between both groups regarding complications with P-value = 0.4. Also **Emerick** *et al.* ⁽¹²⁾ study reported no statistically significant difference between 1ry and 2ry provox regarding site leakage, spasm and stenosis with P-value > .05.

Boscolo-Rizzo *et al.* ⁽³⁾ reported that primary and secondary TEP were equally safe and effective. By contrast **Maniglia** *et al.* ⁽¹³⁾ stated that long-term speech restoration appears to be more successful in the primary procedure than in the secondary (although not statistically significant). Although the complication rate (minor type) in the primary procedure may be higher, they felt that it is still justified because in their study, only a small number of patients underwent the secondary procedure.

CONCLUSION

Primary voice rehabilitation of the laryngectomized patients, besides eliminating the need for a second operation, may have important advantages such as shorter duration of postoperative aphonia, earlier voice restoration and more rapid acquisition of fluent speech. It is as successful as secondary tracheoesophageal puncture in terms of final voice quality. Secondary TEP ensure optimal wound healing and offers reasonable expectations. The acquisition of speech as well as the incidence of complications was not modified by the intention whether primary or secondary.

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