

The Use of Ultrasound in Determining the Length of the Provox II Voice Prosthesis

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ABSTRACT

The use of speech prosthesis after total laryngectomy has become an international standard for voice restoration today. Provox II voice prosthesis is not permanently inserted, and as such, it must meet the criterion of achieving prolonged retention time within the walls of tracheo-esophageal fistula (TEF). Complications after the insertion of speech prosthesis are familiar and anticipated but efforts are being made in order to reduce them. Part of the complications is caused by inadequate choice of the length of the prosthesis. The Department of Otorhinolaryngology and Head and Neck Surgery in Rijeka conducted a study which included 91 patients in the period from 01.01.2004. to 31.12.2010. We used ultrasound and computerized neck tomography on 58 (63.7%) patients in preoperative procedure through which we determined the length of the subsequent TE fistula. At the same time we used this opportunity to specify the length of the speech prosthesis we have inserted primarily or secondary. The number of respondents who had complications, and with whom we used neck ultrasound during preoperative procedure in order to determine the length of the prosthesis, was significantly smaller than the number of respondents who had complications but with whom we did not use the above mentioned procedure (5.6% vs. 15.5%, $p=0.042$). Comparing our results to other studies, we believe that we managed to reduce the number of complications caused by inadequate length of the prosthesis, by routine preoperative use of neck ultrasound. This procedure has extended the median retention time of the prosthesis within the TE fistula, thus improving the results of speech restoration using voice prosthesis on laryngectomized patients.

Key words: tracheo-esophageal fistula (TEF), Provox II voice prosthesis, neck ultrasound

Introduction

There are three options for voice restoration of laryngectomized patients: the adoption of esophageal speech, the use of electric sound generators-electrolarynx and tracheo-esophageal puncture and insertion of voice prosthesis within tracheo-esophageal (TE) fistula.

For more than 25 years, tracheo-esophageal speech has been the method of choice in voice restoration after total laryngectomy^{1,2}. There has been a constant need for voice restoration after the first successful laryngectomy performed by Billroth in 1873³.

Singer and Bloom were the first ones to insert the silicone voice prosthesis in the tracheo-esophageal (TE) fistula⁴.

In 1988, Provox voice prosthesis (Atos Medical AB, Hörby, United Kingdom) was used at the Department of

Otolaryngology, Head and Neck Surgery, Institute for tumors, Amsterdam, The Netherlands, and there has been a continuing need for its further improvement ever since^{5,6}.

The insertion of voice prosthesis can be done immediately during total laryngectomy – the primary insertion, or a few months or years after the laryngectomy -secondary insertion.

Insertion of the prosthesis is not permanent and requires periodic replacements. These replacements are conditioned by the occurrence of anticipated complications which are described in the literature⁷⁻⁹.

Basically, we distinguish between complications caused by the prosthesis itself from complications associated with the canal of the TE fistula.

The content leakage through the prosthesis occurs in 73% of cases¹⁰. The content leakage around the prosthesis (13%) is due to the subsequent expansion of surgical puncture, insertion of the inadequately sized voice prosthesis, or the radiation effect. Hypertrophic scars or the TE fistula infection are minor causes for the replacement of the voice prosthesis.

Materials and Methods

Our retrospective clinical study involved 91 patients at the Clinic for Otorhinolaryngology and Head and Neck Surgery in Rijeka in the period of seven years (January 2004 until December 2010).

Statistical analysis was carried out using Statistics Windows, release 8.1 (Stasoft, INC., Tulsa, OK, USA). Data on age are as mean ± standard deviation (SD), and for these results, we used one-way analysis of variance (ANOVA) to test differences between groups. In order to analyze the differences in gender and observation of complications, we used the Pearson χ^2 -test. We used multivariable logistic regression to define the influence of age, size of the prosthesis, the methods of determining the size of the prosthesis and implantation of the same on the occurrence of complications. For post-hoc analysis we used t-test for proportions. All statistical values were considered significant at p level of 0.05.

The group was consisted of 80 (87.9%) men and 11 (12%) women. The age range of patients was 41-81 years, with the mean age of 58.9 years. There was no specific statistical difference in age ($p=0360$) and gender ($\chi^2=0.07$, $p=0791$) between the respondents with the determined length of the prosthesis after the ultrasound and computerized tomography and the ones who did not have the same procedure. If we consider all the respondents, there were significantly more men ($p<0.001$). Preoperative evaluation of patient with carcinoma of the larynx must include the neck lymph node status using ultrasound. At the same time we determine future length of the TE fistula and thus choose a specific length of the prosthesis, 58 (63.7%) patients underwent a preoperative procedure with ultrasound and computerized tomography. The preoperative procedure for the remaining 33 (36.2%) patients did not include this method. In this group of patients, during surgery we usually implanted voice prosthesis 8 mm. In the postoperative time, when the fistula is formed, we use the Provox Measure tool to determine the length of voice prosthesis.

Ultrasound examination of the neck was carried out using multi-frequency probes from 7.5.11 MHz, on the GE Logiq 500 PRO device, Milwaukee, Wisconsin, USA.

The probe is laid horizontally in the area of the left side of the neck, below the lower pole of the left lobe of the thyroid, in the designated place for the esophagus. After the esophagus is identified, the patient is required to swallow repeatedly, in order to clearly see the position of the inner lining of the esophagus. We determine the distance between the rear wall of the trachea and the inner wall of the esophagus. We have determined the same

TABLE 1
DISTRIBUTION OF RESPONDENTS IN RELATION TO THE OCCURRENCE OF COMPLICATIONS

Groups	Complications N(%)		Statistic
	No	Yes	
UTZ-CT	48 (52.2)	5 (5.6)	$\chi^2=9.78$ $p=0.002^*$
Blind	24 (26.7)	14 (15.5)	
All	72 (78.9)	19 (21.1)	

* indicated statistical significance

TABLE 2
DISTRIBUTION OF RESPONDENTS IN RELATION TO THE OCCURRENCE OF COMPLICATIONS - POST HOC ANALYSIS

Group	P
Ultrasound-CT	<0.001
Blind	0.569
Ultrasound-CT without complications	0.014
Ultrasound-CT with complications	0.042

distance during the computerized tomography of the neck. Equal distance in the height of the upper back part of the left sternoclavicular joint was determined on axial images. We compared the obtained values with each other. Using this preoperative examination, we have determined the length of the Provox II voice prosthesis.

64 (70.3%) patients underwent primary insertion of a voice prosthesis and 27 (29.6%) of them the secondary insertion. The number of complications related to the insertion of the voice prosthesis was monitored in both groups (Table 1).

Since the number of patients with complications varies in different groups a post-hoc analysis was performed (Table 2).

Through logistic regression of the data we determined the influence of age, method of insertion, use of preoperative neck ultrasound, selecting the length of the voice prosthesis on the likelihood that a respondent has a complication (Table 3).

TABLE 3
EFFECT OF AGE, THE LENGTH OF THE PROSTHESIS, THE METHOD OF DETERMINING THE SIZE OF PROSTHESIS AND PROSTHESIS INSERTION ON THE OCCURRENCE OF COMPLICATIONS

Variable	p	Odds Ratio	95% CI
Age	0.377	1.02	0.97 to 1.07
Insertion	0.557	1.38	0.46 to 4.06
Method	0.007*	2.44	1.27 to 4.69
Prosthesis length	0.013*	1.64	1.10 to 2.43

* indicated statistical significance

Successful speech restoration through tracheo-esophageal speech was achieved with 83 (91%) patients.

Discussion

The golden standard of voice restoration after total laryngectomy is tracheo-esophageal puncture (TEP) and the insertion of voice prosthesis in a surgically created fistula in tracheo-esophageal (TE) wall. The silicone voice prosthesis allows the air from the airway to enter the esophagus during closed tracheostomy^{11,12}.

Due to air pressure, the pharyngo-esophageal mucosa vibrates and thus produces the voice.

The reason for total laryngectomy for all the patients was laryngeal cancer T3 and T4, marked according to international classification.

Atos Medical Group offers Provox II voice prosthesis in six sizes (4.5, 6, 8, 10, 12.5, 15 mm). Selection of the length of voice prosthesis is individual.

Our study indicated that Provox II, 8 mm voice prosthesis is usually implanted with a statistical significance ($p=0.05$) which does not differ from similar studies.

Indicator of the appropriate size selection of the voice prosthesis is successful speech restoration through tracheo-esophageal speech.

The success of voice restoration in our study was achieved with 83 (91%) patients, in similar studies it varies between 70-95%¹³⁻¹⁵.

It is recommended to use the neck ultrasound in order to determine the neck lymph condition for patients with T3, T4 laryngeal cancer¹⁶.

Apart from the above mentioned, we used the neck ultrasound to determine the length of the future TE fistula on 58 (63.7%) patients. Unsatisfactory results of speech restoration are the consequence of complications related to TE puncture / fistula, problems related to prosthesis or poor motivation and cooperation with the patient. Atraumatic insertion, proper cleaning and adequate selection of the prosthesis are the basic measures that need to be taken, in order to have proper rehabilitation^{17,18,19}.

Ulcers that occur as a result of insertion of inadequately sized voice prosthesis can be prevented by selecting one that is of accurate size. Therefore, the local status of tracheotomy is important for TE voice restoration²⁰.

Our study showed that 19 (20.8%) patients required prosthesis replacement due to the complications caused by inadequate size of the prosthesis.

Post-hoc analysis revealed that the group of patients that underwent preoperative procedure of neck ultrasound in order to determine the length of the prosthesis, have significantly lower number of complications than the group that did not go through the procedure ($p<0.001$).

The patient group which was included in the above mentioned preoperative procedure has significantly more respondents who do not have complications related to the length of the voice prosthesis in relation to the number of respondents who have no complications but with whom we did not use the neck ultrasound (52.2% vs. 26.7%, $p=0.014$).

That is, the patient group that underwent the preoperative use of neck ultrasound has significantly fewer respondents who have complications in relation to the number of respondents who have complications from the groups where we did not use the neck ultrasound (5.6% vs. 15.5%, $p=0.042$).

Summary description of the odds ratio processed by logistic regression indicates that the length of the prosthesis variable significantly affects the likelihood that a respondent will have a complication.

Conclusion

The use of the neck ultrasound on laryngectomized patients in preoperative determination of the voice prosthesis length, which was inserted in the TE fistula during either primary or secondary insertion, resulted in significantly lower percentage of complications due to inappropriate selection of the prosthesis length.

Comparing our findings with other studies, we believe that we managed to improve the results of speech restoration with the speech prosthesis by a routine use of the neck ultrasound. We also consider that the use of non-invasive and easy accessible neck ultrasound in daily practise can significantly help with the selection of the proper length of the Provox II voice prosthesis.

Neck ultrasound can be used before primary or secondary insertion and also during regular ambulatory prosthesis replacement. The use of neck ultrasound is just another step in the further improvement of the TE voice restoration after total laryngectomy.

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UPOTREBA ULTRAZVUKA U ODREĐIVANJU DULJINE PROVOX II GOVORNE PROTEZE

SAŽETAK

Upotreba govorne proteze nakon totalne laringektomije danas je sa razlogom postao međunarodni standard u rehabilitaciji glasa. Provox II govorna proteza nije trajno ugrađena te kao takva mora zadovoljiti kriterij postizanja što duljeg vremena zadržavanja unutar stijenke traheoezofagealne (TE) fistule. Komplikacije nakon ugradnje govorne proteze su poznate i očekivane ali se nastoje umanjiti. Dijelom su komplikacije uzrokovane odabirom neadekvatne duljine proteze. U Klinici za Otorinolaringologiju i kirurgiju glave i vrata Rijeka u studiju je uključeno 91 pacijenata u razdoblju od 01.01.2004. do 31.12.2010. godine. Kod 58 (63,7 %) pacijenata smo u prijeoperativnoj obradi koristili ultrazvuk (utz) i ct vrata kojim smo odredili duljinu buduće TE fistule. Ujedno smo ovim putem odredili i duljinu govorne proteze koju smo ugradili primarno ili sekundarno. Broj ispitanika koji imaju komplikacije a kod kojih smo u prijeoperativnoj obradi koristili utz vrata za određivanje duljine proteze značajno je manji u odnosu na broj ispitanika koji imaju komplikacije a kod kojih nismo koristili navedenu obradu (5,6% vs. 15,5 %; p=0,042). Uspoređujući naše rezultate sa ostalim studijama, smatramo da smo rutinskom prijeoperativnom upotrebom utz vrata smanjili broj komplikacija uzrokovanih neadekvatnom duljinom proteze, produžili srednje vrijeme zadržavanja proteze unutar TE fistule te na taj način poboljšali rezultate govorne rehabilitacije govornom protezom kod laringektomiranih bolesnika.