MEDICAL UNIVERSITY
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FACULTY OF MEDICINE
DEPARTMENT OF NEUROSURGERY AND ENT DISEASES

VOICE REHABILITATION OF LARYNECTECTOMY PATIENTS THROUGH VOICE PROSTHESES
ABSTRACT

AUTOR`S EPHETAR

The dissertation for the acquisition of educational and scientific degree "DOCTOR"
of

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The dissertation contains 114 standard pages, including 1 table and 20 figures. 185 literary sources are cited, of which 15 of Cyrillic and 170 in Latin.

The dissertation is discussed and proposed for the defense of an extended department Council of the Department of Neurosurgery and ENT Diseases at MU "Prof. Dr. Paraskev Stoyanov"- Varna. The official protection will be in electronic environment on Wednesday 17th of December 2021

Contents

Abbreviations used

EENC Endo-extralaryngeal needle carrier

HPV

VFS

Human papillomavirus

Video fluoroscopy

GER Gastroesophageal reflux

GP Voice prosthesis

DCC Diagnostic and Consulting Center

Esophagus

EzS Esophagoscope

ISMO Infections related to medical care

LE Laryngectomy

LS Laryngoscope

MHAT Multi-profile hospital for active treatment

NHIF National Health Insurance Fund

TEP Tracheoesophageal puncture

TEF Tracheoesophageal fistula

Tr Trachea

UMHAT University multidisciplinary hospital for active treatment

ENT Ears, nose, throat

1. Introduction

The upper respiratory and digestive tracts are the sixth most common localization of oncological diseases in humans, as in up to 90% of cases histologically, squamous cell carcinoma is found. Carcinoma of larynx in particular is the 21st most common cancer diseases (1.0% of all malignancies) with about 170,000 new cases per year worldwide and 900 in our country. People in advanced age are markedly more affected age with a peak incidence between the 5th and 7th decade and the male sex. The main risk factors leading to the development of laryngeal cancer, are smoking, alcohol consumption, infection with certain strains of human papillomavirus (HPV), chronic exposure to irritants, such as unconstitutional and constitutional factors, age, gender and presence of provocative conditions such as GER.

The main stage in the treatment of laryngeal cancer in its advanced stages is the surgical removal of the laryngeal complex. It's complicated surgical intervention developed in the late XIX century, which quickly affirms in ENT practice, despite initial discouragement reports. Many gradual improvements in surgery methodologies ultimately lead to good patient survival after intervention and the rise of constitutional complications as a result of the procedure - anosmia, swallowing disorders and frequent respiratory ones. What determines the highest degree of disability laryngectomy patients, however, is a loss of phonator function.

There are currently many alternatives to vocal rehabilitation after laryngectomy. It is currently accepted as the gold standard implantation of a voice prosthesis in a surgically shaped tracheoesophageal fistula. This methodology is easy to implement, with a well-studied low-risk profile, technically can be provided in different ways and most importantly - provides good and fast results in terms of vocal activity and quality of life with acceptable risks and the need for additional care laryngectomy patients.

In the present dissertation the results are presented and analyzed from voice rehabilitation of laryngectomized patients with voice prosthesis from two clinical centers that are representative of our country. They are rated the effectiveness of the method, the frequency and type of prosthetic complications speech rehabilitation after laryngectomy in the Bulgarian population, characteristics of vicarious phonation and its impact on the quality of life of patients. Experience and results are shared with conventional ones surgical techniques for implantation, as well as with its own modification of some of them.

The methodology is slowly making its way into otorhinolaryngological practice us due to the lack of trained medical and non-medical staff, the need for relatively frequent replacement of expensive prostheses consumables not covered by the NHIF and the general ignorance of health professionals who work with such patients. These factors as well as changes in design, composites, placement methods and tracking remain pressing issues that need to be addressed in future.

2. Purpose and tasks

Based on the current state of the topic set forth in the literary review, and the scientific and clinical problems extracted at the end, the present research formulates the following goal:

To analyze the experience of two Bulgarian centers for voice rehabilitation of laryngectomized with voice prostheses in order to optimize the practical approach in these patients.

In order to achieve the set goal, the following research formulations are formulated

tasks:

1. To analyze the state of the problem with the voice rehabilitation of patients after laryngectomy in our country.

2. To make a comparative analysis of the different surgical techniques for implantation of speech prostheses

3. To critically analyze the results of your own modified methodology for TEP and implantation of a voice prosthesis

4. To analyze the applicability of video fluoroscopy for preoperative assessment of local status and choice of voice prosthesis

5. To analyze the main phonological characteristics of tracheoesophageal speech

6. To create modern multimedia content for informing patients for vocal rehabilitation options after laryngectomy.

3. Material and methods

Material

Material base for realization of the dissertation work

1) Clinic of ENT diseases University Hospital "St. Marina ", Varna

2) Department of ENT diseases, University Hospital "Plovdiv" AD, Plovdiv

A retrospective non-interventional two-center clinical was performed study based on medical documentation. Included are patients who meet the inclusion criteria and have no exclusion criteria. Patients with advanced laryngeal carcinoma treated with complete laryngectomy and a combination of preoperative and conventional chemo- and radiation therapy. All patients underwent surgical treatment with standardized approach to intervention. Surgical treatment is held at UMHAT "St. Marina" - Varna and UMHAT Plovdiv, where patients were followed in the early and late postoperative periods for occurrence of complications. The training of patients for speech. From each of the patients the standard for both hospitals informed consent to conduct diagnostic and therapeutic interventions (including laryngectomy, complex chemo- and radiotherapy, voice prosthetics, monitoring and follow-up). On this one reason and due to the retrospective nature of the study was not collected explicit informed consent of patients to participate in the study. From both clinical centers were officially authorized to use medical documentation. All diagnostic and therapeutic procedures are carried out in accordance with the ethical standards of the relevant legislation of Republic of Bulgaria, the institutional recommendations and the declaration of Helsinki (1975/2008), on the ethical principles of medical Human Research and the Research Ethics Commission (KENI) of Medical University - Varna "Prof. Paraskev Stoyanov "(protocol 026- 14 / 23.05.2017).

Patient population

The study included a total of 51 patients (47 men, 4 women, mean age 61.5 ± 7.99 (41-94 years) at which tracheoesophageal was performed fistula for implantation of a voice prosthesis. There are thirty-six patients were initially operated on and followed up in the ENT department of UMHAT "Plovdiv" AD and 15 patients were primarily operated and followed in the Clinic of ENT diseases - University Hospital "St. Marina ", Varna. Two patients (S.Z.H. and R.S.I.Z.) underwent surgical treatment in both clinics. They have performed more than one procedure with different techniques. When analyzing the demographic indicators of the patient population are reported once. There were a total of nine patients who had to performing secondary TEP several times due to temporary full obliteration of TEF. In the analysis of operative interventions and related indicators, individual interventions are taken into account.

Methods

Based on several studies in patients after laryngectomy, analyzing both similar and some different indicators of voice rehabilitation with TEP and prosthesis we defined criteria for inclusion of patients as well as exclusion criteria. Criteria for inclusion of the patients in the analysis are: 1) adult patients; 2) patients after laryngectomy as a result of laryngeal carcinoma; 3) patients with good response to surgical and radiotherapy and / or combination therapy; 4) patients with no evidence of residual disease or recurrence; 5) patients in stable general medical condition. The exclusion criteria were: 1) patients in a very impaired general condition; 2) patients who are not in able to understand the nature of the intervention; 3) patients with ongoing radiotherapy and / or combination therapy; 4) patients with evidence of residual disease or recurrence; 5) patients in poor mental health; 6) patients who are considered to be in the upper extremities due to movement disorders or mental and psychological disorders able to service the prosthesis or report complications; 7) patients with critically narrow or unstable tracheostomy. All patients have advanced laryngeal carcinoma treated by

complete laryngectomy and a combination of preoperative and conventional chemo- and radiation therapy. All patients underwent surgical treatment with standardized approach to intervention. Surgical treatment is held at UMHAT "St. Marina" - Varna and UMHAT Plovdiv, as patients were followed up and monitored prospectively for the onset of complications. The first patient underwent surgery on 02.2013 and the follow-up of the last patient is until 05.2021.

Retrospectively collected medical records for each patient in the study was organized and indexed in a separate medical file, including: 1) Demographics (names, ID number, date of birth, age, gender); 2) Medical data, general condition, concomitant diseases, oncological history); 3) Information on surgical (TEP) treatment (date of operation, surgical technique, individual features of the intervention, type of prosthesis, complications from prosthetics; 4) Specific methods of examination (imaging methods, video fluoroscopic examination, computer tomography, photographs, videos, primary audio recordings or separated from videos audio recordings).

Studies were performed mainly on the basis of medical documentation of indicators related to surgical treatment, and some perioperative indicators in laryngectomized patients undergoing treatment for the purpose voice rehabilitation through voice prostheses from two clinical centers in Bulgaria. The various surgical techniques for TEP and implantation were analyzed in a comparative plan. The applicability of video fluoroscopy for preoperative assessment of local status and selection the size of the voice prosthesis. Basic phonological ones were analyzed characteristics of tracheoesophageal speech.

Standard surgical technique

The necessary tools to create a tracheoesophageal fistula includes a rigid Hasslinger-type esophagoscope, a guide to the central venous vessel, specially modeled hollow s-shaped trocar for tracheoesophageal fistula, Folley catheter size 14 Ch, steel guide for situating the catheter in the fistula and a set of esophagoscopy forceps. With the development on its own set of s-shaped hollow trocar and foil catheter guide, suitable for sterilization and intended for use, we strive to reduce the cost of the procedure.

The procedure for creating a tracheoesophageal fistula is performed under complete anesthesia by a team of two ENT specialists. The patient is placed in Boyce's position - the neck is flexed and the head is extended in the atlanto-occipital joint. The placement of gauze, which protects the teeth on the upper jaw and retracts the upper lip, facilitates the next steps in manipulation. The assistant slowly inserts the esophagoscope with his right hand from the right side of the tongue and the neopharynx along the right piriform fossa to the level of the tracheostomy, where the end of the esophagoscope is freely palpated through the tracheostomy foramen. In most cases, when it comes to corlent patients, the movement of the endoscope in the esophagus can be traces from the operator and on the front of the neck. Once the end is palpated of the esophagoscope under the tracheostomy, the latter is rotated 180 degrees with slit upwards, which allows protection of the posterior wall of the esophagus at the introduction of the trocar. The trocar is inserted about 5 mm from the upper edge of the tracheostomy on its posterior wall. When visualizing the end of the trocar in lumen of the esophagoscope, a central venous guide is inserted through the trocar vessel and the latter is pulled to the upper end of the esophagoscope by means of a pinch for foreign bodies. The trocar is retracted, releasing the distal end of the guide for a central venous vessel, and to it is placed a steel guide with attached in the other end of the foil catheter. This was followed by a slow and gradual withdrawal of the whole chain to the exit of the foil catheter balloon through the proximal end on the esophagoscope. The latter is released by the drivers, after which gently by

pulling from the outside and under the endoscopic control of the operator by means of a pinch is pushed back into the lumen of the esophagus. The point of the intervention is to position the foil catheter balloon below the level of fistula in the direction of the cardia of the esophagus. The foil balloon the catheter is inflated with 2 ml of physiological serum to prevent its accidental prolapse through the newly formed fistula. The catheter is fixed behind the patient's ear with adhesive tape for 24-48 hours. After this period the physiological serum is withdrawn from the balloon and the catheter is removed. The length of the fistula is determined using a standard measuring device and determine the optimal prosthesis size.

Modified Lichtenberger-Brown technique for tracheoesophageal Puncture

Our modified secondary TEP technique is based mainly on developed by G. Lichtenberger endo-extralaryngeal needle holder (EENC - endo-extralaryngeal needle carrier). Preoperatively on the instrument inserts a nonlatonic catheter (20 CH) with attached to its tip by suturing non-resorbable surgical suture (eg 1/0 USP). The body of the catheter is cuts an additional side hole through which to enter it the main body of the instrument so that the tip of the catheter coincides with the tip of EENC. It is recommended that the surgical suture be located at the bottom side of the catheter so that the tip of the catheter and the instrument protect it from the scalpel.

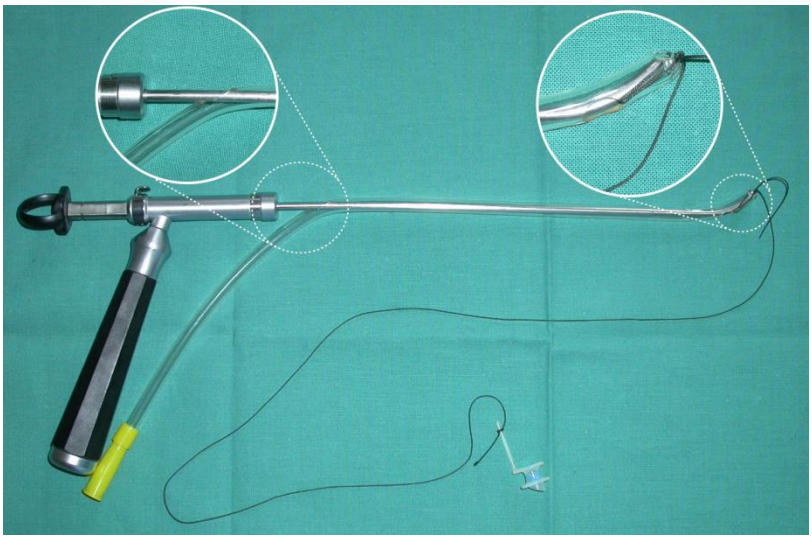


Figure 1. Preparation of the endo-extralaryngeal suture of Lichtenberge (EENC) with non-laton catheter and attachment of the prosthesis (our modification)

The surgery itself is performed under general anesthesia with ventilation technique with intermittent apnea. The original TEP — technique of Lichtengberger is also performed under general anesthesia, but with jet-ventilation. Perioperatively, patients receive antibiotic prophylaxis with gentamicin 80 mg i.v.

We used two different ways to implement EENC. In the first we used a standard rigid surgical laryngoscope system Kleinsasser. At a later stage, we also experimented with an intubation-type laryngoscope Macintosh. Both approaches do not seek or achieve direct visualization at the site of the puncture itself, and only at the entrance to the esophagus. From this area caudally EENC with a non-laton catheter placed on it introduce without direct visual control over the tip of the instrument.

Regardless of the TEP technique, the main important point is the choice of the site of the puncture itself. Palpation with a finger through the tracheostomy (removed tracheal tube, apnea patient) allows tactile assessment of thickness and the consistency of local tissues. The top of the instrument with the catheter placed on it so that it protrudes clearly through the posterior tracheal wall in the area where the TEP will be performed. Then against this tip a small puncture incision

is made in the posterior tracheal wall 3-4 mm long with an N11 scalpel. The depth of the incision should ensures that the tip of the scalpel is inserted into the soft catheter. During the incision passes the tip of the EENC with the catheter until the guide thread is shown. The flood the tip of the catheter further slightly dilates the tissues. It's necessary sometimes additional dissection to widen the hole using a curved a dissecting instrument (eg a mosquito) until the tip of the catheter is presented well in the tracheal lumen. The guidewire is released from the catheter and removed pull with a tool gently through the tracheostomy. The EENC is subtracted together with the non-laton catheter. With careful traction of the guide thread through the tracheostomy, the prosthesis attached to it is passed through the mouth and neohypopharynx retrograde until it appears through the opening of the TEP and is positioned correctly in it.

In the postoperative period, patients initially switch to soft and gradually - on a free diet over the next 1-3 days. Attempts to phonation begin immediately after intervention in low-trauma interventions and especially in patients who have had prosthetics in the past and have experience or in the next 2-3 days.

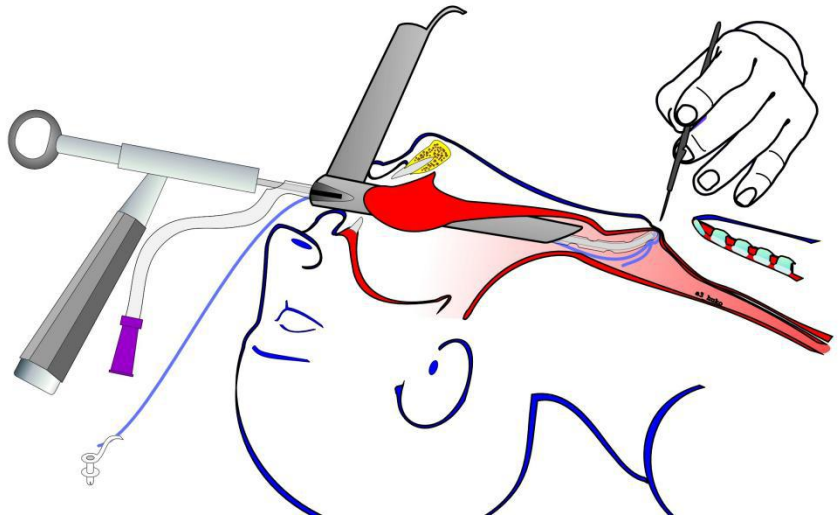


Figure 2. Schematic representation of the operational statement for single-stage tracheo-oesophageal fistulization and prosthetics in using the Kleinsasser direct laryngoscope system

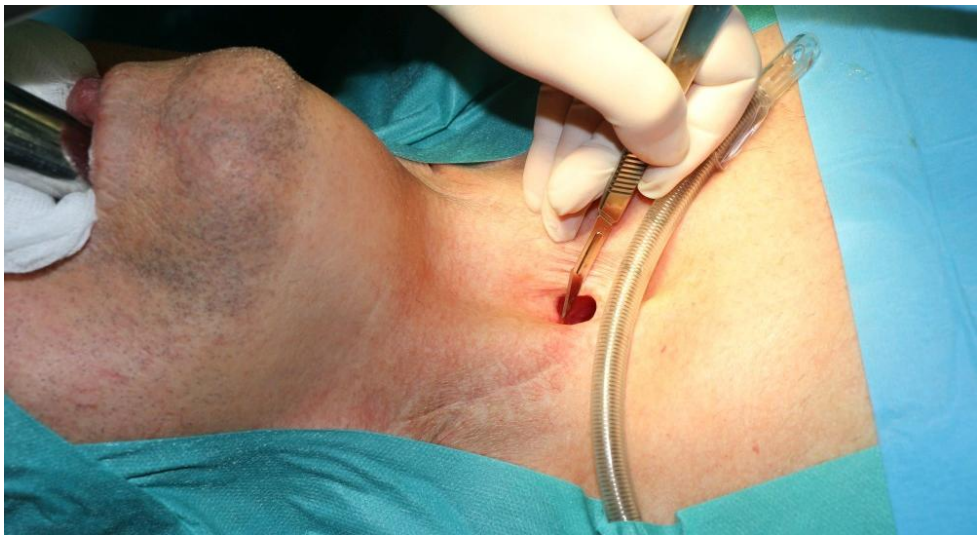


Figure 3. Our modification of the Lichtenberger-Brown technique for tracheo-esophageal fistulation - direct access Kleinsasser type laryngoscope

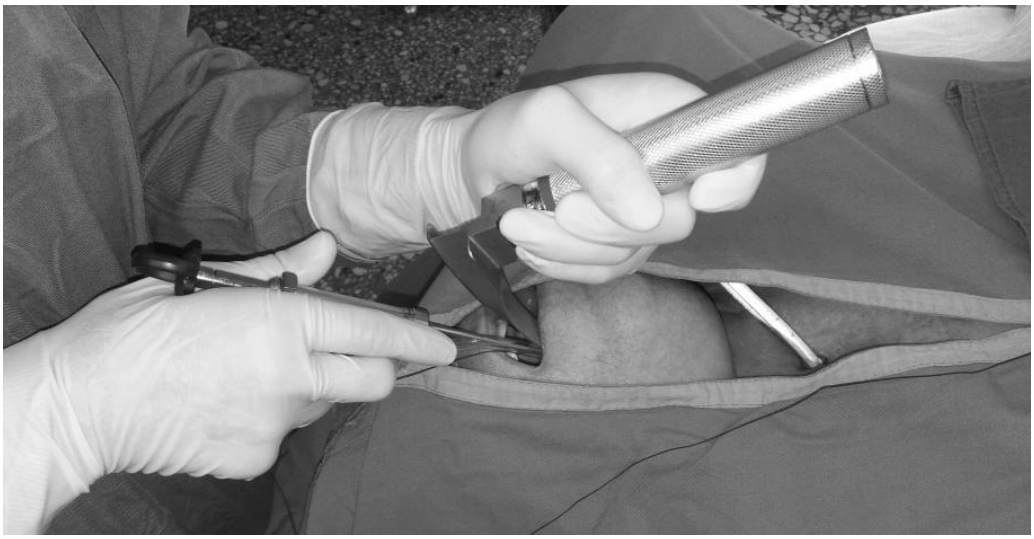


Figure 4. Our modification according to Lichtenberger-Brown techniques for tracheo-esophageal fistulation - direct access Macintosh type laryngoscope

Placement and replacement of the prosthesis

At primary imposition or replacement of an old prosthesis, the fistula is it is necessary to clean from secretions and crusts, and if necessary to impose an expander for about 15 minutes. Compliance with these conditions provides possibility for optimal positioning of the prosthesis and reduces the risk of

complications, such as spontaneous prolapse of the prosthesis, its displacement with accompanying risk of aspiration and infection.

The prosthesis is placed in an anterograde plan. The provided in the guide set on which the prosthesis is strung is inserted into tracheoesophageal fistula.

For the Low Pressure model, an alternative method of placement is provided gel capsule in which the prosthesis is placed and thus introduced into fistula. After a short period, the capsule is dissolved and the prosthesis is fixed. IN our practice we have an attempt to place through a gel capsule, which was not satisfactory. This led to the removal of the prosthesis and its re-imposition on the anterograde method.

Sometimes the replacement of the prosthesis by the classic anterograde method with a pin of the kit is very difficult due to individual characteristics of patients who are difficult to classify.

When the anterograde implantation of the prosthesis is unsuccessful, in ours in practice we apply our own method for retrograde imposition. Thin non-latonic a catheter is inserted through the fistula opening and by mesopharyngoscopy monitors reaching its tip into the oral cavity, where it engages with Kocher's instrument and is brought out. The tongue of is sewn to it the voice prosthesis, taking care that the thread does not cut through the material of the device. At the next stage, the posterior end of the catheter is slowly and carefully is pulled until it is completely withdrawn through the fistula opening and visualized on the tongue of the prosthesis, the prosthesis being attached with a small hemostatic a tool to help it move and lock it properly. After fixing the prosthesis, the thread connecting the prosthesis to the catheter is cut and checking that the prosthesis is functioning optimally by driving the patient to talk. If necessary, the prosthesis is refixed immediately until it is reached of optimal results.

At the beginning of our clinical experience with voice prostheses for patient comfort after placement we cut the tongue of the prosthesis. This method, in turn, led to cases of loss of the prosthesis, as a result of which we stopped this practice

and we started to fix the prosthesis with a silk thread around the neck that passes through the tongue.

Video fluoroscopic examination

For the purpose of the analysis archival images of patients are used, subjected to VFS in the preoperative period before the TEP. A clinically established methodology used in others was used studies focusing on the anatomical features of the neohypopharynx after laryngectomy. Briefly, patients underwent video fluoroscopy research. Because in all cases it is a secondary tracheoesophageal fistulation with a significant distance from the laryngectomy and there is no doubt about the integrity of the digestive tract in the field of intervention, a standard barium suspension was used for contrast sulphate (barium porridge) (DECA-BAR 100 g). The study was conducted in lateral position. Video mode of documentation of was used images (4 images / second). Images are selected from the captured images the most appropriate, clearly showing the tracheoesophageal septum, cannula and stoma.

Images in which the neohypopharynx is filled with contrast material, clearly distinguishes the contour of the posterior tracheal wall and the contour of the tracheostomy cannula. It is measured on each image several times the distance from the posterior tracheal wall to the neohypopharyngeal lumen (puncture zone) and the diameter of the tracheal cannula. The software generates the measured distance in pixels. The average value of received. Because the diameter of the tracheal is known in advance cannula, from it and the proportions derived from the VFS is calculated the thickness of tracheoesophageal septum.

Analysis of phoniatric indicators

The recordings were made using two techniques. The direct recording is performed via Olympus LS-12 Linear PCM Recorder in a quiet room. The distance to the microphones was about 30 cm from the patient's lips. Sky performed calibration of the gain. The recording was made at a frequency of sampling 44.1 kHz, 16 bit and stored in WAVE format (Waveform Audio File Format; .wave, .wav). In the second method, the entries were made with non-standardized video recorders. Only in the second stage were they converted resampled to the above format. The manipulation and analysis of so the received audio files were performed with the Sopran 1.0.26 for Windows software (Tolvan Data 2009-2020, compiled 29.02.2020). They were initially reset speech segments / instructions from the researcher. The phrases between two poems the bolus air / breaths were marked manually. In patients with esophageal voice was reported any interruption for air insufflation in esophagus. In patients with a laryngeal prosthesis, each was reported break for inspiration. When in doubt, a comparison was made with the videos. The measurements of the phonator blocks were performed with the software, the enumeration of the words for the individual blocks was made by the researcher. The duration of phonation / speech and the number of words spoken with an air bolus.

Statistical design and analysis

Within the descriptive and variational analyzes were calculated frequency distributions, averages with applicable indicators of scattering (standard deviation and range). The relatively small size of sampling is expected to make data vulnerable to outliers.

One of the main objectives of the analysis was to compare the indicators of phonation in patients after laryngectomy with substitutional esophageal speech and after voice rehabilitation through TEP and voice implantation prosthesis. The two groups are comparable in age and main clinical indicators. There are no

women in the group of patients with esophageal speech. In both groups, indicators were not analyzed, which may have one or another probable reason different distribution depending on gender.

For the comparison itself, a T-test was used for independent samples with different dispersions (Independent-samples T-test, Two-sample T-test, unpaired T-test), bilateral option. The software used was Microsoft Excel 2016 (16.0.1338.20334) with the Analysis ToolPak add-in. The hypothesis was tested during the data collection stages, formulation of the hypothesis, acceptance or rejection of the hypothesis under certain rules. Only the so-called a simple statistical hypothesis. H0 or zero (basic, working) hypothesis denotes that hypothesis which is of interest to us, H1 means the alternative (competing) hypothesis that should be accepted when rejecting H0. It is determined the level of significance α of the error check and its practicality application, the so-called p-value of the criterion. A statistically significant result is obtained in the cases of $p \leq \alpha$ - then the main hypothesis H0 is rejected. When $p > \alpha$ there is a statistically insignificant result and the main hypothesis H0 is accepts - there are no substantiated statistical arguments for its rejection. For significance level at which the null hypothesis is rejected, $p < 0.05$ was chosen.

4. Results

Patient population

The patient population included in the analysis included 51 patients (47 men, 4 women, mean age 61.5 ± 7.99 (41-94) years) in whom performed tracheoesophageal fistulation and implantation of a voice prosthesis. Thirty-six patients were initially operated on and followed up in the ENT department of UMHAT "Plovdiv" AD. Fifteen patients were followed in the ENT Clinic - University Hospital "St. Marina", Varna, as 13 (86.7%) of them were primarily operated on in the clinic, and two patients were first operated on and implanted abroad. Two patients underwent surgical treatment in both clinics. To them more than one procedure has been performed with different techniques. In the analysis of demographic indicators of the population these patients are reported once. There were a total of nine patients who had to undergo secondary TEP several times due to temporary complete obliteration of TEF. In the analysis of operational interventions and related indicators take into account the individual interventions. 49 patients had laryngectomies on squamous cell carcinoma of the larynx (96.1%). In two patients the primary neoplasm was laryngeal sarcoma (3.9%).

Gender characteristics

Of all 51 patients, 7.8% (n = 4) were female, the remaining 92.2% (n = 47) were male. The mean age of prosthetic women was 62.8 ± 10.6, minimum age 49, maximum age - 72 years. The average age of prosthetic men is 62.4 ± 8.7, minimum age - 41, maximum age - 94 years.

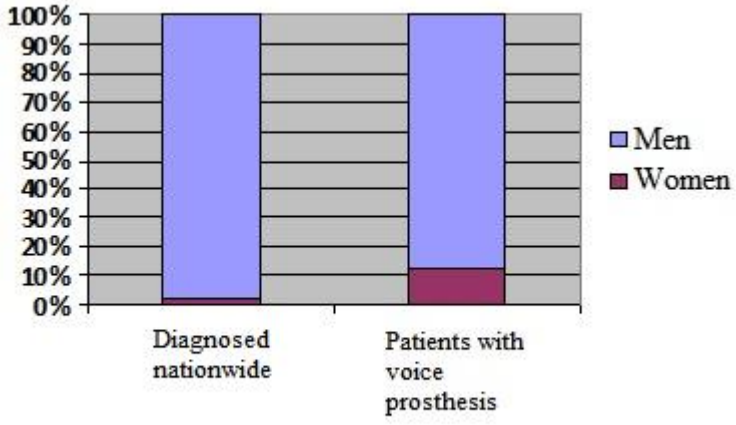


Figure 5. Comparison of men: women among those diagnosed cases of laryngeal carcinoma nationwide and the ratio in patients with voice prosthesis

This gender distribution does not correspond to the overall gender distribution with respect to laryngeal carcinoma in our population, where the incidence of women with laryngeal carcinoma is 2.12% of all cases. The high percentage of women in the group of prosthetic patients compared to the percentage in general of women with laryngeal carcinoma is rather accidental. No it can be argued that female patients are more prone to vocal rehabilitation with TEP and prosthesis.

Evaluation of the indications for laryngeal prosthetics

All patients in the cohort met the inclusion criteria for laryngeal prosthetics, and do not meet the exclusion criteria. All patients have received the necessary explanations incl. through training and information materials necessary for the success of the methodology, and have given their informed consent to proceed with the procedure.

The following voice prostheses were used: Blom-Singer® low pressure voice prosthesis (Helix Medical, LLC, Carpinteria, CA, USA / EMERGO EUROPE, The Hague, The Netherlands) (109), Blom-Singer Duckbill Indwelling Voice Prosthesis (InHealth Technologies®, Freudenberg Medical, Carpinteria CA 93013, USA) (14), Provox2 Prosthesis (Atos Medical AB, Hörby, Sweden) (9)

Provox3 Prosthesis (Atos Medical AB, Hörby, Sweden) (3 pcs.). The choice of prosthesis model for everyone patient was mainly related to accessibility (availability on the market in Bulgaria, affordability for purchase and delivery) and the individual anatomical and topographic characteristics of the patient postoperatively. In some patients different prostheses were used in the different shifts. The selection of prostheses is was unsystematic and largely dependent on accessibility. The design of the study it is not targeted and has no potential for comparative evaluation of different species prostheses in terms of surgical technique and complications, quality of phonation, duration of use of the prosthesis associated with itself prosthesis complications.

Results related to surgical treatment

The main group of patients undergoing surgical treatment with conventional technique includes 36 people (mean age 62.8 ± 10.5; interval 41-94 years). The majority of patients (88.9%) were male 63.1 ± 10.5; interval 41-94 years). There are four female patients (11.1%) mean age 60.5 ± 11.7; interval 46-70 years. In the past, everyone patients underwent laryngectomy for primary advances laryngeal carcinoma (100% squamous cell carcinoma). Only one patient of this group underwent postoperative radiotherapy. When creating TEF rigid was used according to the conventional Blom & Singer methodology Hasslinger esophagoscope system, central venous vessel guide, hollow s-shaped TEF trocar, 14Ch foil catheter, and endoscopic forceps. At all patients the procedure was performed under general anesthesia. With a patient in position of Boyce, a rigid esophagoscopy was performed under visual control until reaching the level of the tracheostomy. Rotation of the esophagoscope at 180° provides an atypical position of the tool at which its tip is directed to the posterior wall of the esophagus, and the beveled anterior opening - in a plane, parallel to the posterior tracheal wall. TEP followed with the help of a trocar about 5 mm from the upper edge of the tracheostomy, passing the guide transstomally and pulling it with forceps through the esophagoscope. The transstomal foil catheter is retracted

through the guide. After release from the metal guide the foil catheter balloon is positioned below the level of the fistula in caudal direction to the stomach. The next day or after 48 hours the catheter was removed, and the length of the fistula was measured directly implanted prosthesis of appropriate length. The intervention was successful at 32/36 of the interventions (89%). In two patients (5.6%) in the postoperative period developed severe complications with a picture of local tissue infection, evolved to mediastinitis, which required explantation of the prosthesis and long-term antibiotic treatment. TEF obliterated spontaneously within respectively at 1 and 3 days, a more complete cessation of saliva flow through fistula. Both patients recovered without residual effects and without need for additional surgical treatment. Two other patients (2/36; 5.6%) were unable to phonate with the prosthesis. It was originally performed augmentation and lavage of the prosthesis. Normal was found passability and function of the valve mechanism. However and despite active training patients could not speak when trying to force expiration in obstructed tracheostomy air insufflation occurred in stomach. Attempts to replace the prosthesis with a wider one also did not lead to Good luck. After an in-depth analysis of the clinical situation and discussion with patients decided to perform a lateral myotomy pharyngeal constrictors. The intervention was performed under general anesthesia and antibiotic prophylaxis. The TEFs themselves were revised intraoperatively, no suspicious changes were found in them. They were temporarily removed prostheses and inserted foil catheters. In one of these two patients 5th postoperative day in clinical data for normal healing of surgical wounds the catheter was removed. A new prosthesis was implanted. The patient gradually developed a good laryngeal phonation with the help of the prosthesis. In the second intervention there was an additional serious complication - in cricopharyngeal myotomy penetration into the lumen of neohypopharynx. A primary suture of the defect was applied. In the late postoperative period in this area developed a fistula with significant swelling of saliva and food bolus through the fistula. She was placed nasogastric probe.

This pharyngocutaneous fistula did not respond to standard conservative measures and due to the persistence of clinically significant impose plastic with a pectoral flap to close the defect.

Our modified Lichtenberger and Brown TEP equipment administered to 15 patients (all men) (mean age 59.9 ± 7.1 (49-70) years. The majority (86.7%) have been subjected to laryngectomy for primary advanced laryngeal carcinoma, and two (13.3) were with sarcoma. This high percentage is not for atypical tumor types indicative. The incidence of rare laryngeal malignancies in the clinic of UMHAT "St. Marina "is low and coincides with similar ones distributed by others centers and registers. This is an accidental natural fall of these two patients in the group undergoing TEP with prosthesis implantation, which is smaller than the total group of laryngeal carcinoma patients from the institution. In three of the patients an additional unilateral was performed, and in three more - bilateral cervical dissection in one stage with laryngectomy. When one of the patients in the postoperative period had a complication - pharyngeal fistula, healed secondarily. All patients in this group are were subjected to postoperative medium cumulative radiation therapy 58 Gy (56-60 Gy). A total of 18 secondary TEPs with direct implantation of a voice prosthesis under general anesthesia. The average time the interval between laryngectomy and the first TEP varies from 4 to 32 months. When three patients the intervention was performed after obliteration of the previous one existing TEP (1 patient underwent a total of 4 procedures, two patients have 2 procedures). In the first four interventions we used direct surgical laryngoscope type Kleinsasser. For the rest 11 interventions EENC of Lichtenberger was introduced using intubation Macintosh type laryngoscope. None of the interventions were sought or achieved direct visualization at the puncture site. They were implanted 15 prostheses InHealth Technologies and 3 prostheses Provox 3. In several case (we can not specify the exact number) in the final phase of positioning the prosthesis it came out through the TEP, which required intraoperatively repeat the entire procedure of attaching the prosthesis to the catheter and EENC with guide thread and transoral insertion. The intervention was successful in 14/15 of the interventions (93.3%). In the only patient with

early clinical evidence of failed implantation on the first postoperative day when we tried to call, we found that no air passes to the hypopharynx neither by the patient's efforts nor by our insufflation. The conducted VFS and computed tomography showe

The mean follow-up of patients was 14 months. They are not included here late complications associated with the usual use of dentures.

In patients in need of prosthesis replacement, the intervention was performed under local anesthesia with 10% lidocaine using the provided from the manufacturer's guide to remove the old and implant the new prosthesis, in accordance with their model. In case of discrepancy between the model of the old and the new prosthesis, the old one was removed with a needle holder or a curved hemostatic instrument, and was implanted with the provision of manufacturer's guide.

Phoniatric indicators in alaryngeal speech

The vocal rehabilitation of the patients proved to be exceptional variability. In 85% of cases, patients speak up to half an hour later prosthesis placement. In some cases due to the manipulation of formation of tracheoesophageal fistula occurs swelling and soreness of the soft tissues around the tracheostomy, which requires conservative treatment, including most commonly an antibiotic and a corticosteroid. After sounding off local inflammatory symptoms within 5-10 days patients developed normal alaryngeal phonation by voice prosthesis. All patients from the analyzed cohort with successful TEP and prosthesis implantation (excluding patients in whom it is necessary explantation, both patients in need of additional cricopharyngeal myotomy) were satisfied with functional results. The time required to deliver a speech after primary prosthetics, was up to 6 hours, and was largely dependent on the intensity of the training by the medical team. In re-prosthetics, patients spoke immediately after the procedure (when performed under local anesthesia) or after the effects of anesthesia. One of the patients within a few hours after prosthetics perform phonation with good enough quality and duration for satisfactory singing function.

The average duration of phonation in patients with esophageal speech with one air bolus is 1.12 ± 0.53 seconds, minimum duration 0.4 seconds, maximum duration 1.99 seconds. In patients with laryngeal prosthesis the average duration of phonation with one inspiration is 13.1 ± 7.23 seconds, minimum duration 1.21 seconds, maximum duration 20.13 seconds.

Patients with esophageal speech utter an average of 2.58 (1-5) words with one bolus air. Patients with a voice prosthesis pronounce 16.74 (1-50) words at one inspiration (6.5 times more). Separately the patient with a voice prosthesis and an automatic pneumatic valve utters 10.3 words after one inspiration

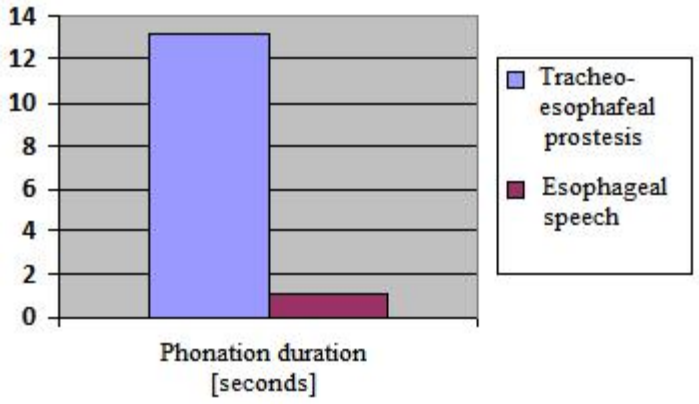


Figure 6. Duration of phonation with tracheo-esophageal prosthesis and esophageal speech with one air bolus, p = 0.0003

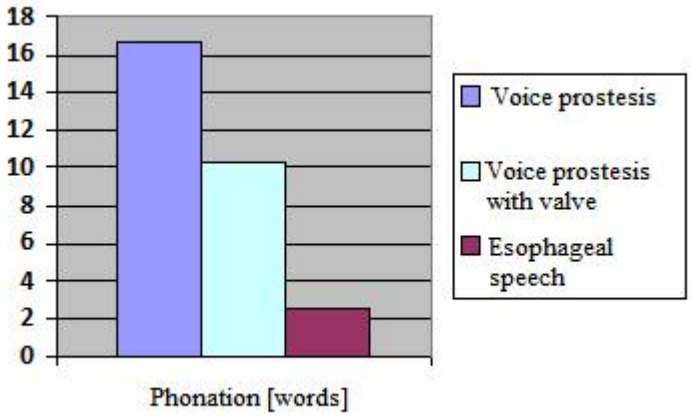


Figure 7. Number of words with one air bolus with tracheo-esophageal prosthesis (with finger control and automatic valve) and esophageal speech, p = 0.01

The rate of speech averaged 1.54 words per second in a patient with esophageal speech and 2.01 words per second in patients with a voice prosthesis (1.3 times more). The patient with a voice prosthesis and an automatic pneumatic valve pronounces 1.51 words per second. The quality of the speech produced with a voice prosthesis does not differed significantly from the qualities of esophageal speech, but significantly differed in its duration. The duration of effective phonation with a single air bolus is statistically higher in use of a voice prosthesis compared to esophageal speech ($p = 0.0003$).

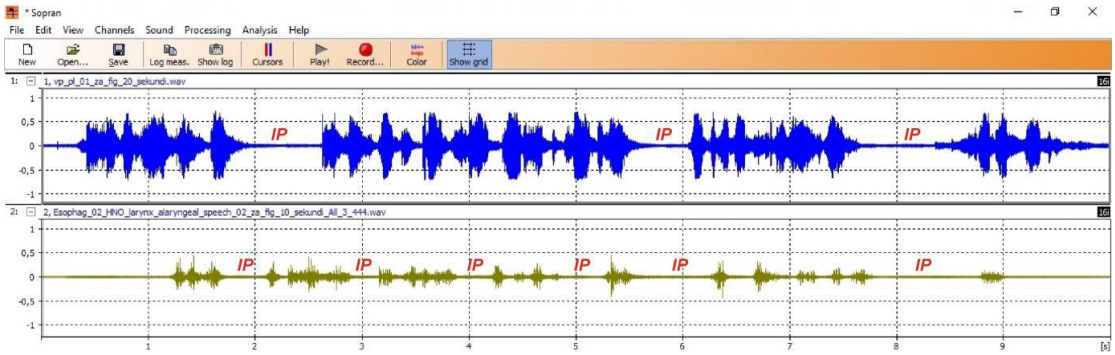


Figure 8. Comparative representation of the phonator curve at patient with TEP and voice prosthesis (blue color - above) and patient with esophageal speech (green - below). Phrases between pauses for Intake pauses (IP - intake pauses) are significantly longer and speech is much more dynamic and effective in the patient with a voice prosthesis.

Average effective life of a speech prosthesis

For the cohort of 36 patients in the indicated time interval were used a total of 69 prostheses, an average of 1.92 prostheses per patient for the specified period. From the specified number of patients only 16 needed more than one prosthesis in the specified time range. Based on these 16 patients, the mean duration of effective life of a prosthesis until the manifestation of functional problems requiring the patient to seek medical attention or to require replacement or explantation of the voice prosthesis is 185 days, as the minimum lifespan of the prosthesis is 30 days and the maximum 930 days.

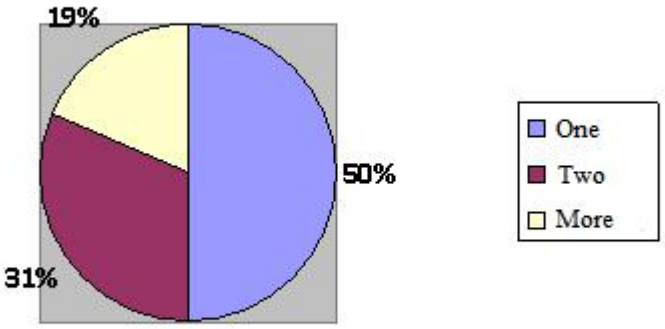


Figure 9. Comparison of some patients according to the number of the prostheses they used for the study period

The main indications for prosthesis replacement in our analyzed group of patients have the appearance of lychee through the prosthesis, prolapse or prosthesis obstruction of the course of the tracheoesophageal fistula. In thirty patients (58.8%) fistula dysfunction occurred with fluid leakage around the prosthesis. There were two cases of spontaneous prosthesis failure (3.9%). In one, the prosthesis had entered the trachea and had to be extracted through rigid bronchoscopy (OP 278 / 22.03.2009; ID2009042317400000). The patient's physique and preserved very good cervical mobility allowed the intervention to be performed under local anesthesia with bronchoscope. In the second case, the prosthesis had fallen out. In the rest In 13 cases (25.5%) the replacement was necessary due to the development of various factors appearing as complications from the prosthesis itself - granulations around prosthesis, soreness in the area, mild inflammatory reactions, spontaneous mucosal closure (total n = 6), mediastinitis (n = 2), displacement of the prosthesis (n = 2) or the patient's desire to replace the prosthesis or replace it with another model (n = 3) (Figure 7).

In two cases, prosthesis dysfunction was a clinical indicator of recurrence in the area of the tracheostomy.

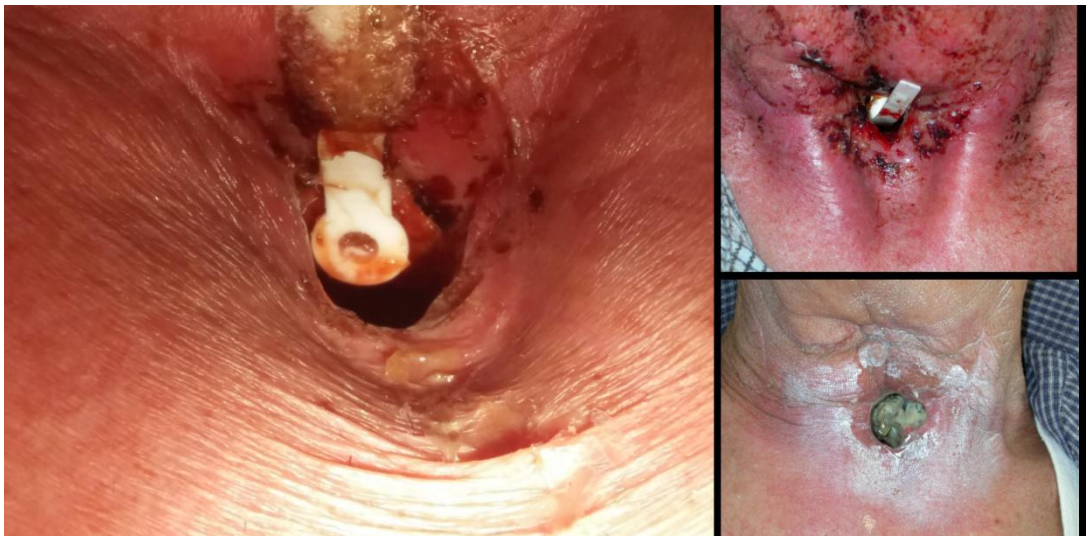
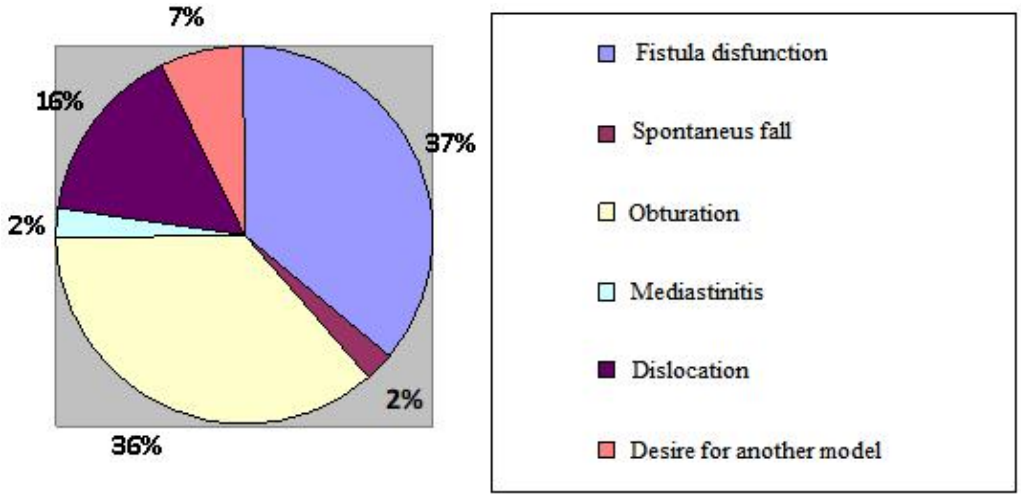


Figure 10. Changes in the stoma and voice prosthesis in case of stoma recurrence. On the right the interval between the photos at one and the same patient is 2 months old, the second tumor necrosis is distinct

Outside the group of patients analyzed here, we have two who were candidates for surgical voice rehabilitation (P.K.M., 69 2010041309381700 and I.P.S., 76, 20201230093836), which were critical stoma stenosis or unstable stoma collapsing after removal of cannula. In both cases it was assumed that they are not suitable for voice prosthetics with shunt. One patient underwent plastic surgery with a triangular lamp and the stenosis was corrected. However, the residual lumen and configuration of the stoma with a deep rostral recess did not allow implantation in the second stage.



F*igure 11. Reason for prosthesis replacement*

Analysis of complications of tracheoesophageal puncture

The reported complications of laryngeal prosthetics vary significantly in scientific medical periodicals. They were in our cohort observed almost all reported complications.

Mild complications without danger to the patient's life

The most commonly observed group of complications was associated with fistula dysfunction and leakage of fluid around the prosthesis. As it was already mentioned, such complications were observed and a reason for replacement appeared the prosthesis in thirty of the cases (58.8%).

Complications that are relatively life-threatening

In the analyzed cohort, despite the large number of fistula dysfunctions, no large-scale aspiration has been reported liquids or food particles in the airways. Against this background however, two cases (3.9%) of spontaneous prosthesis failure were observed and its enclaving in the right main bronchus, requiring bronchoscopy for removal of the prosthesis and in the second stage placement of a new one. Despite the small size of our sample, these data are comparable to those reported by large ones centers and studies.

In one case, when placing the prosthesis due to excessive pressure and lack of cooperation on the part of the patient, the prosthesis fell into digestive tract. This necessitated emergency fibrogastroscopy for its localization and removal.

Complications that pose an absolute danger to the patient's life

In the study group, two patients (3.9%) developed the most severe reported complication of laryngeal prosthetics - acute mediastinitis. Relative to the two separate surgical techniques used, the frequency of mediastinitis using a conventional technique with a rigid esophagoscope Hasslinger system was 5.6% (2/36), and in the modified Lichtenberg technique and Brown - 0% (0/15). Both patients were male, aged 64 years and older 67 years. Constitutional features that directly favor the development of mediastinitis were not observed in them. The age of patients, the volume of initial surgery and subsequent ones radiotherapy procedures in the area, as well as the lack of tunic adventitia of the esophagus, act as synergistic factors favoring the development of this severe complication of laryngeal prosthetics with direct risk to the patient's life. In both patients with mediastinitis it was necessary prosthesis explantation and long-term antibiotic treatment. TEF obliterated spontaneously within 1 and 3 days, respectively. The conservative treatment was adequate and no additional surgical treatment was required.

Prosthesis maintenance

In our practice, patients almost without exception prove incapable to service the prosthesis in the manner described in the literature review, therefore we recommend cleaning the prosthesis without removing it, using gauze, water and mucolytic spray. In some cases, the prosthesis is blocked by dried secretions and cleaning it at home without removing it is not enough. Our preferred approach in such moments is for the patient to schedule a visit to the ward, where the prosthesis should be removed and cleaned carefully, if possible, or if there is damage to it, it should be replaced.

5. Discussion

Physiological and vicarious voice formation after laryngectomy

In order to minimize the negative consequences of LE (physical and psychosocial), it is necessary to conduct effective voice rehabilitation of patients. Historically, there are many different methods of rehabilitation - through different pneumatic devices, formation by surgical method of a fistula protected by muco-muscular duplicates, electrolarynx, esophageal or tracheoesophageal fistula with implantation of a voice prosthesis.

Tracheoesophageal puncture technique

Tracheoesophageal puncture (TEP) and placement of a voice prosthesis in it is an effective method of voice rehabilitation after laryngectomy, which significantly improves the quality of life of patients. The devices used for this purpose, provide a one-way flow of air through the prosthesis and do not allow the passage of esophageal contents into the trachea. Introduced in practice for the first time in 1979 by Singer and Blom, who offer performing tracheoesophageal puncture (TEP) with implantation of unidirectional valve prosthesis as a method for voice rehabilitation. This method proves to be highly effective as it meets the criteria that other methods for Voice rehabilitation fail, namely: 1. Provides normal swallowing without aspiration; 2. Mediates effective voice production 3. Surgical manipulation is relatively easy, allows it to be repeated performance; 4. The implanted prosthetic valve protects against stenosis and aspiration; 5. The method is applicable to patients undergoing radiation therapy.

Patients easily and quickly learn to use the device. In ours days the use of TEP is the gold standard for voice rehabilitation of patients after laryngectomy, as the method is easy to implement, reliable and provides an effective way to communicate.

The voice prosthesis can be implanted during laryngectomy (primary TEP) or in the second stage after LE (secondary TEP). Brown et al. report that there is no significant difference between subjective and objective voice qualities of patients with primary and secondary TEP. Not detected difference in patient satisfaction with the voice produced. According to authors the advantage of the primary over the secondary TEP is avoiding re-operative intervention and earlier voice intervention rehabilitation compared to secondary TEP. According to Guttman et al. the primary TEP provides satisfactory voice rehabilitation immediately after LE, but is associated with a shorter "life" of the voice prosthesis (4.2 months) compared with the second implant (9.06 months). Dentures with round Intraesophageal ends are easier to place and therefore are recommended as a choice at first implantation. At a later stage, if it turns out that very high phonator pressure is needed, which is uncomfortable for patient, a low-pressure prosthesis may be considered plate mechanism. In the group of patients we follow, there are only two with primary implantation. Both have been operated on and implanted in clinical centers outside Bulgaria. In our case it was performed in these patients repeated secondary TEP after removal of the original prosthesis on various causes and closure of the fistula. Otherwise, all other patients who have been laryngectomized in the two clinical centers (ENT Clinic - University Hospital "St. Marina", Varna and Department of ENT Diseases, University Hospital Plovdiv AD, Plovdiv), as well as in other Bulgarian ENT clinics, are with us implanted for the first time secondarily. There are several main reasons motivating our choice of behavior. First, it is the expected higher rate of postoperative complications after laryngectomy with primary TEP. According to Scherl et al. and other authors worse prognosis for voice rehabilitation is present in the presence of the following factors: secondary TEP, TEP after radiotherapy and use of a lamp for reconstruction time of LE. There are studies that show a higher frequency of complications and those that, comparing primary and secondary TEP, no find significant differences. This aspect is still the subject of controversy in specialized literature In the clinical centers where we conducted training, secondary implantation is preferred and this is largely was also decisive for our choice.

Secondly, specific to Bulgaria aspect is the difficult organization of the supply of voice prostheses. In the context the large open intervention to remove the larynx is difficult patients to be introduced to the problem and informed as well as they take informed decision. The potential risks of complications do one-stage intervention unattractive to patients. Not least place comes the purely technical aspect with postoperative thickening of tracheoesophageal septum as a result of perioperative edema. This involves the initial implantation of a longer prosthesis and possibly its replacement in the second stage with a shorter one. The phenomenon of thinning of The tracheoesophageal septum is well known over time and has been observed in our patients. The effect of post-radiation fibrosis on the change in tissue thickness. It is not known how gradual tissue thinning in the area of TEP is related to the conduct or not of radiation therapy. In the conditions of restrictions (patients in our country at the moment have to pay the cost of the prostheses themselves) similar size changes in amount represent an additional financial burden to our patients. Unsatisfactory voice production, periprosthetic lysation, dilatation of tracheoesophageal fistula, formation of granulations, etc. Complications may occur due to incorrectly selected size (larger or smaller) of the implanted prosthesis. Our study has no design or data, which allow some comparison between early and late postoperative indicators for primary and secondary TEP. Our choice to apply mainly secondary TEP is dictated by our subjective preferences and partly by organizational factors.

As potential advantages of our modification of the technique of Lichtenberger-Brown for tracheoesophageal puncture and vocal implantation prosthesis we can specify the following:

1) There is no need to use a rigid endoscope (either esophagoscope or direct surgical laryngoscope). This reduces the risk of trauma to the mucosa and other layers of the wall and, accordingly, to related complications. No direct visualization of the TEP area through the neohypopharynx / esophagus or at placement of the voice prosthesis, nor to verify the position of the internal intraesophageal flange. This can be a special relief in cases with narrow

esophagus, scarred or post-radiation compacted tissues behind the tracheostomy, curved course of the lumen or limited mobility of cervical spine and head. However, the method does not completely eliminates the possibility of incorrect placement of the intraesophageal flange, as is the case in our group of patients (established by VFS and subsequent esophagoscopy). However, we believe that surgical experience would allow us to assume such a potential complication and take additional diagnostic procedures only in suspicious cases, thus eliminating the routine inspection and routine trauma from esophagoscopy.

2) The leading role of the dilatation method for forming the channel of tracheoesophageal fistula as described in the original technique of Lichtenberger. In our opinion, the fundamental disadvantage of using dilator or dilating trocar as the main tool is excessive concavity of the surrounding tissues and strong traction in the direction perpendicular to the wall of the organ. Such an impact is difficult to be controlled precisely and seems to contradict the pursuit of minimally invasiveness of the puncture itself. The swelling of the injured in this way tissue can be significant and pre- or intraoperatively selected length of the voice prosthesis to be insufficient to cover the entire course of tracheoesophageal fistula through swollen tissues. The puncture incision with snarling tool (scalpel) is much less traumatic and can be refine more easily, and in case of need - to expand gradually until a sufficient portion of the rounded tip of the catheter with thread. There are three arguments against the use of a scalpel: 1) the danger of perforation of the posterior wall of the esophagus; 2) increased risk of bleeding from the incision wound and 3) increased risk of periprosthetic lysation through the seemingly wider incision opening. We believe that the risk to the back wall of the esophagus is eliminated by the protective effect of the soft tip of the catheter into which the blade of the scalpel is inserted after penetrating the mucosa, and by very good performance of the exact location of the incision from the curved tip of EENC through the stoma. With regard to bleeding, we consider (based on the fact that in the case we analyzed, it was always weak, it was controlled only with temporary compression, no use of an electrocautery was required or other method of hemostasis and we have not observed cases of postoperative bleeding) that it

does not pose a potential risk in this anatomical area, especially under the condition that the manipulation is performed to the maximum near the midline. Regarding the risk of periprosthetic makeup we did a study of the available literature, in which we did not find any results showing that it is elevated when using a scalpel (cutting tool).

3) Lichtenberger's original technique is partially simplified - avoided the need to use the specific conical dilator, and use tools that are available in each operating room and with which each surgeon works routinely on a daily basis. However, EENC is very convenient: easy to enter, its length and diameter are specifically selected for interventions in this area with transoral access, its handle provides a comfortable grip, the surgeon, located on the patient's head, works in an ergonomic posture and the whole construction of the EENC allows stable and accurate targeting of working peak by rotation and movement along the the patient's esophagus / body. All this makes it undoubtedly more appropriate for this intervention by the long gynecological forceps used in the analogous technique of Brown. We also believe that working with Macintosh type intubation laryngoscope is easier, less traumatic and has an advantage, especially in patients with insufficient head extension or those with preserved teeth, in which the transoral introduction of direct a Kleinsasser-type laryngoscope would be more difficult.

4) The nelaton catheter placed on top of the EENC provides more gentle contact with the esophageal mucosa compared to the metal tip of the esophagus. tool. We must not forget that it is, after all, designed for introduction under visual control in the airway with a constantly open lumen, ie. not intended for sliding on the mucosa. In addition, our experience shows us that sometimes the tip of the EENC-loaded needle may partially protrude from the lumen in case of accidental pressing of the piston or in case of involuntary traction on the thread. In a similar case, the introduction of blindly a needle holder with a bare needle tip would be particularly dangerous and traumatic for the mucosa.

Complications

In our study, the conclusions are based on the first in Bulgaria comparative analysis of patients with voice prosthesis and non-prosthetic patients. Even a small one, almost everyone was observed in our cohort complications of prosthetics reported in scientific medical periodicals. The development of complications (related to the prosthesis or tracheoesophageal fisutla) requires removal (temporarily or permanently) of the voice prosthesis or replacement with a new one. In our study, the complications that led to voice prosthesis removal are similar to the data and recommendations in specialized literature and include a permanent inability to phonate (n = 2; 3.9%), obstruction by secretions and deposits (n = 30; 58.8%), some form of clinically manifested moderate- or moderate-severe fistula dysfunction (n = 30; 58.8%), dislocation (n = 13; 25.5%), mediastinitis (n = 2; 3.9%), and desire on the part of the patient to switch to another prosthesis model (n = 3; 5.9%). The values and percentages in our results here are conditional - are calculated to the total number of patients on the condition that patients have different number of implants and some of the reasons for changes mentioned here are were in the same patient at different times. In terms of the heavy Complication mediastinitis can be emphasized that it is manifested only in the group with conventional implantation technique using rigid esophagoscope and does not occur in the intervention group in our modified technique by Lichtenberger and Brown. However, this comparison is not statistical credibly, firstly against the background of different groups of patients and secondly - due to differences in perioperative care in the two groups of patients. Against this background, no reliable superiority of the new technology can be claimed of TEP and implantation for severe complications

Voice rehabilitation through TEP and implantation of a voice prosthesis in Laryngectomy patients represent an enhancing quality of life intervention in patients after laryngectomy or laryngectomy with subsequent radiation therapy

due to advanced laryngeal cancer. The results from the present dissertation show both the advantages of the method and and its disadvantages given the half-life of the prosthesis and the development of complications in such patients. The complications of the method vary from such without risk to life, such as granulation around the prosthesis and low-volume flow of fluids around it, to those with a relative risk such as aspiration of the prosthesis, and complications with absolute risk to the patient's life such as mediastinitis and ileus when swallowing the prosthesis. However, even against the background of these complications, the benefits of laryngeal prosthetics dominate over other voice rehabilitation methods.

In the group of patients we analyzed, it makes a relative impression the long time period of use of a prosthesis of an average of 185 days (ranging from 30 to 930 days. Large studies in the available literature indicate the average life of a prosthesis of a comparable model about 86 days, as in secondary implantation the average value is even lower - 54 days. One of The possible explanation is socio-economic - the price of the prosthesis in our country is paid by the patient or the clinic where the implant is performed, but not from the NHIF. This probably causes patients to delay prosthesis replacement with new until the moment of complete impossibility for further use. Other explanations are possible, but this seems most likely against the background of our observations. Certainly the difference in results in terms of the long period of use of a prosthesis in our country compared to the data reported in the world literature is a question that should be clarified in further studies at national and international level

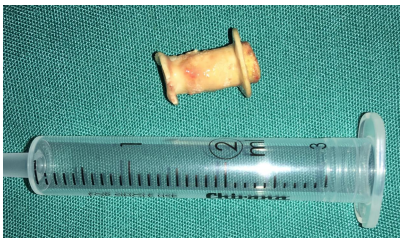


Figure 12. Voice prosthesis 13 months after implantation with scars of biofilm, final wear and defects in the material

In the observed patients we had two who did not proceed to surgical treatment despite their desire. The reasons were in one case stenosis, and in the other - instability of the stomach, left without a cannula. this is also accepted as the main contraindication for this type of voice rehabilitation. The practical rule is that the diameter of the stoma should be about 14 mm. Some authors suggest modifying the voice prosthesis through excision of the lateral sections of the tracheal flange, where it would be possible implantation in stoma with dimensions 8x10 mm. From a surgical point of view point it is difficult to predict the final size of the definitive tracheostomy. Too large stoma is difficult to close tightly with your finger and get get phonation. Too small stoma complicates even the spontaneous breathing. Additionally, the prostheses occupy part of their lumen and create conditions for turbulence of the air flow and excessive drying of secretions with additional narrowing by crusts. It is also difficult to maintain and the replacement of the prosthesis itself. It can be used for small stoma fenestrated silicone cannula. The ideal option would be surgery dilatation of the stomach with a triangular lamp, but this therapeutic approach is with difficult to predict late postoperative results. Preoperative assessment of patients candidates for tracheoesophageal fistula with implantation of voice prosthesis varies widely in different centers. Blom and Singer originally recommended the placement of a catheter in the neohypopharynx and air insufflation. The effectiveness of this approach is particularly contested in relation to the negative predictive value.

When applying our modified Lichtenberger-Brown technique for TEP initially used a standard rigid surgical laryngoscope Kleinsasser system for access. This decision was mainly influenced by the original technique described by Lichtenberger. At a later stage we passed to use an intubation laryngoscope type Macintosh. This approach is in the basis of Brown's technique. The goal of both approaches is only to achieve visualization of the entrance of the neohypopharynx and possibly the entrance of esophagus. This avoids the risk of mistyped the leading instrument and pressure in a possible retrolingual diverticulum. We maintain the view that the introduction of a tool with a rounded tip, and c our case and additionally protected with a soft catheter is no more risky than standard dilatation "blindly", as in pharyngeal or esophageal stenosis. We believe that the modified Lichtenberger and Brown technique is extremely suitable for patients with anatomical features or condition after surgical treatment of the neck and in particular - of neohypopharynx, which make it difficult to insert a rigid esophagoscope such as contractures, fibrosis, kyphosis. In similar clinical situations there are described methods that are based on fibroesophagoscopy or even retrograde transgastric esophagoscopy. There were patients in the group we analyzed one in which the visualization of the hypopharynx by esophagoscope or direct laryngoscope was impossible. Most of the patients were present teeth of both jaws, cervical osteophytes, reduced mobility of spine in the cervical region, moderate post-radiation induration of neck and fibrosis with partial calcification of the prevertebral structures. This patient was one of the reasons we were looking for an alternative new one technique other than conventional, which is not dependent on rigid endoscope.

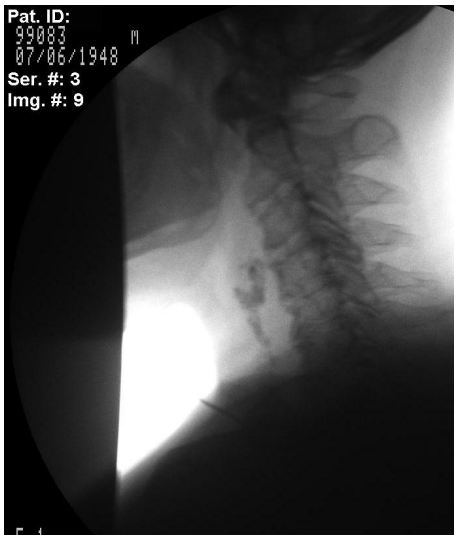


Figure 20. Patient with reduced cervical mobility due to osteophytes and fibrosis with calcification of the prevertebral fascia in area

Since the last decades of the XX century leading method of speech rehabilitation of patients after laryngectomy is tracheoesophageal fusilization with implantation of a voice prosthesis, originally introduced in routine clinical practice by Blom and Singer. Some of the options at implementation of this intervention in secondary TEP include the use of fibroesophagoscopy (transorally or transnasally). Techniques with are also described retrograde insertion of the fibrogastroscope through a mini-laparotomy or gastrostomy. There are two major groups of drilling tools that are used for TEP - cone-shaped needles and trocars with increasing diameter (operate by piercing and gradual dilatation of the stroke) or scalpel (cutting tool). Clinical trials have also been made using a laser.

The majority of complications related to the TEP procedure itself are due to the use of rigid endoscopes. From this point of view the techniques of TEPs that do not use a rigid endoscope are expected to have advantages in this regard. That was one of the reasons we turned to Lichtenberger technique at the start of TEP interventions. IN its original appearance, the technique proposed by it is based on the original endo-extralaryngeal needle (EENC - endo-extralaryngeal needle

carrier) and a specific set of conical metal piercing and dilating tip for catheter and thread-locking metal ball. Our initial experience with this technique of gradually dilating the hole in the wall between the esophagus and the trachea was not encouraging. Themselves conducting the lead puncture with EENC was relatively easy and accurate. We only found a restriction on the freedom of movement of the tool from the rigid Kleinsasser type laryngoscope. The next stage - the transition to the cone through the tissues and the shaping of the course of the TEP was technical difficulty for us. To achieve it required a very strong traction with the guiding thread and the stretching of the surrounding tissues seemed traumatic. This procedure was even more difficult in patients after radiotherapy and topically compacted and fibrosed tissues behind the stoma. With them even at the initial puncture with the sharp needle was difficult to predict place. Gradually we became convinced that the use of a cutting tool (scalpel) and dissector is easier and at first glance more atraumatic for tissues. Such an approach is fundamental in Evans technique. Lichtenberger also reports that even in his hands the technique of TEP with EENC and subsequent dilatation, sometimes requires the additional use of a cutting tool.

The aspiration of the vocal prosthesis in the tracheobronchial tree represents a potentially life-threatening complication. Patient with such a situation will undoubtedly be an unusual situation in most emergency centers in our country, first due to the low awareness of colleagues for voice prosthetics through TEP and prosthesis, secondly - due to impaired verbal communication of the laryngectomy patient. An additional complicating factor in the diagnosis is that phonator prostheses can to remain difficult to notice against the background of the many superimposed radiological shadows of the bony, vascular and parenchymal elements of chest. The method of choice for confirming or rejecting the diagnosis, as well as for the extraction, is bronchoscopy. This is it again intervention that can be implemented in an emergency in extremely few clinical centers in our country. In those observed by us patients we have one case of prosthesis aspiration (1/53, 1.9%). This one frequency corresponds to those reported in the literature by other centers (4% -8%) The implantation was performed in Plovdiv, the patient lives in

Dulovo, where the accident occurred. Referral to the clinic in Varna for diagnosis and treatment is based on personal acquaintances between colleagues. It's clear, that without a developed "safety net" of those familiar with the situation otorhinolaryngologists and pulmonologists, covering the entire territory of our country, patients with a similar condition are at risk of aspiration and respiratory failure, as well as from suboptimal diagnosis and therapeutic behavior.

In two cases, prosthesis dysfunction was a clinical indicator of recurrence in the area of the tracheostomy. There are clinical observations that are slow progressive and unaffected by standard measures makeup around the voice prosthesis is a typical symptom of regional recurrence and can be taken for indicator for more active diagnostic measures. The expected frequency of similar an unfavorable clinical scenario is about 8%.

Applicability of video fluoroscopy

Disadvantage of TEP is the high cost of consumables and the need for their periodic replacement. This is the reason to look for a method of determination of the approximate size of the prosthesis for each patient individually before its implantation. Precisely selected size of the voice prosthesis is key factor for achieving highly effective voice rehabilitation. Video fluoroscopy with contrast to the neohypopharynx is important in the preoperative period for the detection of possible stenoses or diverticula of the neohypopharynx, as well as for a preliminary assessment of the length of the necessary prosthesis. Such a practice is not standard in the postoperative care and follow-up of patients after laryngectomy. IN our clinic, however, it is accepted in routine practice and we believe that contributes to the choice of behavior in both early and late postoperative period in laryngectomized patients. Our experience shows that video fluoroscopy with contrast to the neohypopharynx is recommended for successive TEP and implants in the same patient. Over time, the thickness of the tissues of the tracheoesophageal septum shows dynamics. This is a well-known phenomenon. VFS at each successive implantation or replacement of the prosthesis can objectify changes in the length of the fistula and to support the

preoperative choice of the length of the prosthesis. VFS-assisted prosthesis selection is non-invasive, easy to perform, well-tolerated by patients method for determining the thickness of tracheoesophageal septum. If the research methodology is followed, anatomical structures are easily identified. This allows for precision assessment of the thickness of the tracheoesophageal septum and determination accordingly the approximate size of the voice prosthesis before its implantation. Properly chosen prosthesis according to the anatomical features of the patient leads to good results from voice rehabilitation and minimization of complications. VFS was also used in cases of suspected obstruction of prostheses to specify the position of the intraesophageal flange.

Voice production

The electrolarynx in our country is still (mostly traditionally) accepted as main method of voice rehabilitation after laryngectomy. Undoubtedly despite decades of technical development, this type of devices generate speech with a low degree of intelligibility and a very mechanical sound that gives way on all characteristics of that achieved with a tracheoesophageal shunt and prosthesis. Base models generate a monotonous tone. Speech is fused, weak articulate. Even newer models (two-button) that allow bitonal speech and the latest - with a multifunction button that allow modulating the voice by tone and intensity give voice and speech with worse characteristics of those with an implantable voice prosthesis. Most studies unanimously support the superiority of the tracheoesophageal voice prosthesis over the electrolarynx in terms of speech intelligibility. No coincidentally, it is considered the "gold standard" today. Phonation through electrolarynx is far from comparable to that when using voice prosthesis in terms of the natural "human" sound of the voice and the intelligibility of articulate speech. In our practice based mainly of secondary implantation, the electrolarynx could play an important role in the postoperative period, allowing patients some verbal communication from the first hours after laryngectomy. In this period the great some patients rely on communication with the treatment team in writing notes. In many of them, this form of communication is difficult to slow down writing, uncomfortable writing

conditions, the need to put on glasses, etc. Patients are limited in time and manage to ask few questions often they get annoyed and then get discouraged when they can't have a dialogue in writing at the speed they desired. It is in this context that the electrolarynx it can be very helpful because most patients are able to get started quickly to use the device and within an hour to have some understandable speech. Undoubtedly the possibility of such verbal alaryngeal communication will improve the mental state of patients in the earliest and severe for them first postoperative days. The cumbersome procedure of supplying state-funded auxiliary devices in our country does not allow timely provision of electrolarynx to patients after laryngectomy. From a practical point of view, opportunities must be sought to provide reversible electrolarynxes in clinics.

Learning esophageal alaryngeal speech is a long and demanding process long-term work with a speech therapist. Consistently, patients are trained to absorb and release air, reproduce consonants, vowels and diphthongs, one-syllable words, two-syllable words, and gradually the goal is both syllables to sound with a bolus of air, to pronounce simple phrases (again with a single bolus), the articulation and emphasis of vowels, diphthongs and consonants and active dialogue. Data from The literature shows that the intelligibility of speech achieved through is better tracheosophageal shunt and prosthesis. These patients have more amount of air, because white dorbs can hold much more air from the esophagus. In this way, patients can pronounce up to 25 - 30 words without interruption (air intake) compared to 4-6 words in the best esophageal speech. This applies to English. The speech in patients with tracheosophageal shunt and prosthesis is more natural and as melody, as most of them are able to modulate the pitch of tons within certain narrow limits, reaching 7-8 semitones. The use of the natural source of air (lungs) in this type of laryngeal speech is easier and natural - there is no need for patients to learn ingestion of air into the esophagus, then contract chest muscles and relax the cricopharyngeal muscle, for to phonate. In the analysis of the phonator indicators we used sampling at 44.1 kHz, 16 bit and storing files in WAVE format, guaranteeing complete spectral information without compression losses. This one format is widespread in modern recording and computing

technique and is recognized by any software Some of the records were made with non-standardized video recorders and in the second stage were converted and resampled to the above format. In general, the frequency of sampling is recommended to be twice as high as the highest frequency of the sound that can be registered. This means that if we want to record phonation in the range up to 8 kHz, we need a sampling frequency 16 kHz. Again based on Nyquist-Shannon's sampling theory based and the concept that any signal can be accurately reconstructed by records if the sampling rate is twice its maximum frequency range. Because human hearing senses maximum frequencies up to 20 kHz, the sound recording is based on a sampling frequency of 44.1 kHz (CD standard for sound recording). Human (laryngeal) speech includes frequencies up to 10 kHz. i.e. frequency would be sufficient for the terms of reference in our analysis at a sampling rate of 20 kHz. The higher frequency does not give any real advantages. However, we focused on the maximum possible for our equipment frequency of 44.1 kHz. One of its main technical advantages is that it is wide common and standard. The use of a lower non-standard frequency sampling would give us insignificant memory savings at the expense of risk from perturbations and artifacts in file conversion.

Numerous studies, based on clinical practice, have found a better comprehension of speech achieved through a tracheosophageal shunt and prosthesis. The main factor for this is the presence of a larger amount of air (close to natural) in the lungs compared to the capabilities of upper esophagus. Thus, patients with TEP and voice prosthesis can pronounce up to 25-30 words without interruption (intake of air) compared with 2.8-6.3 words in the best esophageal speech. Patients with excellent esophageal speech are able to pronounce 85 to 120 words per minute. Both indicators refer to English. Speech through a tracheosophageal shunt and prosthesis is distinguished by some melody, as its tonal range covers 7-8 semitones. When the patients we followed with esophageal voice had their average speech output is 92.1 words / minute. This puts them in the group of "virtuosos", who have a speech output of 85 to 120 words per minute. Of course to a great extent degree it is not correct to compare the results of two

Bulgarian patients with indicators of eight English speakers, primarily due to the language difference. Such comparisons would require further standardization and validation of the set of words with respect to at least the syllables and phonemes. From another side, from a practical point of view the very small number of such patients both in our group and in one of the few but most representative in this regarding publications from the available scientific literature worldwide show that in practice organizing such a study for validation and an exact comparison is not possible. Even against this background we can assume that the difference in voice production with esophageal speech (92.1 words per minute) and the one with a voice prosthesis (124.2 words per minute) for Bulgarian speakers patients showed the benefits (134%) of alaryngeal speech with TEP and prosthesis compared to esophageal. The voice production with TEP and prosthesis is similar to that of a speaking healthy patient of about 120 words per minute.

The use of an automatic pneumatic valve for speech with TEP and voice prosthesis without the use of hands turns out to be a factor worsening some indicators. Speech output with such a valve is 90.7 words per minute. This result is similar to speech production with esophageal voice and significantly inferior to that with TEP when using a finger to control the opening and closing of stoma for inspiration and phonation (73%). The explanation for this seems to lie in the need for additional initial expiratory effort to close the valve, which takes both time and air volume. Only one patient in The group analyzed by us uses introductions in practice from Blom and Singer tracheostomy valve. The patient underwent a laryngectomy in another state, and even during this intervention the primary one was performed implantation and is trained to use a valve. In this way, the patient was able to phonate through the tracheoesophageal shunt without using finger / hand to obturate the stomach. The voice was very good, the patient

he controlled the valve skillfully with his breathing. The barely perceptible "click" of the valve did not disturb the intelligibility of speech. From an acoustic point of view much more perceptible and even intrusive was the auscultatory perceptible lychee of air at the beginning of expiration before closing the valve. The

inconveniences which led to the abandonment of this technique by the patient were related mainly with the high price of consumables - about 5 EUR per day (for one leather sticker set). From our side, we observed an atypical one excessive humidity of the stomach, much higher than all others our patients. Of course, the presence of a filter in front of the airway does considered an important protective device for the respiratory system. However, in the patient we observed more frequent inflammations around the tracheal prosthesis flange, which were a common cause of multiple controls reviews. After the patient stopped using the valve economically causes, periprosthetic inflammation decreased sharply.

There are significant variations in voice production between patients in our group with TEP and voice prosthesis. With this form of laryngeal speech patients utter an average of 16.8 ± 13.4 (3.2-50) words with one inspiration. Analysis of video and audio recordings shows that this is mainly due to the effort to initiate phonation (resistance of the neohypopharynx and of the voice prosthesis, the configuration of the structures and the tone of the muscles in area) and pulmonary function, which is often significantly impaired in this group of patients due to concomitant diseases such as COPD. In the course of the use of a voice prosthesis undergo natural parallel processes of increase the risk of bruising and complications and increase the resistance of the prosthesis itself for the air jet.

Another advantage of alaryngeal speech with TEP and prosthesis is that it is created airway resistance, similar to the natural resistance of larynx. However, it can vary over a relatively wide range over the course of operation of a prosthesis, which is associated with both the formation of specific biofilm on it, and with fatigue and wear of the material and construction.

Factors limiting laryngeal prosthetics in Bulgarian population

Despite the good results worldwide for voice rehabilitation of laryngectomy patients using TEP and voice prosthesis, in our country this type rehabilitation is not strongly represented. This is due to both the limitation of training of medical

staff on the intervention and subsequent monitoring of patients and the cost of the prosthesis itself, which is not financed by the NHIF. So far we have no observations whether private health insurers undertake reimbursement of this medical device. An additional factor that shakes patients from this intervention is the varying price of the prosthesis not only according to the model but also according to the distributor, the place of purchase, as well as the indivisible market economic component of this medical device.

Future guidelines in laryngeal prosthetics for the Bulgarian population

Based on the presented results, the effectiveness of the laryngeal prosthetics after laryngectomy is undeniably a quality-enhancing factor of life and giving good results compared to its alternatives. On at national level it is necessary to create an information program and reimbursement of voice prostheses by the NHIF. This would allow Bulgarian patients to have alternatives and to make informed choices. On international level despite the indisputable data on the advantages of the methodology for rehabilitation requires more technical improvements and of the implants, and of the surgical technique, and of its contents the organization of the rehabilitation itself. Development of new composites, models and their improvement is extremely necessary for the purpose of extension the effective life of the prosthesis.

The innovative modified secondary equipment presented by us here implementation of TEP and fistula is based on the EENC of Lichtenberger. The technique is precise, safe and easier to perform compared to the original technique. The use of a cutting tool instead of a dilating tool is an improvement especially in terms of penetration through seals and scar-fibrosed tissues. Based on our clinical experience we can say that the soft tip of the nelaton catheter is more atraumatic for tissues compared to the metal tip of EICC by Lichtenberger et al standard metal terminals, introduced more easily through stenotic and curved areas of the lumen of the neohypopharynx / esophagus, and represents semi-elastic pad in the area of the TEP incision.

Today, based on the world and our own clinical experience, we can argue that the vocal rehabilitation of laryngectomized patients through voice prosthesis is an effective method and its widespread use in everyday ENT practice should be proclaimed, for which both the training of medical and non-medical staff throughout the country, and covering the costs of the prosthesis itself by the NHIF. For the need of these steps are evidenced by the large number of patients with laryngeal cancer in our country, compared with an extremely small percentage prosthetic by them, as well as the contrast in sexual intercourse in patients with laryngeal carcinoma and prosthetic ones.

6. Conclusions

The analysis of the experience and the results of the voice rehabilitation of laryngectomized patients with voice prostheses from two leading clinical centers in Bulgaria they reveal important medical and non-medical aspects of the process. Although in countries that have publishing activity in the specialized medical literature, this method of rehabilitation is imposed as the main and leading in recent decades, in our country its spread is still rather sporadic. Many additional activities are needed for optimizing the practical approach in these patients. The main looks are raising the awareness of medical and non-medical staff and approval of a model of reimbursement of medical devices (voice devices) prostheses) from the NHIF.

Both globally and in our country, it is exceptional inhomogeneity of the surgical techniques used for TEP. In view of the little one number of procedures performed and the subjective preferences and capabilities of individual clinical centers and specialists is almost impossible to do standardized study with design and number of patients to prove advantages of one of these techniques over the others or of the primary over secondary prosthetics. Our results confirm the observations from world practice on the role of rigid endoscopy for peri- and early postoperative complications. The modified methodology developed by us for TEP and implantation of a voice prosthesis based on EENC by Prof. Lichtenberger there seem to be advantages over standard access, but this observation does not reaches statistical reliability.

Additional diagnostic method as in the preoperative phase preparation, as well as for postoperative monitoring and detection of complications in both the early and late postoperative periods is video fluoroscopy. The availability of an opportunity for such a study within the hospital establishments assists in the choice of prosthesis size, the planning of intervention and management of the postoperative period and can be emphasized as recommended.

7. Contributions to the dissertation

1. A large population of laryngectomized patients was analyzed in Bulgaria with regard to voice rehabilitation through the placement of voice prostheses.

2. A modification of the Lichtenberger-Brown method for

tracheoesophageal fistulization, which minimizes the risk for complications such as injury and penetration of the posterior wall of esophagus.

3. The applicability of video fluoroscopy as a method for objectification of the thickness of the trachoesophageal septum and the position of the inner flange of the voice prosthesis.

4. A comparative phoniatric analysis between sound production through esophageal, alaryngeal speech and such after placement of a voice prosthesis, objectifying the indisputable advantages of alaryngeal speech by means of a voice prosthesis.

5. Promotion of the method for voice rehabilitation of laryngestomized patients with voice prostheses in Bulgaria, already applied successfully for years in the ENT department at UMHAT Plovdiv AD, ENT clinic to UMHAT Sveta Marina EAD, Varna and ENT clinic of UMHAT Kaspela Plovdiv city.

8. Publications and scientific communications related to the dissertation labor.

Publications:

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2. Assenov A, Sapundzhiev N, Spasova B, Stoyanov G, Assenova M. Current opportunities for alaryngeal speech. MedInfo 2021: 1; 208-211

3. Sapundzhiev N, Nikiforova L, Assenov A. Phonatory results in speech rehabilitation after laryngectomy with voice prosthesis. Varna medical forum 2021; 10 (1): online first DOI: http://dx.doi.org/10.14748/vmf.v0i0.7928

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Multimedia content

Martinova I, Elenkov L, Stoyanov T. The human voice. Yes let's talk about. 2018. Available from: MU-Vi.tv https://www.youtube.com/watch?v=nWH6DNadDzw&t=513s