

## **Quality of life in patients with laryngectomy, endoscopic tracheoesophageal voice restoration, and surgery**

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### **ABSTRACT**

**INTRODUCTION:** Esophageal voice, electrolarynx, and voice prostheses with primary or secondary tracheoesophageal puncture (TEP) comprise voice rehabilitation techniques for laryngectomized patients. Our objective was to evaluate the impact of the TEP procedure on patient quality of life (QOL) as a secondary procedure with flexible endoscopy compared as a primarily procedure.

**MATERIALS AND METHODS.** We conducted a non-randomized and prospective study from January 2000 through May 2006 in patients after total laryngectomy who underwent voice rehabilitation. Three groups were formed, including Group 1 comprising patients after total laryngectomy without prosthesis, group 2 with laryngectomized patients with a secondary TEP procedure, and Group 3, with patients with a primary TEP procedure. The endoscopic technique was with a flexible endoscopy (Olympus 1T140 Ltd., Tokyo, Japan).

Descriptive statistics were carried out with Student *t*, ANOVA, and  $\chi^2$  tests.

**RESULTS.** Forty five patients (36 males, 80%, and nine females, 20%) with an average age of 57.125 years participated in the study. The University of Washington Quality-of-Life (UW-QOL) evaluation was statistically significant regarding the variables of swallowing ( $p = 0.006$ ), speech ( $p = 0.004$ ), taste ( $p = 0.04$ ), mood ( $p = 0.02$ ), and anxiety ( $p = 0.05$ ), as well as the quality-of-voice variable, all these better in Group 2.

**CONCLUSIONS:** Tracheoesophageal restoration as a secondary procedure via endoscopy offers fewer complications, improved patient well-being and voice quality, and is more patient-accessible as compared with other types of rehabilitation.

**KEY WORDS:** quality of life, rehabilitation, voice prostheses, endoscopy.

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## INTRODUCTION

Cancer of the larynx is the second most common site of cancer of the upper aerodigestive tract, the most prominent histologic type being squamous cell cancer. There are 136,000 new cases diagnosed throughout the world, with 5-year survival of 68%.<sup>1</sup>

Treatment for cancer of the larynx comprises the cure for cancer, whether by surgery, radiochemotherapy, and at present preservative surgery and/or laser. Care for the functional and social sequelae that accompany a total laryngectomy comprises voice rehabilitation designed to aid the patient in having verbal communication, which allows the patient to reintegrate into society. There are three types of voice rehabilitation for the patient: a) esophageal voice; b) artificial larynx, and c) voice prosthesis by tracheoesophageal puncture.<sup>2</sup>

Prosthesis placement can be performed primarily via transoperatorily, and secondarily via endoscopy by means of a tracheoesophageal puncture (TEP)<sup>2</sup> (Singer, Blom 1981). This is at present the best method for voice rehabilitation post-laryngectomy because it achieves phonation in 80–90% of cases<sup>1–3</sup> and with a low rate of complications.<sup>4</sup> Nonetheless, despite its being best choice disadvantages have been reported concerning placement of the primary prosthesis (surgical) in comparison with secondary placement via endoscopy.<sup>5</sup> The world literature refers high success rates when this is placed in a primary manner, which is not reproducible at our Institute, thus diminishing the success of complete rehabilitation by means of this method. The objective of our study was to evaluate quality of life (QOL) in patients with voice prosthesis placed during the surgical process or by endoscopy once cancer therapy has been concluded.

## MATERIALS AND METODOS

We carried out a clinical non-randomized assay during the period from January 2000 through May 2006. We formed three groups that were composed as follows: Group 1, patients with laryngectomy with prosthesis placement; Group 2, prosthesis placement via endoscopy on finalization of oncologic treatment, and Group 3, prosthesis placement during oncologic surgery. We analyzed clinical, demographic, and treatment variables. We utilized Blom-Singer or Bivona prostheses. Inclusion criteria comprised patients operated on with total laryngectomy due to cancer of the larynx, both sexes, submitted to voice rehabilitation therapy, and completing the Washington University Quality-of-Life Questionnaire. The value of each variable was quantified as 100–0, the best score being better well-being and functionality. (Outstanding was a score of 100, 80 was good, 60 was fair, and 40, deficient.) The endoscopic technique was with a flexible endoscopy (Olympus 1T140 Ltd., Tokyo, Japan).

We performed descriptive statistics of the variables with frequencies, central tendency, and dispersion measurements. We conducted Student *t*, ANOVA, and  $\chi^2$  tests, and utilized Stata 7 statistical package software.

## RESULTS

A total of 45 patients were included in the study who complied with study inclusion criteria, 36 males (80%) and nine females (20%), mean age was 57.125 years (range, 34–76 years). Age and weight had no statistical significance and were comparable ( $p = 0.26$ ). Twelve patients were controlled diabetics and seven were hypertensive. Pre-operative treatments included neoadjuvant chemotherapy in five patients and pre-operative radiotherapy in nine. Thirty one patients received post-operative radiotherapy as adjuvant treatment. In Group 1 (surgery without prosthesis), there were 16 patients with mean age of 57.12 years (range, 34–76 years): seven patients has esophageal voice, four patients had whispering voice, and five had an artificial larynx.

Group 2, the group in which patients had a prosthesis placed via endoscopy, consisted of 19 patients with mean age of 62.73 years (range, 34–83 years), while Group 3 patients had prosthesis placement during the trans-operative period with 10 patients, mean age 56.21 years (range, 30–72 years). Complications were as follows: in Group 1, dysphagia (one case), aphonia (one case), and sub-maxillary edema and pain (one case); in Group 2, fistular enlargement (one case), infection in the prosthesis placement zone (one case), pharyngocutaneous fistula (one case), and prosthesis extrusion (one case), and in Group 3, fistula enlargement (two cases) and dysphagia and stenosis (one case); the global rate of complications among the three groups was 20%.

Results of the statistical analysis in the Washington University Questionnaire analysis were the following: in Group 2, the swallowing variable with 78.9% (Good) in comparison with the following groups: Group 1 with 75% (Good) and with a low score in Group 3, with 50% (Fair), which was statistically significant ( $p = 0.006$ ).

Taste showed statistical significance because Groups 1 and 2 achieved a score of 100% (Good) and Group 3, a score of 80% (Fair) ( $p = 0.04$ ). Mood was demonstrated in Group 1 with 100% (Good), in Group 2 with 94.7% (Good), and in Group 3, with 70% (Good) ( $p = 0.02$ ), while anxiety was shown at 100% in Group 1 (Good), Group 2 with 94.7% (Good), and and in Group 3, with 90% (Good) ( $p = 0.05$ ). The following variables contemplated in the questionnaire were not statistically significant (see Table 1)

## DISCUSSION

On accepting submission to larynx surgery, the patient should accept the new situation of the disease and know which the post-surgical changes, care, and rehabilitation are to be, thus lending support to the phoniatic rehabilitation that is directed toward helping the patient find novel ways and methods for new achievement of verbal communication for the patient's reintegration into society. Voice rehabilitation has been attempted since 1873, when Billroth and Gussenbauer conducted the first total laryngectomy.<sup>6</sup> Then, first efforts at voice rehabilitation were performed, leaving in place a tracheoesophageal fistula. Later, in 1874 Gussenbauer described the use of the first artificial larynx;<sup>9</sup> however, esophageal voice continued to be the voice rehabilitation method-of-choice at some centers. The three voice rehabilitation types for laryngectomized patients include the following:

a) Esophageal voice: b) Artificial larynx: c) Voice prosthesis or tracheoesophageal voice: At the Mexico City-based Instituto Nacional de Cancerología (INCan), esophageal voice is considered the method-of-choice for the rehabilitation of patients who have been submitted to a total laryngectomy, because the results tend to be satisfactory in terms of ability to communicate, and the procedure does not imply a great economic investment for patients. Notwithstanding this, the disadvantage of this procedure lies in the fact that it requires time for its practice and perfection, and the

majority of patients seen at the Institute do not achieve complete rehabilitation, the use of an artificial larynx; however, the sound that is produced is not always intelligible for persons around the patient, its use is limited because of its excessive cost, and it is usually resorted to when different voice rehabilitation techniques have failed. Voice prosthesis is the most profitable method in terms of costs and benefits; it is a good option because the patient is able to have oral communication immediately after its placement, because it does not imply the investment of too much time for voice emission<sup>5</sup>, and because it is at present the best method for vocal rehabilitation post-total laryngectomy in that phonation is achieved in 80–90% of cases<sup>7,8</sup>. Compared with our study, we found a phonation success rate of 100%, the main factor being information from the patient as well as from the treating physician, and psychological and phoniatry help, which is afforded to the patient prior to and after the surgical procedure among options for his/her voice rehabilitation. The Voice and Speech Laboratory at the Massachusetts Eye and Ear Infirmary reviews primary- and secondary-type prosthesis placement with success rates ranging from 30–93%<sup>2</sup>. The success of tracheoesophageal voice restoration includes several factors such as pre-operative evaluation of patients as potential candidates for the procedure, and the surgeon's knowledge of the disease, his/her ability, and experience.<sup>2</sup>

The endoscopic technique at our Institute consists of establishing a tracheoesophageal puncture performed by means of a flexible endoscopy (Olympus 1T140 Ltd., Tokyo, Japan) in patients, and consists of placing a needle from the trachea to the esophagus. The needle is utilized for directing a metal guidewire, and later a catheter, from the trachea to the esophagus to serve as a stent. After 4–6 days<sup>8</sup>, the catheter is exchanged for a voice prosthesis, and voice rehabilitation can proceed.

This simple procedure requires some minutes in the physician's office under direct vision, and is safe and reproducible. Patients need no antibiotic prior to the procedure, and initiate oral feeding immediately, and are treated as ambulatory patients. Prosthesis placement is not exempt from major or minor complications. The majority of the former have a repercussion on the patient's general health status, while minor complications involve local repercussions, the majority of which are lesser complications. Order of appearance are infections, generally candida colonization that occurs in 6% of cases, and in our study, surgical or endoscopy-related complications, which were reflected in 3.4% of cases<sup>2,9,10</sup>.

The material of which the prosthesis is made is silicon, which possesses excellent mechanical properties, but which is susceptible to being colonized by fungi, the latter forming concretions in the esophageal portion of the prosthesis that give rise to an obstruction of the air flow and to an increase in resistance to the passage of air, this manifesting itself in voice-quality diminution. Colonization is favored by the decrease of saliva in irradiated patients; this is resolved by changing the prosthesis, because administration of antifungals does not provide satisfactory results<sup>13</sup>.

Fistular displacement and migration, stoma stenosis, and the prosthesis hitting the posterior wall of the hypopharynx are reported together in 32% of cases<sup>2</sup>, and in our study, in 11.11% of cases. The increase or closing of the stoma is reported in 19–22% of cases, and in our study, in 8.33%. Other complications that presented in our work comprised the leaking of material such as saliva through or around the prosthesis. There are other complications that were not reported in our study, including immediate aphonia or dysphonia, pharyngeal spasm or hypertonicity, granuloma of the tracheostoma, excessive discharge of mucus through the tracheostoma, or stomach gas, cough, stomal stenosis, and other major complications such as septicemia, aspiration-

associated pneumonia, esophageal perforation, pneumomediastin with mediastinal abscess, cellulitis, and cervical osteomyelitis. nother factor that has been documented is pre- or post-surgical radiotherapy, which causes fistular enlargement, pharyngeal stenosis that causes dysphagia, and diminution of voice insufflation, which permits adequate function of the prosthesis The decision of prothesis placement during the trans-operative period or secondary procedure via endoscopy has not been well-defined, and proceeds according to the surgeon's experience and ability. One reason that some surgeons do not perform prosthesis placement is that the anatomic structures suffer from deformations; on leaving the prosthesis in place, complications take place, as well as failure in rehabilitation; thus, surgeons prefer other techniques to aid the patient in voice emission, such as the performance of cryopharyngeal myotomy or pharyngeal plexus neurectomy<sup>12,14</sup>. Nonetheless, not all surgeons have the experience and the dexterity to carry out this type of procedure, and it is documented in the literature that one reason comprises the fear of complications that can present in performing this type of technique<sup>2</sup>. Another reason that can influence this type of procedure not being carried out is due to social aspects, the cost, and scarce interest in or knowledge of rehabilitation techniques by the surgeon<sup>2</sup>.

There are studies that present varied results in this regard; they support prosthesis placement in a second intent, and with a less aggressive technique, feasible, and ambulatory, i.e., by means of endoscopy.

At our Institution, we conduct few surgical procedures for voice emission via prosthesis; thus, this is carried out in a secondary manner by means of flexible endoscopy with patient selection and consulting performed by the Phoniatory Service. An insufflation test is performed so that, in the case of being optimal, the prosthesis is placed via endoscopy 4–6 weeks after radiotherapy and in a short time, the patient can speak.

In the case of cancer of the pharynx, the different and multiple management studies show satisfactory result rates that are not reproducible in Mexico due to the influence of the academic level, the population, the socioeconomic stratum, and the resources available for diagnosis and treatment. Therefore, we are obliged to evaluate locally the feasibility we possess with the resources and factors that influence the success of the different treatments that improve QOL; one of the available tools comprises QOL questionnaires.

Quality of life is a multidimensional concept without a universally accepted definition. It is defined according to the WHOQOL Group Quality of Life Evaluation (Geneva, Switzerland, World Health Forum, 1996) as follows: (it is the) perception of the individual concerning his/her life position within the cultural context and the system of values in which he/she lives and with respect to his/her goals, expectations, norms, and preoccupations. It is an extensive and complex concept that includes physical health, psychological state, level of independence, social relationships, personal beliefs, and the relationship with the outstanding characteristics of the environment.

In the past in the oncologic field, the study goals comprised treatment results, survival, locoregional control, and percentage of tumor response, while QOL factors were excluded and were secondary to analysis of the diagnosis. The importance of carrying out this type of study, such as that presented herein, has as its goal the exposure of the different therapeutic alternatives that offer similar results regarding survival and locoregional disease control. A consequence is also better knowledge of the functionality and the achievement of maximum well-being post-treatment, allowing to choose among the different management options, and in this special case of patients

with cancer of the head and neck in which therapeutics entertain controversy and limitations, with an evolution that tends to be worse in comparison with other anatomic areas<sup>15</sup>.

Applied in our study, we compared QOL among the different groups; to measure QOL, we utilized the survey validated by the University of Washington (UW-QOL)<sup>17</sup>. In our study, the following dimensions were outstanding (here in order of statistical significance): speaking; mood; anxiety, and swallowing. Speaking is one of the primordial aspects of the laryngectomized patient's well-being, because being able to communicate allows the patient to express emotions, needs, and personal independence. This was demonstrated significantly that in the group that achieved phonation with endoscopy-associated prosthesis placement in comparison with the surgical group and the group without prosthesis, showing high scores in mood, appearance, and anxiety. This could be due to the fact that these patients were able to count on a treatment that had been already defined or a follow-up treatment, in which surgical treatment, radiotherapy, and chemotherapy were carried out, a treatment during which patients did not experience the stress of an aggressive treatment and did have the opportunity of recovering their voice and communicating, this being accompanied by a consequently improved well-being. Thus, it can be demonstrated that recuperation and rehabilitation of the voice is a fundamental factor in improving patient QOL, and in our study this was statistically significant. The process of voice rehabilitation implies a cost to, attitude toward, and discipline from the patient, as well as the constant support of the Therapist and the Psychologist for a better QOL despite having a disease whose prognosis is reserved. Unfortunately, many patients submitted to surgery for cancer of the larynx do not achieve the benefits of voice rehabilitation due to multiple factors, such as socioeconomic, academic, etc.

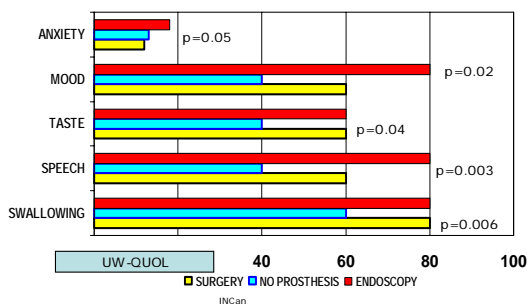
As mentioned earlier, the goal of QOL surveys is to be allowed to evaluate the different therapeutic modalities that permit improvement of patient well-being and to elect the modality with less morbidity, because independent of the therapeutics these do not change patient survival. Thus, we have to utilize the modality of voice rehabilitation, which possesses the greatest impact on the QOL of laryngectomized patients<sup>16,19</sup>.

## **CONCLUSIONS**

In cancer of the larynx, patient individualization and selection is determinant in their treatment, the ideal being that which allows for voice preservation and rehabilitation. QOL surveys are an important tool in the evolution of treatment results of cancer of the larynx, as well as the different voice rehabilitation methods.

The success of each voice rehabilitation modality is determined by knowledge of the disease by the patient and voice rehabilitation options, as well as the surgeon's experience and the resources available. There are at present novel surgical techniques with lasers and a promising adjuvant therapy with organ preservation and rescue surgery. Despite the existence of these new techniques, cancer presentation at advanced stages continues to persist, together with limitation of resources; thus, these new modalities are not within reach of our population. The Prosthesis placement via endoscopy offered by our Institution is safe, available at a low cost, with a short recuperation period, fewer complications, and better QOL in comparison to the primary placement.

### QUALITY OF LIFE



### Washington Quality of Life UW-QOL

DIMENSIONS	GROUP 1 NO PROSTHESIS	GROUP 2 ENDOSCOPY	GROUP 3 SURGERY
PAIN	NO	NO	NO
APEARANCE	NO	NO	NO
RECREATION	NO	NO	NO
JOB	NO	NO	NO
MASTICATION	NO	NO	NO
SWALLOWING	YES	YES	YES
SPEECH	YES	YES	YES
SHOULDER/PAIN	NO	NO	NO
TASTE	NO	NO	NO
MOOD	YES	YES	YES
SALIVA	NO	NO	NO
ANXIETY	YES	YES	YES

VARIABLES	GROUP I n=16	GROUP II n=19	GROUP III n=10
QUALITY OF VOICE	Bad a Regular	Good	Regular to Good
COMPLICATIONS	Dysphagia (1) Aphonia (1) Submaxilar edema (1) Pain (1)	Puncture enlargement(1) Infection (1) Fistula (1) Prosthesis displacement (1)	Puncture enlargement(2) Dysphagia and stenosis (1)

### Demographyc Clinics Data

VARIABLES	GROUP 1 n= 16	GROUP 2 n= 19	GROUP 3 n= 10	p
AGE	57.12	62.17	56.2	P=0.26
SEX	Hombres 15 Mujeres 1	Hombres 15 Mujeres 4	Hombres 8 Mujeres 2	
IMC	33.06	23.54	27.57	P=0.24
KARNOSFKY	80	80	80	
ECOG	1	1	1	
CLINIC STATE	II n=2 III n=9 IVA n=5	II n=3 III n=8 IVA n= 5 IVB n= 3	II n=1 III n=5 IVA n=4	
RADIOTHERAPY UMIOTHERAPY	14 2	16 3	6 4	
DIABETES	4	7	1	
HYPERTENSION	4	2	1	

## REFERENCES

1. Pou A.M. Tracheoesophageal voice restoration with total laryngectomy. *Otolaryngol Clin N Am* 37 (2004) 531-545.
2. Singer M.I, Blom E.D, Hamaker R.C. Further experience with voice restoration after total laryngectomy. *Ann Otol Rhinol Laryngol* 1981; 90: 498-502
3. Glenn Bunting W. Voice following laryngeal cancer surgery: troubleshooting common problems after tracheoesophageal voice restoration. *Otolaryngol Clin N Am* 2004; 37: 597-612.
4. Andrews J.C, Mickel R.A, Manson, et al. Major complications following tracheoesophageal puncture for voice restoration. *Laryngoscope* 1987; 97: 562-567.
5. Singer M.I., Hamacker R.C., Blom E.D. Revision procedure for tracheoesophageal puncture. *Laryngoscope* 1989; 99: 761-763.
6. Wang R., Bui T., Sauns E., Ditkoff, M. Long-term problems in patients with tracheoesophageal puncture. *Arch. Otolaryngol* 1991; 117: 1273-1276.
7. Baugh, R.F., Lewin J.S., Baker S.R. Vocal rehabilitation of tracheoesophageal speech failures. *Head Neck* 1990; 12(1): 69-73.
8. Simpson C.B., Postma G.N., Stone R.E., Osso R.H. Speech outcomes after laryngeal cancer management. *Otolaryngol Clin N Am* 1997; 30: 189-205.
9. Wetmore S.J., Ryan S.P., Montague J.C., et al. Location of the vibratory segment in tracheoesophageal speakers. *Otolaryngol Head Neck Surg* 1985; 93: 355-360.
10. Garth R.J.N., McRae A., Rhys Evans P.H. Tracheo-esophageal puncture. A review of problems and complications. *J. Laryngol-Otol* 1991; 105: 750-754.
11. Ho C.M., Wei W.I., Lau W.F, Lam K.H. Tracheostomal stenosis after immediate tracheoesophageal puncture. *Arch. Otolaryngol.* 1991; 117: 662-665.
12. Singer M.I., Blom E.D., Hamaker R.C. Pharyngeal plexus neurectomy for alaryngeal speech rehabilitation. *Laryngoscope* 1986; 96:50-53.
13. Trudeau M., Schuller D., Hall D. The effects of radiation on tracheoesophageal puncture. *Arch. Otolaryngol.* 1989; 115: 116-117.
14. Op de Coul B.M., van den Hoogen F.J., van AS C.J., Marres H.A., Joosten F.B., Manni J.J., et al. Evaluation of the effects of primary myotomy in total laryngectomy on the neoglottis with the use of quantitative video-uoroscopy. *Arch. Otolaryngol. Head Neck Surg.* 2003; 129(9): 1000-1005.
15. Hassan S.J., Weymuller E.A. Assessment of quality of life in head and neck cancer patients. *Head Neck* 1993; 15: 485-496.
16. Schwartz S ET AL. Quality of life outcomes in the evaluation of head and neck cancer treatments. *Arch Otolaryngol Head Neck Surg* 2001; 127: 673-8.
17. [http://depts.washington.edu/soar/projects/dxcat/hnca/qol\\_uw.htm](http://depts.washington.edu/soar/projects/dxcat/hnca/qol_uw.htm)
18. Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA .The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Submitted to *Archives Otolaryngol Head Neck.* 24: 521-529, 2002.





FIG 5



FIG 6



FIG 7



FIG 8



FIG 5



FIG 6



FIG 7



FIG 8