

VILNIUS UNIVERSITY

— VILMA BELEŠKIENĖ —

THE EFFECTIVENESS
OF THE LASER EUSTACHIAN
TUBOPLASTY FOR CHRONIC
SECRETORY OTITIS

Summary of Doctoral Dissertation

Biomedical Sciences, Medicine (06 B)

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VILNIAUS UNIVERSITETAS

— VILMA BELEŠKIENĖ —

LÉTINIO SEKRECINIO
VIDURINĖS AUSIES UŽDEGIMO
CHIRURGINIO GYDYS
LAZERINE TUBOPLASTIKA
EFEKTYVUMAS

Daktaro disertacijos santrauka

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LIST OF ABBREVIATONS

dB – decibel

BET – balloon Eustachian tuboplasty

ET – Eustachian tube

ETD – Eustachian tube dysfunction

LET – laser Eustachian tuboplasty

OME – otitis media with effusion

PSEQ – perfect sequences

PTA – pure tone average

SPSS – statistical package for social sciences

1. INTRODUCTION

An impaired Eustachian tube is closely linked with such middle ear diseases as chronic otitis media, tympanic membrane perforation, secretory otitis, or cholesteatoma, yet the origin of the pathology and the role of the ET in the pathogenesis remain unclear to this date. Eustachian tube (ET) dysfunction is most common in children and almost 40 per cent of children under 10 years of age experience temporary ET dysfunction. In adults this condition is relatively rare and it is believed that prevalence of ET dysfunction ranges from 0, 9 to 5 per cent.

Objective high-quality and technically simple tests for ET function can be clinically essential in order to better understand the pathogenesis and stages of and to determine the treatment for these diseases. Knowledge about the ET function would be beneficial in planning surgical treatment of the middle ear and inferring outcomes of such treatment. In recent years, a number of clinical articles have presented data on a range of distinct ET test methods like sonotubometry, tubomanometry, manometric tests, tensometry, CT, and MRI, however there is no consensus on their application and use in daily practice. Most testing methods are subjective and non-specific, likewise objective methods are insufficiently standardised and they poorly correlate with the clinical picture or are non-physiological, therefore employed only under certain pathological conditions. Among the many studies, there is no 'golden standard' which could be widely used and serve as a benchmark to all.

Even though a number of clinical trials have been carried out to evaluate the effectiveness of the test and sonotubometry is rightly recognized as an objective and physiological test of Eustachian tube function, in clinical practice it has not become widespread and it is not used. The measurements obtained can sometimes be interfered with due to noise pollution from the nasopharynx because of saliva movement during swal-

lowing; therefore artefacts are recorded. In other cases, additional curves of unknown origin may be generated and they are difficult to interpret. When performing different maneuvers during the course of measurement (dry swallowing, water swallowing, Toynbee maneuver, yawning), the spectrum of results differ quite a lot. One of the possible drawbacks of sonotubometry is that the inconsistent results may be caused by the properties of the acoustic signal itself (commonly the test uses an 8 kHz signal). Recently, for sonotubometric examination, a specific broadband class of signals, the so-called perfect sequences (PSEQ) was offered and successfully proved results of objective ET openings. It can be assumed that the use of PSEQ signal may improve results and improve the validity and reliability of the test.

Treatment options for causative ETD are limited and there is no unified approach to a well-defined and established treatment strategy. Absence of adequate methodology is observed, and the effectiveness of many therapies is questionable or limited. Since endoscopy has become more available, it has led to an increase in detailed examination and treatment of nasopharynx and ET pharyngeal orifice inlet. Over the past decade, the newly introduced surgical laser Eustachian tuboplasty (LET) is a promising method to treat causative chronic middle ear diseases. However, to this date the attitude to this treatment methodology has been ambivalent and irresolute. Various authors receive quite different treatment efficiency results and it is believed that a successful outcome can be expected in 36-92% cases. Such different outcomes may be due to the heterogeneous nature of patient populations and differences in survey methods or criteria to evaluate the results. In most cases, LET results were evaluated in patients with both acute and chronic secretory otitis forms, while treatment was conducted in patients with various forms of chronic otitis (retraction, atelectasis, mucosal otitis, etc.). For these reasons, LET has not found a clearly defined position in treating

chronic ear diseases. In recent years, the new ETD methodology called balloon Eustachian tuboplasty (BET) has slowed down research in LET application because the former methodology is safe and efficient (about 80%) and it is suitable for children and adults. Given the fact that BET is a expensive procedure requiring disposable means and sets of instruments, LET can be an optimal and inexpensive alternative to effectively treat patients with chronic serous otitis media once proper selection of patients is conducted and indications are clearly defined.

THE AIM OF THE STUDY

To determine the effectiveness and prognostic criteria for the surgical treatment of chronic secretory otitis media by applying laser Eustachian tuboplasty and to establish functional changes in the ET function by employing objective diagnostic methods.

OBJECTIVES OF THE STUDY

1. To establish the rate variation of sonotubometry with perfect sequences in healthy adults and to identify an optimal and technically simple test to provoke Eustachian tube openings.
2. To assess the research data related to sonotubometry with perfect sequences in patients with nasal obstruction.
3. To examine the relationship between Eustachian tube function and chronic middle ear diseases by applying sonotubometry with perfect sequences (PSEQ).
4. To assess the effectiveness of surgical treatment of chronic secretory otitis media by applying laser Eustachian tuboplasty.
5. To determine factors which influence the results of the surgical treatment of chronic secretory otitis media through laser Eustachian tuboplasty.

THE SCIENTIFIC NOVELTY OF THE STUDY

The research determined functional parameters for ET sonotubometry with PSEQ acoustic signal in healthy subjects and those with nose and middle ear pathologies. Characteristics for patients with nasal obstruction and those with chronic otitis media were assessed. Etiopathogenetic, diagnostic and clinical factors and patterns of applying surgical laser Eustachian tuboplasty to treat chronic secretory otitis media were assessed. The research clarified significant criteria that help to predict outcomes of such surgical treatment. A complex study scheme was prepared to facilitate reliable assessment of the patient's condition and employment of an optimal method of treatment.

No data on objective ET function tests or information on the clinical application and results of laser Eustachian tuboplasty have been acquired in the lithuanian scientific medical literature.

PRACTICAL VALUE

A novel objective test based on sonotubometry using PSEQ stimuli was researched and introduced in Lithuania in order to examine the ET function. Sonotubometry with PSEQ stimuli can be employed for diagnosing middle ear diseases, in differential diagnosis as well as in selecting treatment methods and evaluating and predicting treatment outcomes. The research assessed possibilities to examine the ET function in healthy subjects as well as in patients with difficulty breathing through the nose and in those with chronic middle ear otitis media. The study is objective, easily performed and applicable in everyday clinical otorhinolaryngological practice.

A novel causal treatment for chronic secretory otitis media has been researched and introduced in Lithuania by way of applying laser Eustachian tuboplasty. Prior ineffective, now this treatment enables to achieve good results in patients with chronic secretory otitis media. An original

scheme how to examine and treat ET dysfunction has been developed and it includes indications for surgical treatment. Practical plans have been introduced in the Ear, Nose and Throat Clinic of Vilnius University Hospital. Complex schemes customization yields treatment outcomes of chronic secretory otitis media in cases where treatment through tympanostomy operation is ineffective. In addition, by applying these schemes complications of treatment are prevented, medical costs are reduced and patients' treatment time is shortened.

HYPOTHESIS

A hypothesis is that in case the nasopharyngeal endoscope does not record the ET valve opening in patients with chronic secretory otitis media, treatment through laser Eustachian tuboplasty can be effective.

STUDY PROGRAMME

Given the goals and objectives, the following research programme was set out and it included several stages:

1. The selection of the study groups which meet the certain inclusion criteria,
2. The application of sonotubometry with perfect sequences (PSEQ) in order to assess the function of the Eustachian tube (ET):
 - a) in healthy individuals,
 - b) in persons with nasal obstruction,
 - c) in patients with chronic secretory otitis media in case the condition can be etiologically related to the ET dysfunction.
3. The evaluation of the nasopharyngeal videoendoscopy data in patients with rhinologic and otological pathology.
4. The identification of factors which significantly predispose to the outcomes of the sonotubometry.

5. The pre-treatment analysis and assessment of the questionnaire, the ear and nasopharyngeal videoendoscopy and the ET function in patients with chronic secretory otitis media.
6. The treatment of chronic secretory otitis media through surgical laser Eustachian tuboplasty.
7. The assessment of the questionnaire, the ear and nasopharyngeal videoendoscopy and the ET function in patients with chronic secretory otitis media after performing surgical laser Eustachian tuboplasty.
8. The identification of factors which significantly predispose to the outcomes of the treatment of chronic secretory otitis media through surgical laser Eustachian tuboplasty.

2. MATERIAL AND METHODS OF THE STUDY

The study was carried out in the Ear, Nose and Throat Clinic of Vilnius University Hospital in 2010-2015. The study was approved by Vilnius Regional Biomedical Research Ethics Committee (Permission No 158200-13-575-170).

The study consisted of two parts. In the first part of the study, in order to objectively assess ET function, PSEQ-based sonotubometry results were assessed in healthy persons and in patients with ET dysfunction. The parameters of the study were set, the optimal dynamic tests were designed, the rate options and features for patients with nasal obstruction and chronic middle ear disease were determined. All subjects performed comprehensive examination which included collection of anamnestic data, otoscopy, rhinoscopy, tympanometry, Valsava test and sonotubometry using PSEQ stimuli, whereas patients with nasal obstruction and middle ear pathology underwent an additional test using nasal and nasopharyngeal videoendoscopy.

The second part of the study was aimed to causally assess the effectiveness of surgical laser Eustachian tuboplasty in patients with chronic secretory otitis media; prior to entry into the study these patients endured lengthy and ineffective treatment with other methods. The subjects underwent detailed preoperative and postoperative examination; treatment effectiveness was assessed and predisposing factors were analyzed. The comprehensive study included collection of anamnestic data, otoscopy, rhinoscopy, laryngoscopy, tympanometry, pure tone audiometry, Valsava test, nasopharyngeal and ET retropharyngeal videoendoscopy, and sonotubometry using PSEQ stimuli.

During the research work 310 persons were examined. In the first part, sonotubometric parametres were examined in 105 healthy subjects. In order to assess the correlation relationship and characteristics of the sonotubometry results in persons with nasal obstruction or middle ear pathology and perfect sequences (PSEQ), 47 patients suffering from nasal obstruction and 43 with OME were studied. In this study, the control group consisted of 39 individuals who had no previous history of ear disease and had no otological complaints. In the second part, in order to assess the effectiveness of surgical laser Eustachian tuboplasty in patients with chronic secretory otitis media 37 patients were examined and performed unilateral and bilateral surgical laser Eustachian tuboplasty (a total of 51 laser Eustachian tuboplasty operations). The control group consisted of 39 patients who underwent a total of 53 tympanometry operations.

Research methods

The middle ear tests

Otoscopy. Otoscopy was performed with 30° or 0° 2,7 mm or 4 mm endoscope (Karl Storz, Tuttlingen, Germany/ Olympus, Tokyo, Japan). The eardrum position and structure were inspected.

Impedansometry. Impedansometry was done using “Interacoustics AT235” (Interacoustics A/S, Middelfart, Denmark). In assessing the tympanograms a modified Jerger classification was used (Jerger J., 1970). The curve types: A (from 50 to -100 daPa, height - >0,2ccm), B (flat curve, height - <0,2ccm), C1 (from -101 to -200 daPa, height - > 0,2 ccm), C2 (< - 201 daPa, height - > 0,2 ccm).

Pure tone audiogram. Pure tone audiogram was conducted using the “Interacoustics AC 40” clinical audiometer, calculating average PTA-ABG. The hearing results were evaluated according to the guidelines of Committee on Hearing and Equilibrium.

The Eustachian tube tests

Valsalva maneuver. The maneuver is performed by pressing one's nose shut, closing one's mouth and then pressing out air through one's ears. After purging one must feel a snap, then the test is viewed positively. The test is evaluated as positive or negative, while the purging quality is determined subjectively by the subject themselves.

Sonotubometry. *Sonotubometry device.* In the current study the sonotubometry technology with PSEQ stimuli was employed according to A. Telle et all. With consent and permission of the authors, the sonotubometry device was constructed by the authors of this study. The system was connected to a computer with the SonoTube software installed. For acoustic stimulation, the external sound card PreSonus FIREBOX was used (*PreSonus FIREBOX, Inc., Baton Rouge, Louisiana, USA*). To send stimulus signals, professional headphones were tuned (*Shure E3, Heilbronn, Germany*; frequency response from 25 Hz to 18.5 kHz). The headphones were attached to a specially adapted nozzle which could be inserted into the nasal vestibule. For pervasive signals, the sound had an intensity level of 71 dB. To record sound, a miniature microphone was used (*Sennheiser KE 4, Wedemark, Germany*; frequency response from 20 Hz to 20 kHz). In order to capture the sound energy transmitted

from the speaker to the microphone, a sonotubogram was drawn. As the acoustic stimulus signal, a novel specific broadband class of signals, the so-called perfect sequences (PSEQ) were used. Being periodic and deterministic random noise signals, PSEQ signals have an ideally have a flat spectrum. With PSEQ signals, all frequency components (0 – 24 kHz) are stimulated equally during every period.

Measurement procedure. The testing was conducted with the subject sitting in a quiet room. Headphones with a special nozzle were placed into the nostril on the opposite side of the investigative ET. 15-second long sounds were produced for each measurement cycle at a sound intensity pressure level of 71 dB. A miniature microphone was inserted into the outer ear canal and it recorded signals transmitted from nose to ear. After measuring one ear, the testing sides were switched. Three different consecutive maneuvers were performed: dry swallowing, water swallowing with a small (2 ml) water bolus and water swallowing with a large (5 ml) water bolus. 10 cups with the 2 ml water bolus and 10 cups with the 5 ml water bolus, were presented to the individual for the water swallowing maneuver, in order to swallow equal size sips of water. In order to measure each maneuver, the subjects were instructed to swallow 10 times. The tests were repeated until the subject swallowed 10 times for each maneuver. Consecutively, each subject performed 60 swallowing maneuvers, with 30 for each ear. As the quality of the research may be conditioned by a number of factors affecting the nature of the sound, or on the patient's ability to correctly perform an intricate and demanding series of 60 test maneuvers, in cases of obviously visible artefacts or when the sonotubograms did not record, the test was repeated. *Measurement.* Each measurement was recorded digitally and presented on a computer screen as a diagram (sonotubogram). On the x-axis, time was registered in milliseconds and on the y-axis, the ordinate change in the sound intensity in the outer ear canal was measured using a logarithmic

dB scale. Each sonotubogram was analyzed and the following factors were taken into consideration: the number of ET openings produced against the number of tests maneuvers performed, the amplitude and duration of each registered opening, and the form of the resulting curve. An amplitude of >5 dB was required to classify a curve as an opening of the ET. Values of the amplitude and duration of each measured ET opening were calculated. The curves were classified into 1 of 4 different forms: 1) spikes with a sharp curve rise and a descent and including one clear peak, 2) double-peaks when the crest curve has a double peak, 3) descending curves with a wider base and going downward gradually, 4) plateau curves with a broad base and going downward suddenly (Figure 1). All ears were analyzed as separate independent objects.

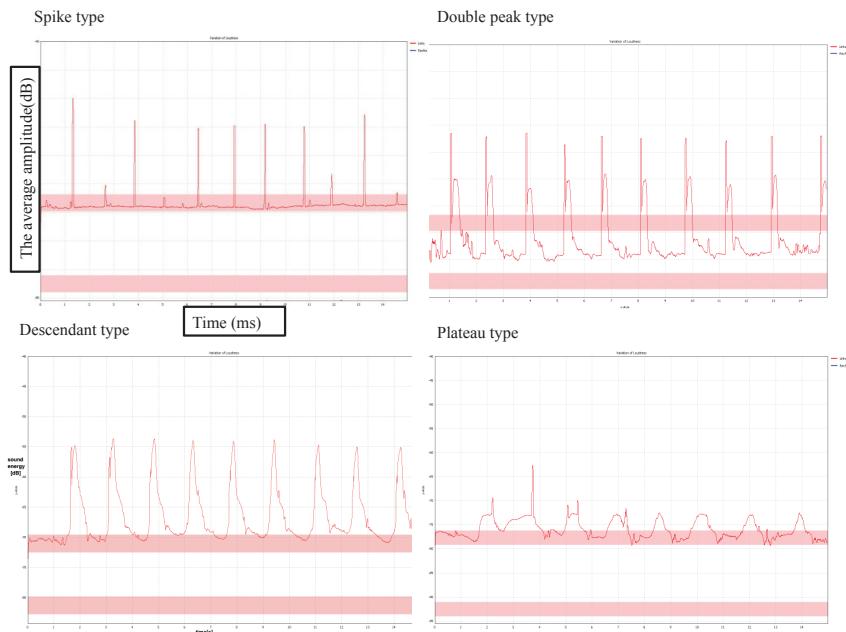


Figure 1. Sonotubograms curves types.

Nose and nasopharyngeal tests

Rhinoscopy and videoendoscopy. Rhinoscopy was performed using a 2.7 mm diameter rigid 30-degree endoscope (Olympus, Tokyo Japan). The rhinoscopy examined changes in the nasal and nasopharyngeal mucous membrane as well as possible causes and degree of the nasal obstruction (deviation of the nasal septum, i.e. absent, small, pathological; the lower shell condition, i.e. normal, mild edema, obstruction). The nasopharyngeal videoendoscopy evaluated the nasopharyngeal lymphoid tissue (yes/no), mucosal edema (yes/no), and in the ET pharyngeal site: lymphoid tissue (yes/no), mucosal edema (yes/no) and the quality of the opening (opens/does not open). ET valve opening was examined by inserting the endoscope deep into the nose and then turning it slightly up in the front part of the entry so that the valve lumen could be exposed. To stimulate the opening, two tests were performed, namely pronouncing the letter 'k' and swallowing saliva.

Laryngeal tests

It is performed using Karl Storz endoscope to evaluate pharyngolaryngeal mucosal changes and gastroesophageal reflux symptoms (rate, redness, swelling, hypertophy).

Patients' study was conducted by using a study scheme which then served as a base for a data recording questionnaire. The study included patients from different regions of Lithuania who had been treated in the Ear, Nose and Throat Centre of Vilnius University Hospital Santariskiu Clinic.

All the subjects had been surgically treated for chronic secretory otitis media more than once by repeatedly applying tympanostomy without long-term clinical effect. Upon endoscopy, all the subjects were suspected to have the obstruction of retropharyngeal ear opening and ET valve area.

Criteria for selecting the study participants:

- 1) otoscopically visible fluid in the tympanic cavity,
- 2) at least two tympanostomy operations in the anamnesis,
- 3) during nasopharyngeal videoendoscopy, not detected opening of the ET pharyngeal orifice.

To diagnose chronic secretory otitis media, the patients' study included collection of anamnestic data, otoscopy, rhinoscopy, laryngoscopy, tympanometry, pure tone audiometry, Valsalva test, nasopharyngeal and ET videoendoscopy, and sonotubometry using PSEQ stimuli.

Medical anamnesis data. The subjects were assessed anamnestically on the presence of previous tympanostomy operations (2 times, 3 times, 4 times), other diseases / disorders (gastroesophageal reflux, chronic sinusitis, chronic rhinitis), previous operations (adenotonsillectomy, septoplasty, ethmoidectomy), chronic otitis symptoms (yes/no), most troublesome symptoms (ear congestion, poor hearing, tinnitus), all complaints (ear congestion, poor hearing, autophonia, tinnitus, feeling of fluid overflow, popping), the quality of breathing through nose (good, satisfactory, unsatisfactory), allergy symptoms (experienced, not experienced), antihistamine use (yes/no), anti-reflux treatment (yes/no), disease duration (up to 5 years, > 5 years), smoking (yes/no).

The course of laser Eustachian tuboplasty (LET). It was performed under general intubation or local intubation anesthesia (sol. lidocaine 2%). Before surgery, a gauze pad is used (tetracaine 0.5% and adrenaline 0.001% solution) and it is inserted deep into the nasopharynx 20 min. before the operation. All patients received endonasal surgery through nostrils. During the operation, rigid endoscopes (30 degree, in diameters of 3 mm or 2.7 mm, Karl Storz, Tuttlingen Germany/ Olympus Tokyo Japan) were inserted into the nose. Depending on the anatomical features of the nasopharynx, the endoscope is inserted either into the opposite nostril of the surgical side or into the same nostril together with the laser

tip. With the endoscope, the ET valve is visualized, after which the cartilaginous part of the medial plate is identified with the instrument. The plate is treated as the sign and anatomical mark for the surgical manipulation position. During the operation, the CO₂ laser is used (Lumenis Israel) at a power setting of 2-4W every 0.2 s ongoing pulse or the 980-nm diode laser is applied (Lasering Italy) at a power setting of 4W every 0.2 s long ongoing pulse at 0.8 s intervals.

Upon completion of the laser Eustachian tuboplasty, tympanostomy of the damaged ear was performed by inserting a Shepard-type tympanostomy tube in the anterior quadrants of the eardrum.

Evaluation of laser Eustachian tuboplasty results

The treatment results were evaluated after 1 month and 12 months after surgery and then every 6 months. The latest recent available data was used to undertake the final assessment of the treatment effect. The effectiveness was assessed based on otoscopy, tympanogram and pure tone audiometry results, Valsava test, and nasopharyngeal videoendoscopy. The patients were required to evaluate their condition subjectively as recovered, improved or unchanged. The tympanostomy tube was removed under local anesthesia after 6 months after surgery.

The objective assessment of treatment results

Recovered:

- ≤ 10 dB air-bone gap in the pure tone audiogram plus
- A-type tympanogram plus
- no fluid in the tympanic cavity otoscopically.

Improved:

- 10-20 dB air-bone gap in the toned threshold audiogram plus
- positive Valsalva test.

Unchanged

- B-type tympanogram and negative Valsalva test or
- 30 dB air-bone gap in the pure tone audiogram or
- fluid in tympanic cavity otoscopically.

Control group

The control group consisted of 39 subjects. The selection criteria were the following:

- secretion behind the eardrum cavity, observed during the otoscopic examination,
- at least one tympanostomy operation recorded in the anamnesis.

The control group was evaluated based on collected anamnestic data, otoscopy, rhinoscopy, laryngoscopy, tympanometry, pure tone audiometry, Valsalva test, nasopharyngeal and ET retropharyngeal videoendoscopy, and sonotubometry using PSEQ stimuli. The control group were performed tympanostomy by microscopic incision in the anterior eardrum quadrants and placing a Shepard-type ventilation tube. The tympanostomy tubes were removed after 6 months after surgery. The treatment results were evaluated after 1 month and 12 months after surgery and then every 6 months. The latest recent available data was used to undertake the final assessment of the treatment effect. The effectiveness was assessed based on otoscopy, tympanogram and pure tone audiometry results, Valsalva test, and nasopharyngeal videoendoscopy, and sonotubometry using PSEQ stimuli. The patients were required to evaluate their condition subjectively as recovered, improved or unchanged.

Statistical analysis of the data

Statistical data analysis was performed with the help of SPSS 23.0 for Windows and „Excel for Windows” program batches. For describing

quantitative indicators the total number of observations was calculated, the average, the standard deviation, minimal and maximal meanings. Qualitative indicators were described by providing their distributions in percent. Pursuing to compare quantitative indicators among the two groups parametric Student t criteria was applied. In comparing of two qualitative indicators chi square (χ^2) criteria was applied. For assessing the impact of interaction of prognostic factors on LET effectiveness simple logistic regression model was applied. Differences were considered statistically significant, if the probability meaning p of the error is $< 0,05$.

3. RESULTS

3.1. Eustachian tube opening measurement by sonotubometry using perfect sequences for healthy adults

The testing was conducted on 105 individuals (33 females (31.4%) and 72 males (68.6%)). All of individuals were able to complete the test. The average age of the subjects was 26.03 (SD ± 6.20) (range 19-53 years). A total of 60 measurements were performed on each individual (3 test maneuvers, 10 swallowing events, 2 ears per individual). In total, 6,300 measurements were performed. Using this sonotubometry methodology, in 6,180/6,300 measurements (98.1%) objective ET openings were registered, which qualified them as valid and corresponding to the criteria. Out of all not detected Eustachian Tube openings, almost half were reported during low-sip water maneuvers (49.17%), 30% occurred during large-sip water test maneuvers, while concealed ET openings during dry saliva swallowing test maneuvers constituted only 20.83%. The results obtained as related to the mean ET opening duration and the mean sound wave amplitude are presented in Table 1 (Table 1). The maximal and minimal opening duration and amplitude for various maneuvers are presented in Table 2 (Table 2). A comparison of different maneuvers showed no significant difference

($P > 0.05$). By form, the sonotubometry curves are summarized in table 3 (table 3). Examples of types of sonotubometry curves are presented in Figure 2. Curve shape did not depend on subject age, sex, test maneuver type, amount of water, nor the size of a sip ($P > 0.05$).

Table 1. Mean results of the sonotubometry for all test maneuvers ($p > 0.05$).

Test maneuver	Mean ET opening duration (ms)	Average sound wave amplitude (dB)
Dry swallowing	284 (SD± 100)	13.90 (SD± 6.74)
2 ml water swallowing	263 (SD± 93)	12.54 (SD± 6.27)
5 ml water swallowing	264 (SD± 92)	13.38 (SD± 6.39)
Total average for all test maneuvers	270 (SD± 96)	13.48 (SD± 6.57)

Table 2. The maximal and minimal opening duration and amplitude for various test maneuvers ($p>0,05$).

Test maneuver	ET opening duration (ms)			Sound wave amplitude (dB)		
	min	max	SD	min	max	SD
Dry swallowing	80	620	0.09	5.01	38.93	6.74
2 ml water swallowing	60	680	0.09	5.01	34.84	6.54
5 ml water swallowing	100	700	0.09	5.01	37,08	6.38

Table 3. Different sonotubogram types associated with different test maneuvers ($P > 0.05$).

Test maneuver	Sonotubogram type (%)			
	Spike	Double-peak	Descendant	Plateau
Dry swallowing	50.95 %	23.33 %	17.14 %	7.62 %
2 ml water swallowing	44.29 %	32.38 %	13.81 %	13.81 %
5 ml water swallowing	49.05 %	27.14%	12.86 %	10.00 %
Total average for all test maneuvers	52.38 %	27.62 %	14.60 %	8.25 %

3.2 Eustachian tube opening measurement by sonotubometry using perfect sequences for patients with nasal obstruction

The testing was conducted on 47 individuals with nasal obstruction (15 females (31.9%) and 32 males (68.1%)). All of them were able to complete the test. The average age of the subjects was 38,17 (SD $\pm 9,63$) (range 20-60 years). A total of 10 measurements were performed on each individual (dry saliva test maneuver, 5 swallowing events, 2 ears per individual). In total, 470 measurements were performed.

The testing was conducted on 39 healthy individuals of control group (21 females (53,8%) and 18 males (46,2%)). All of them were able to complete the test. The average age of the subjects was 26,66 (SD $\pm 7,83$) (range 20-51 years). A total of 10 measurements were performed on each individual (dry saliva test maneuver, 5 swallowing events, 2 ears per individual). In total, 390 measurements were performed. The findings during nasopharyngeal endoscopy are summarised in table 4.

Using this sonotubometry methodology the openings were not detected for 31, 9 % of the nose obstruction patients and for 6,4 % of healthy individuals ($p<0,001$). The results obtained as related to the mean ET opening duration and the mean sound wave amplitude are presented in Table 5 (Table 5). Curves types are summarized in figure 2. Characteristics of the ET openings are summarized in table 6. Correlation of different factors and PSEQ sonotubometry results is summarized in table 7.

Table 4. Findings during videoendoscopy of the nasopharynx in study and control groups

Findings during videoendoscopy		Nasal obstruction study group (n-number of cases)	Healthy individuals control group (n-number of cases)	<i>p</i>
Nose septal deviation	No deviation	(n=6)6,4%	(n=75)96,2%	<0,001
	physiologic	(n=20)21,3%	(n=3)3,8%	0,003
	pathological	(n=68)72,3%	(n=0)0%	-
	norm	(n=6)6,4%	(n=78)100%	<0,001
Inferior turbinates	small oedema	(n=60)63,8%	(n=0)0%	-
	obstruction of meatus	(n=28)29,8%	(n=0)0%	-
	no	(n=72)76,6%	(n=74)94,9%	0,368
	yes	(n=22)23,4%	(n=4)5,1%	0,004
Nasopharynx	no	(n=60)63,8%	(n=78)100%	0,053
	yes	(n=34)36,2%	(n=0)0%	-
	no	(n=78)83,0%	(n=74)94,9%	0,578
	lymphoid tissue	(n=16)17,0%	(n=4)4,3%	0,033
ET pharyngeal orifice	no	(n=70)74,5%	(n=74)94,9%	0,309
	oedema	(n=24)25,5%	(n=4)5,1%	0,001
	yes	(n=90)95,7%	(n=72)92,3%	0,912
ET opening provocative "K" test	opens	(n=71)76,1%	(n=74)94,9%	0,366
ET opening provocative swallowing test	opens			

Table 5. Mean results of the sonotubometry for nose obstruction and healthy individuals

PSEQ sonotubometry	Mean ET opening duration (ms)	p	Average sound wave amplitude (dB)	p
Nose obstruction group	280(SD±147)	0,731	10,35(SD± 4,86)	0,411
Healthy individuals group	274(SD±153)		12,26(SD± 5,40)	

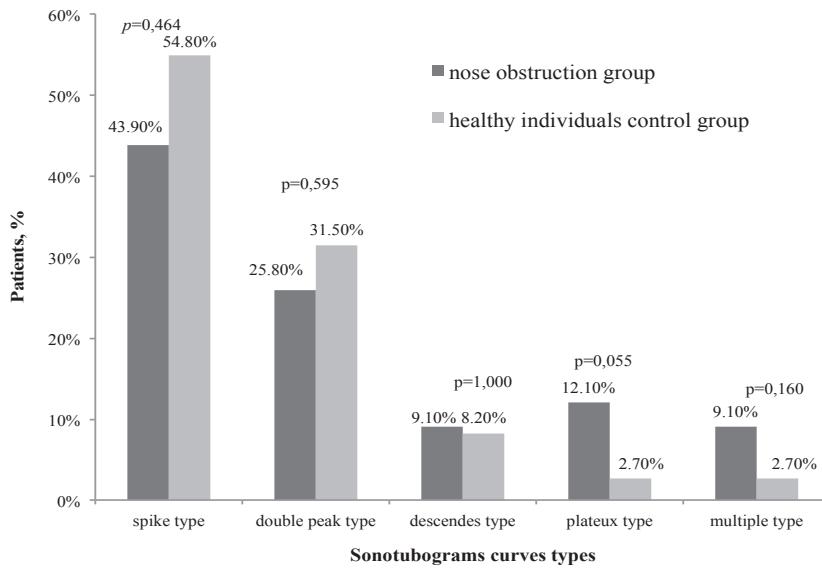


Figure 2. Curves types for nasal obstruction and healthy individuals

Table 6. Characteristics of the PSEQ sonotubometry ET openings in nasal obstruction and healthy individuals groups

Sonotubometry parametre	Nasal obstruction study group (n- number of cases)	Healthy individuals control group (n- number of cases)	p
ET openings were not detected	(n=30)31,9%	(n=5)6,4%	<0,001
Average sound wave amplitude (dB)	10,35(SD± 4,86)	12,26(SD±5,40)	0,411
Cases, then wave amplitude >10 (dB)	(n=39)41,5%	(n=52)66,7%	0,071
Cases, then wave amplitude 5-10 (dB)	(n=25)26,6%	(n=21)26,9%	1,000
Mean opening duration (ms)	280(SD±147)	274(SD±153)	0,731
Detected 5 openings from 5 meneuvres	(n=47)50,0%	(n=66)84,6%	0,039
Detected 4 openings from 5 meneuvres	(n=7)7,4%	(n=3)3,8%	0,515
Detected 3 openings from 5 meneuvres	(n=5)5,3%	(n=2)2,6%	0,462
Detected 2 openings from 5 meneuvres	(n=3)3,2%	(n=1)1,3%	0,628
Detected 1 opening from 5 meneuvres	(n=2)2,1%	(n=1)1,3%	1,000
Spike type sonotubogram	(n=29)43,9%	(n=40)54,8%	0,464
Double peak type sonotubogram	(n=17)25,8%	(n=23)31,5%	0,595
Descendes type sonotubogram	(n=6)9,1%	(n=6)8,2%	1,000
Plateau type sonotubogram	(n=8)12,1%	(n=2)2,7%	0,055
Multiple type sonotubogram	(n=6)9,1%	(n=2)2,7%	0,160

Table 7. Correlation of different factors and PSEQ sonotubometry results in nose obstruction group

Factor (n- number of cases)	Detected openings	p (χ^2)
Age		
20-50 years (n=78)	(n=78)67,9%	0,950
>50 years (n=16)	(n=11)68,8%	
Gender		
female (n=30)	(n=23)76,7%	0,163
male (n=54)	(n=41)64,1%	
Breathing through the nose		
good (n=2)	(n=2)100%	0,014
moderate (n=18)	(n=17)94,4%	
severe obstruction (n=74)	(n=45)60,8%	
Nasal septum deviation		
norm(n=6)	(n=5)83,3%	0,001
physiological(n=20)	(n=20)100%	
pathological(n=68)	(n=39)57,4%	
Inferior turbinates' hypertrophy		
no (n=6)	(n=60)100%	<0,001
moderate (n=60)	(n=48)80%	
obstruction of the meatus (n=28)	(n=10)35,7%	
Symptoms of gastroesophageal reflux		
no (n=82)	(n=59)72%	0,036
yes (n=12)	(n=5)41,7%	
Anamnesis of allergy		
yes(n=20)	(n=55)74,3%	0,013
no(n=74)	(n=9)45%	
Oedema of nasopharynx		
no (n=60)	(n=50)83,3%	<0,001
yes (n=34)	(n=14)41,2%	
Lymphoid tissue of nasopharynx		
no(n=72)	(n=56)77,8%	<0,001
yes(n=22)	(n=8)36,4%	

Table 7 (continuation). Correlation of different factors and PSEQ sonotubometry results in nose obstruction group

Factor (n- number of cases)	Detected openings	p (χ^2)
ET valve opening during swallow yes (n=71) no(n=23)	(n=61)85,9% (n=3)13,0%	<0,001
Provocative “k” test positive(n=90) negative(n=4)	(n=63)70% (n=1)25%	0,094
Oedema of ET pharyngeal region no (n=70) yes (n=24)	(n=54)77,1% (n=10)41,6%	0,002
Lymphoid tissue of ET pharyngeal region no tissue (n=78) tissue(n=16)	(n=61)78,2% (n=3)18,8%	<0,001

3.3 Eustachian tube opening measurement by sonotubometry using perfect sequences for patients with chronic secretory otitis

The testing was conducted on 43 individuals with chronic secretory otitis (28 females (65,1%) and 15 males (34,9%)). All of them were able to complete the test. The average age of the subjects was 29 ($SD \pm 18,62$) (range 18-65 years). In total, 285 measurements were performed.

The testing was conducted on 39 healthy individuals (21 females (53,8%) and 18 males (46,2%)). All of them were able to complete the test. The average age of the subjects was 26,66 ($SD \pm 7,83$) (range 20-51 years). In total, 390 measurements were performed. The openings were not detected for 43,9 % of the OME patients and for 6,4 % of healthy individuals ($p<0,001$). The results obtained as related to the mean ET opening duration and the mean sound wave amplitude are presented in Table 8. Curves types are summarised in figure 3. Characteristics of

the ET openings in OME group are summarised in table 9. Correlation of different factors and PSEQ sonotubometry results is summarized in table 10.

Table 8. Mean results of the sonotubometry for OME patients and healthy individuals

PSEQ Sonotubometry	Mean ET opening duration(ms)	p	Average sound wave amplitude (dB)	p
OME group	261(SD±147)	0,672	7,41(SD± 4,77)	<0,001
Healthy individuals group	274(SD±153)		12,26(SD± 5,40)	

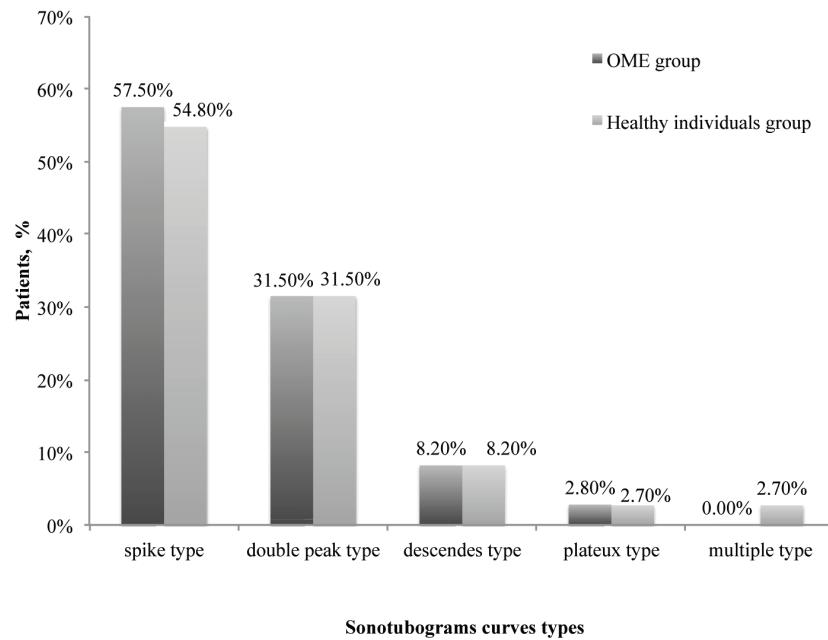


Figure 3. Curves types for OME patients and healthy individuals

Table 9. Characteristics of the PSEQ sonotubometry ET openings in chronic OME and healthy individuals groups

Sonotubometry parametre	OME study group (n- number of cases)	Healthy individuals control group (n- number of cases)	<i>p</i>
ET openings were not detected	(n=25)43,9%	(n=5)6,4%	<0,001
Average sound wave amplitude (dB)	7,41(SD± 4,77)	12,26(SD±5,40)	<0,001
Mean opening duration (ms)	261(SD±137)	274(SD±153)	0,672
Detected 5 openings from 5 meneuvers	(n=13)22,8%	(n=66)84,6%	<0,001
Detected 4 openings from 5 meneuvers	(n=4)7%	(n=3)3,8%	0,462
Detected 3 openings from 5 meneuvers	(n=2)3,5%	(n=2)2,6%	1,000
Detected 2 openings from 5 meneuvers	(n=7)12,3%	(n=1)1,3%	0,022
Detected 1 opening from 5 meneuvers	(n=6)10,5%	(n=1)1,3%	0,044
Spike type sonotubogram	(n=42)57,50%	(n=40)54,8%	0,208
Double peak type sonotubogram	(n=23)31,5%	(n=23)31,5%	0,392
Descendes type sonotubogram	(n=6)8,2%	(n=6)8,2%	0,762
Plateau type sonotubogram	(n=2)2,8%	(n=2)2,7%	1,000
Multiple type sonotubogram	(n=0)0%	(n=2)2,7%	0,510

Table 10. Correlation of different factors and PSEQ sonotubometry results in chronic OME group

Factor (n- number of cases)	Detected openings	p (χ^2)
Gender		
female(n=33)	(n=18)54,5%	0,794
male (n=24)	(n=14)58,3%	
Breathing through the nose		
good(n=30)	(n=15)50%	0,001
moderate(n=21)	(n=17)81%	
severe obstruction (n=6)	(n=0)0%	
Nasal septum deviation in the ipsilateral side		
normal (n=45)	(n=24)53,3%	0,506
physiological (n=8)	(n=6)75%	
pathological (n=4)	(n=2)50%	
Nasal septum deviation in the contralateral side		
normal (n=49)	(n=28)57,1%	0,931
physiological(n=4)	(n=2)50%	
pathological(n=4)	(n=2)50%	
Inferior turbinates' hypertrophy		
norm (n=30)	(n=15)50%	<0,001
moderate (n=19)	(n=17)89,5%	
obstruction of the meatus(n=8)	(n=0)0%	
Oedema of nasopharynx		
no (n=41)	(n=22)53,7%	0,767
yes (n=16)	(n=10)62,5%	
Lymphoid tissue in the nasopharynx		
no (n=40)	(n=17)42,5%	0,358
yes(n=17)	(n=15)58,8%	
ET valve's opening during swallow		
yes(n=22)	n-=15)68,2%	0,178
no (n=35)	(n=17)48,6%	
Provocative "k" test		
positive (n=9)	(n=9)100%	0,004
negative(n=48)	(n=23)47,9%	

Table 10 (continuation). Correlation of different factors and PSEQ sonotubometry results in chronic OME group

Factor (n- number of cases)	Detected openings	p (χ^2)
Oedema of ET pharyngeal orifice		
no (n=41)	(n=26)63,4%	0,076
yes (n=16)	(n=6)37,5%	
Lymphoid tissue of ET pharyngeal orifice		
no (n=35)	(n=18)51,4%	0,366
yes (n=22)	(n=14)63,6%	
Tympanometry		
B type (n=49)	(n=24)49,0%	0,007
C type(n=8)	(n=8)100%	
Retraction if the tympanic membrane		
no retraction(n=26)	(n=18)69,2%	0,038
attical (n=10)	(n=6)60%	
mesotympanic (n=21)	(n=7)33,3%	
Retraction grade		
I°(n=8)	(n=4)50%	0,326
II°(n=12)	(n=5)41,7%	
III°(n=11)	(n=5)45,5%	
Consistency of the fluid in the middle ear		
no fluids(n=18)	(n=7)38,9%	0,210
serous(n=25)	(n=16)64,0%	
mucous(n=14)	(n=6)42,9%	
Amount of the fluid in the middle ear		
no fluid(n=18)	(n=7)38,9%	0,469
moderate(n=7)	(n=4)57,1%	
full(n=32)	(n=18)56,3	

3.4 The effectiveness of the laser Eustachian tuboplasty for chronic secretory otitis

3.4.1 Patient's characteristics, data of videoendoscopy of the nasopharynx and ET function tests before the surgery

A total of 51 (23- single procedure, 28- bilateral) laser Eustachian tuboplasties in study group were performed during the study period (54,1 % - female, 45,9 % - male). The patients' age ranged from 18 to 68 years (average age $42,1 \pm 19,17$).

During the same period a total of 53 (25 single procedure, 28- bilateral) tympanostomies were performed in control group (53,8 %- female, 46,2 %- male). The patients' age ranged from 18 to 75 years (average age $36,87 \pm 15,63$). Characteristics of the participants of both groups are presented in table 11. Changes in the nose and nasopharynx which were evaluated during videoendoscopy in both groups are shown in table 12. Both groups according to the changes in the nose and nasopharynx were statistically equal.

PSEQ sonotubometry before the surgery. In study group the openings were detected for 35,3 % of the cases. The average of the wave sound amplitude was $10,53 \pm 2,36$ dB, the mean duration- 233 ± 118 ms. Curves types: spike type- 33,3 %, a double peak type- 22,2 %, descender type- 11,1 %, plateau type- 11,1 %, multiple type- 22,2 %. Results of the average hearing loss before treatment are shown in table 13.

Table 11. Characteristics of the patients in LET study and tympanostomy control groups

Parametre	LET group (n-number of cases)	Tympanostomy group (n-number of cases)	p
Gender			
female	20	21	1,000
male	17	18	
Average age	42,1±19,17	36,87±15,63	0,078
Average duration of the OME	5,37±2,95	4,62±2,23	0,006
Duration of the OME			
up to 5 years	(n=26)51%	(n=26)49,1%	1,000
> 5 years	(n=25)49%	(n=27)50,9%	
Follow- up duration	3,68±1,20	3,39±1,39	0,229
Operation			
unilateral	(n=23)62,2%	(n=25)64,1%	0,193
bilateral	(n=14)37,8%	(n=14)35,9%	
The most consumptive symptom before surgery			
hearing loss	(n=40)78,4%	(n=36)67,9%	0,318
fullness in the ear	(n=11)21,6%	(n=16)30,2%	
tinnitus	(n=0)0%	(n=1)1,9%	
Average number of tympanostomies in the past	2,5±0,7	1,2±0,43	<0,001
Number of tympanostomies in the past			
1 time	(n=0)0%	(n=40)75,5%	-
2 times	(n=30)58,8%	(n=13)24,5%	
3 times	(n=15)29,4%	(n=0)0%	
4 times	(n=6)11,8%	(n=0)0%	

Table 12. Changes in the nose and nasopharynx in both groups before surgery

	Videoendoscopy	LET group (n-number of cases)	Tympanostomy group (n-number of cases)	P
Nasal septum deviation in the ipsilateral side	normal	(n=32)62,7%	(n=34)64,2%	0,999
	physiological	(n=18)35,3%	(n=18)34,0%	
	pathological	(n=1)2%	(n=1)1,8%	
Nasal septum deviation in contralateral side	normal	(n=40)78,4%	(n=44)83,0%	0,623
	physiological	(n=11)21,6%	(n=9)17,0%	
	pathological	(n=0)0%	(n=0)0%	
Inferior turbinates' hypertrophy	normal	(n=19)37,3%	(n=20)37,7%	0,967
	moderate	(n=21)41,2%	(n=23)43,4%	
	obstruction of meatus	(n=11)21,6%	(n=10)18,9%	
Nasal polyposis	no	(n=39)76,5%	(n=41)74%	1,000
	yes	(n=12)23,5%	(n=12)22,6%	
		(n=45)88,2%	(n=42)79,2%	
Findings in nasopharynx	lymphoid tissue	(n=6)11,8%	(n=11)20,8%	0,290
	oedema	(n=28)54,9%	(n=29)54,7%	
	yes	(n=23)45,1%	(n=24)45,3%	
ET pharyngeal orifice	lymphoid tissue	(n=46)86,8%	(n=42)79,2%	0,174
	yes	(n=59,8%	(n=11)20,8%	
	oedema	(n=26)51,0%	(n=29)54,7%	
ET valve's opening during swallow	yes	(n=25)49,0%	(n=24)45,3%	1,000
	no	(n=0)0%	(n=0)0%	
		(n=51)100%	(n=53)100%	
Provocative "k" test	positive	(n=0)0%	(n=0)0%	1,000
	negative	(n=51)100%	(n=53)100%	

Table 13. The average hearing loss before surgery in both groups.

Average hearing loss(dB)	LET study group	Tympanostomy group	<i>p</i>
Average hearing loss	36,84±10,95	33,94±5,87	0,021
PTA- ABG	28,33±7,69	27,62±5,94	0,427

*3.4.2 Patient's characteristics,
data of videoendoscopy of the nasopharynx
and ET function tests after the surgery*

The objective assessment of treatment results in LET group after 1 month: recovered-19,6 %, improved- 49,9 %, unchanged- 31,4 %. After 12 months: recovered-37,2 %, improved- 31,4 %, unchanged- 31,4 %. The objective assessment of treatment results in tympanostomy group after 1 month: recovered-18,9 %, improved- 56,6 %, unchanged- 24,5 % and after 12 months: recovered-5,7 %, improved- 35,8 %, unchanged- 58,5 %. Results of both groups after 12 months of the follow-up are shown in figure 4.

Evaluating results subjectively in LET group after 1 month recovered- 19,6 %, improved- 49 %, unchanged- 31,4 % and after 12 months recovered- 37,2 %, improved- 31,4 %, unchanged- 31,4 %. In control tympanostomy group after 1 month recovered- 13,2 %, improved- 56,6 %, unchanged- 30,2 % and after 12 months analogically- 9,4 %, 18,9 % and 71,7 % ($p<0,001$).

In LET group the Valsalva maneuver after one month was positive for 35,3 %, after 12 months- 62,7 % of the cases. In control group after one month positive for 37,7 %, after 12 months- 58,5 %.

In LET group the distribution of tympanograms types before treatment and after are shown in figure 5. In control group after 12 months of the follow- up 90,9 % had B type, other- C type tympanograms.

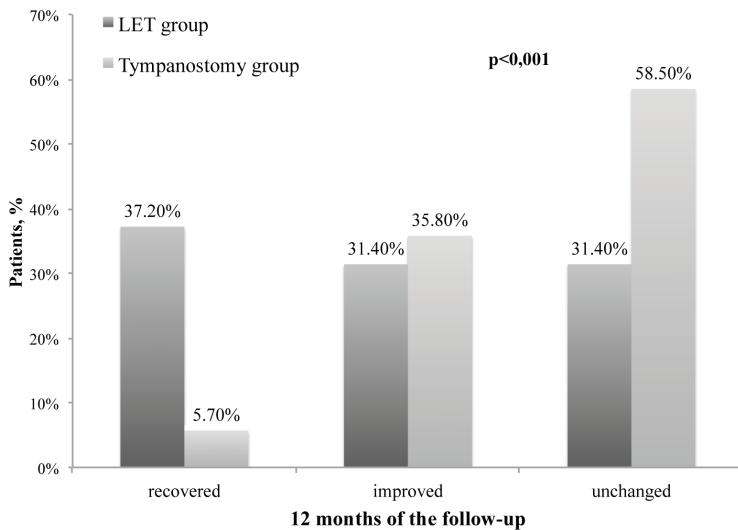


Figure 4. The objective assessment of treatment results after 12 month in LET and control groups

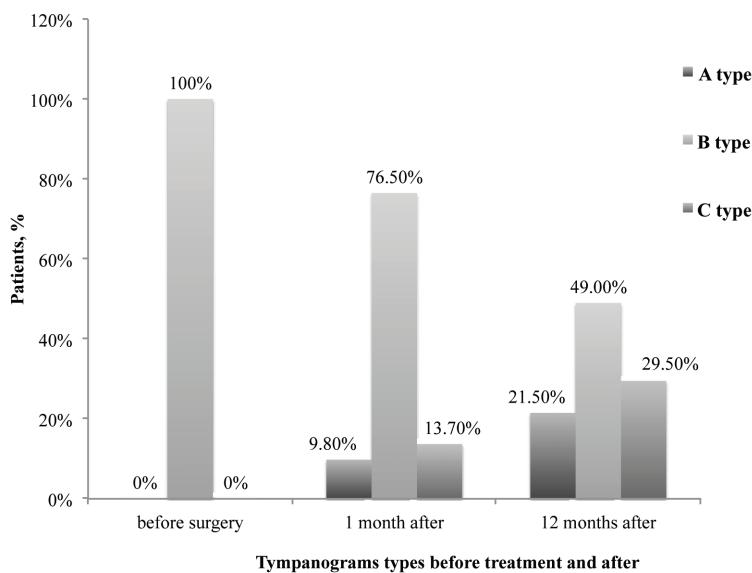


Figure 5. Tympanograms types distribution in LET group before treatment, 1 month and 12 months after.

PSEQ sonotubometry. In LET group after 12 months ET openings were detected for 72,5 % of the cases. The average of the sound wave was 13, 11±3,98 dB, the mean duration- 256±128 ms. The parametres before treatment and after are summarized in table 14.

Table 14. PSEQ sonotubometry before treatment and 12 months after LET.

Parameter	Before surgery (n- number of cases)	12 months after (n- number of cases)	p
Detected ET openings	(n=18)35,3%	(n=37)72,5%	0,043
Average sound wave amplitude (dB)	10,53(SD± 2,36)	13,11(SD±3,98)	0,006
Mean duration (ms)	233(SD±118)	256(SD±128)	0,465
Detected 5 openings from 5 meneuvers	(n=0)0%	(n=8)15,7%	0,003
Detected 4 openings from 5 meneuvers	(n=0)0%	(n=9)17,6%	0,007
Detected 3 openings from 5 meneuvers	(n=7)13,7%	(n=5)9,8%	0,762
Detected 2 openings from 5 meneuvers	(n=6)11,8%	(n=8)15,7%	0,777
Detected 1 opening from 5 meneuvers	(n=5)9,8%	(n=7)13,7%	0,762
Spike type sonotubogram	(n=6)33,3%	(n=10)27,0%	0,768
Double peak type sonotubogram	(n=3)16,7%	(n=3)38,1%	0,405
Descendes type sonotubogram	(n=2)11,1%	(n=6)16,2%	1,000
Plateau type sonotubogram	(n=4)22,2%	(n=9)24,3%	1,000
Multiple type sonotubogram	(n=3)16,7%	(n=9)24,3%	0,739

Pure tone audiogram. The average air bone gap before surgery, 1 and 12 months after surgery in both groups are summarized in figure 6. In LET group the air bone gap after 1 month was $19,23\pm9,68$ dB, in control- $19,56\pm9,34$ dB ($p=0,948$), after 12 months- $15,21\pm11,83$ dB, in control group $24,45\pm6,94$ dB ($p<0,001$). The dynamic of the air bone gap changes in LET group are presented in figure 6, in control group in figure 7. The average hearing loss after 1 month in LET group was $24,66\pm12,70$ dB, in control group- $24,11\pm10,45$ dB ($p=0,338$), after 12 months- $22,50\pm13,45$ dB and $25,35\pm9,87$ dB ($p= 0,018$). The dynamic of the average hearing loss changes in LET and control groups are presented in figure 8 and figure 9.

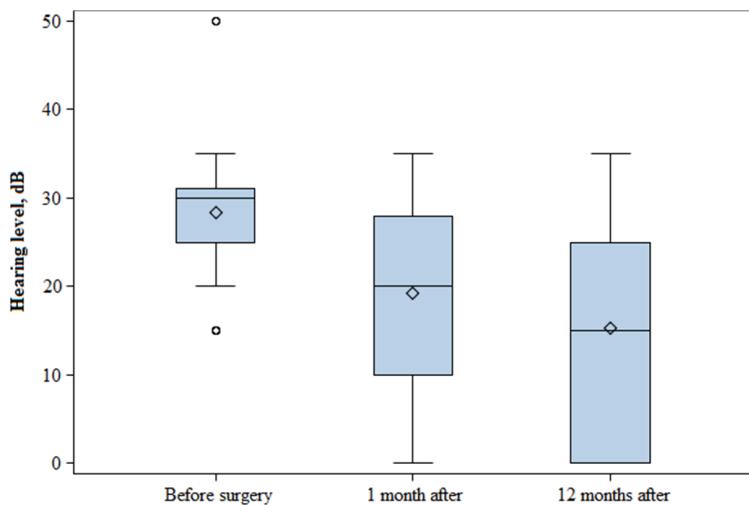


Figure 6. The PTA- ABG dynamic in LET group before treatment, 1 month and 12 months after operation

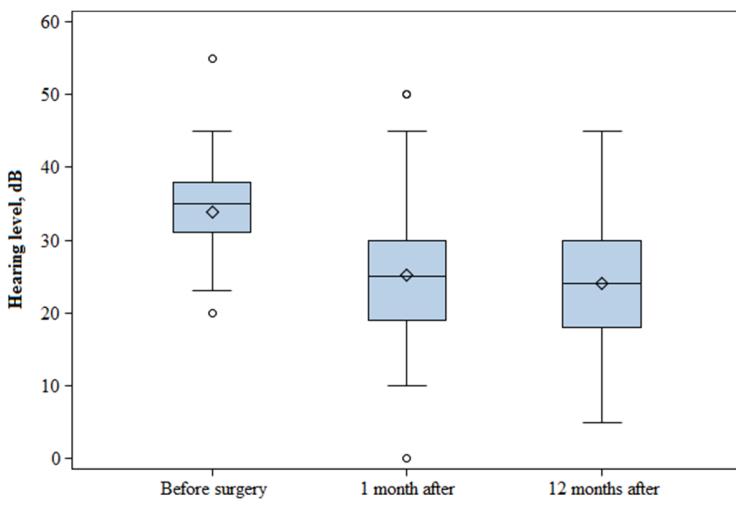


Figure 7. The PTA- ABG dynamic in tympanotomy control group before treatment, 1 month aPnd 12 months after operation

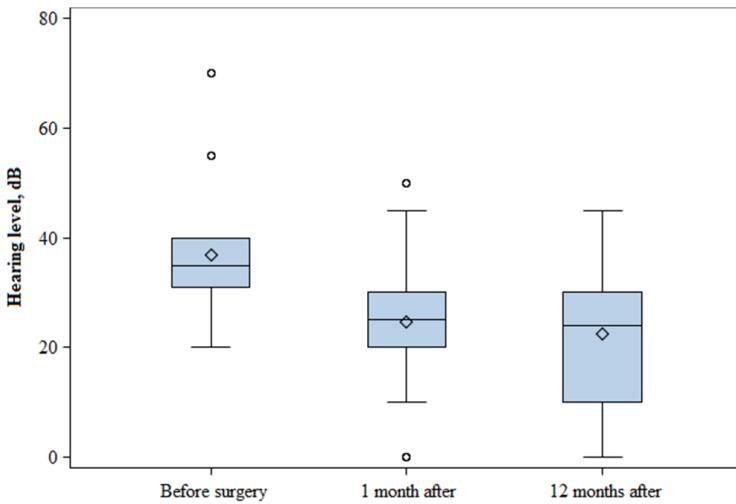


Figure 8. The average hearing loss dynamic in LET group before treatment, 1 month and 12 months after operation

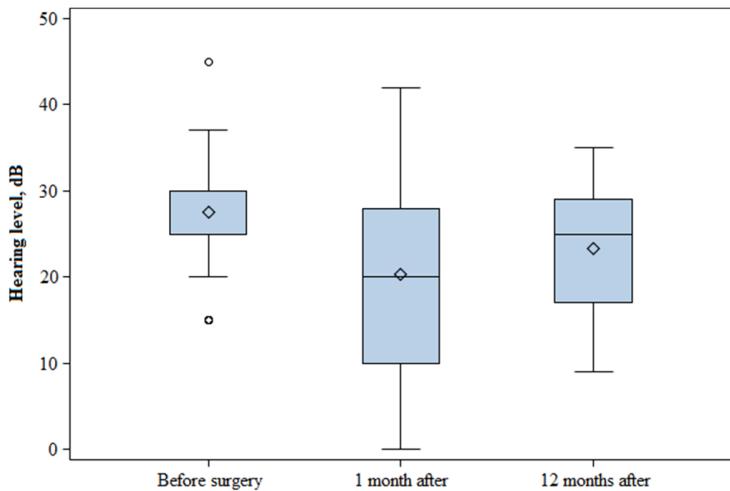


Figure 9. The average hearing loss dynamic in tympanotomy control group before treatment, 1 month and 12 months after operation

Videoendoscopy. 12 months after LET the openings of the ET valve were seen for 60,8 % of the cases, the provocative "k" test was positive for 31,4 %, oedema of the ET pharyngeal site was seen for 43,1 %, lymphoid tissue- 21,6 %.

Complications. We did not observed serious complications. Minor complications were observed for 15,7 % of the LET cases: for 2 % the perforation after ventilation tube, 7,8 %- synechiae in the nose, 5,9 % emphysema within the parotid region was observed, which reabsorbed for all of them next day after the surgery. In control group the complication rate was 15,1 %: 1,9 % the perforation after ventilation tube, 5,7 % discharging ear, 7,5 % extrusion of ventilation tube.

3.4.3 Correlation of prognostic factors and treatment outcomes

Correlation of different factors and effectiveness of the LET after 12 month of the follow- up are presented in table 15. Correlation of video-endoscopy findings in the nasopharynx and effectiveness of the LET are presented in table 16.

Table 15. Correlation of preoperative factors and effectiveness of the LET after 12 month of the follow-up

Factor		Correlation with results		
n- number of cases		After 12 months	After 12 months	<i>p</i>
		improved	recovered	
Age	<20 years(n=13)	(n=1)7,7%	(n=10)76,9%	0,011
	21-50 years(n=19)	(n=8)42,1%	(n=3)15,8%	
	> 50 years(n=19)	(n=7)36,8%	(n=6)31,6%	
Gender	female(n=29)	(n=8)27,6%	(n=9)31,0%	0,207
	male(n=22)	(n=8)36,4%	(n=10)45,5%	
Localization	unilateral (n=17)	(n=2)11,8%	(n=13)76,5%	<0,001
	bilateral(n=34)	(n=14)41,2%	(n=6)17,6%	
Most consumptive symptom	fullness in the ear (n=11)	(n=0)0%	(n=11)100%	<0,001
	hearing loss (n=40)	(n=16)40,0%	(n=8)20,0%	
	tinnitus(n=0)	(n=0)0%	(n=0)0%	
Symptoms before surgery	fullness in the ear (n=51)	(n=16)31,4%	(n=19)37,3%	-
	hearing loss (n=51)	(n=16)31,4%	(n=19)37,3%	-
	tinnitus(n=32)	(n=14)43,8%	(n=8)25,0%	0,022
	autophony(n=16)	(n=1)6,3%	(n=13)81,3%	<0,001
	popping in the ear(n=10)	(n=0)0%	(n=10)100%	<0,001
Breathing through the nose	good(n=10)	(n=2)20,0%	(n=4)40,0%	0,625
	moderate(n=37)	(n=12)32,4%	(n=13)35,1%	
	severe obstruction (n=4)	(n=2)50%	(n=2)50%	

Table 15 (continuation). Correlation of preoperative factors and effectiveness of the LET after 12 month of the follow-up

Factor	n- number of cases	Correlation with results			<i>p</i>
		After 12 months	After 12 months		
		improved	recovered		
Symptoms of gastroesophageal reflux	yes(n=8)	(n=3)37,5%	(n=5)62,5%	0,095	
	no(n=43)	(n=13)30,2%	(n=14)32,6%		
Positive anamnesis of allergy	yes(n=10)	(n=7)70,0%	(n=3) 30,0 %	0,007	
	no(n=41)	(n=9)22,0%	(n=16)39,0%		
Antihistamine use	yes(n=4)	(n=1)25,0%	(n=3)75,0%	0,215	
	no(n=47)	(n=15)31,9%	(n=16)34,0%		
GERL treating	yes(n=2)	(n=1)50,0%	(n=1)50,0%	0,614	
	no(n=49)	(n=15)30,6%	(n=18)36,7%		
Duration	<5 years(n=26)	(n=10)38,5%	(n=12)46,2%	0,043	
	> 5years(n=25)	(n=6)24,0%	(n=7)28,0%		
Smoking	yes(n=20)	(n=13)65,0%	(n=3)15,0%	<0,001	
	no(n=31)	(n=3)9,7%	(n=16)51,6%		
Chronic rhinosinusitis in past	yes(n=24)	(n=9)37,5%	(n=9)37,5%	0,568	
	no(n=27)	(n=7)25,9%	(n=10)37,0%		
Surgery in the past	adenoidectomy(n=10)	(n=0)0%	(n=8)80,0%	<0,001	
	septoplasty(n=6)	(n=0)0%	(n=0)0%		
	ethmoidectomy(n=6)	(n=6)100%	(n=0)0%		
Tympanostomy surgery in the past	2 times (n=30)	(n=13)43,3%	(n=9)30,0%	<0,001	
	3 times(n=15)	(n=3)20,0%	(n=10)66,7%		
	4 times(n=6)	(n=0)0%	(n=0)0%		
Otoscopy	serous(n=34)	(n=8)26,7%	(n=14)46,7%	0,232	
	dense(n=17)	(n=8)47,1 %	(n=5)29,4%		
Retraction	yes (n=4)	(n=0)0%	(n=0)0%	0,009	
	no(n=47)	(n=16)31,4%	(n=19(37,3%)		

Table 16. Correlation of nasal and nasopharyngeal factors and effectiveness of the LET, 12 month after operation

Changes in the nose and nasopharynx		Correlation		
n- number of cases		After 12 months	After 12 months	<i>p</i>
		improved	recovered	
Nasal septum deviation in ipsilateral side	normal(n=32)	(n=9)28,1%	(n=15)46,9%	0,174
	physiological(n=18)	(n=7)38,9%	(n=3)16,7%	
	pathological(n=1)	(n=0)36,8%	(n=1)100%	
Nasal septum deviation in contralateral side	normal(n=40)	(n=9)22,5%	(n=9)47,5%	0,007
	physiological (n=11)	(n=7)63,6%	(n=0)0%	
	pathological (n=0)	(n=0)0%	(n=0)0%	
Inferior turbinates hypertrophy	normal(n=19)	(n=1)5,3%	(n=6)31,6%	<0,001
	moderate(n=21)	(n=13)61,9%	(n=8)38,1%	
	obstruction of meatus(n=11)	(n=2)18,2%	(n=5)45,5%	
Nasal polyposis	no(n=39)	(n=10)25,6%	(n=19)48,7%	0,009
	yes(n=12)	(n=6)50,0%	(n=0)0%	
Lymphoid tissue in the nasopharynx	no(n=45)	(n=16)35,6%	(n=13)28,9%	0,003
	yes(n=6)	(n=0)0%	(n=6)100%	
Oedema in the nasopharynx	no(n=29)	(n=2)7,1%	(n=14)50,0%	<0,001
	yes (n=22)	(n=14)60,9%	(n=5)21,7%	
Lymphoid tissue in the ET pharyngeal orifice	no (n=46)	(n=16)34,8%	(n=16)34,8%	0,267
	yes(n=5)	(n=0)0%	(n=3)60%	
Oedema in the ET pharyngeal orifice	yes(n=22)	(n=3)11,5%	(n=9)34,6%	<0,001
	no(n=29)	(n=13)52,0%	(n=10)40,0%	
ET opening after 12 months	opens(n=31)	(n=9)29,0%	(n=16)51,6%	0,017
	no opening(n=20)	(n=10)30,3%	(n=7)21,2%	
Provocative "k" test after 12 months	positive(n=16)	(n=1)6,3%	(n=9)56,3%	0,027
	negative(n=35)	(n=15)42,9%	(n=10)28,6%	

3.4.4 Prognostic factors

For assessing the impact of interaction on prognostic factors on the LET effectiveness, simple logistic regression model was applied. Results are shown in table 16. Oedema of the ET region in the pharynx was confirmed as a negative prognostic factor for the LET effectiveness.

Table 16. Simple logistic regression for assessing the impact of interrelation of prognostic factor on LET effectiveness

Factor	LO	95 % PI	p
<i>Anamnestic</i>			
Localization of the disease	5,38	1,43-2,02	0,360
Allergy in anamnesis	9,29	2,00-4,30	0,925
Duration of the OME	8,89	2,71-9,19	0,846
Smoking	1,73	4,95-60,94	0,389
Number of tympanostomy operations in the past	5,00	8,5-29,3	0,456
Tinnitus	1,62	4,79-5,51	0,435
Autophony	2,36	5,61-9,96	0,241
Popping in the ear	1,81	3,32-9,92	0,492
Retraction	4,38	5,61-34,26	0,431
<i>Videoendoscopy</i>			
Nasal septum deviation in contralateral side	7,78	1,91-31,67	0,073
Inferior turbinate hypertrophy	14,26	4,22-47,94	0,566
Nasal polyposis	5,70	1,14-2,18	0,413
Oedema of nasopharynx	16,67	4,92-56,17	0,410
Lymphoid tissue in the ET pharynx orifice	8,81	0,99-1,19	0,999
Oedema of the ET pharynx orifice	4,28	1,14-16,07	0,031

4. CONCLUSIONS

1. Sonotubometry with perfect sequences (PSEQ) induces / detects openings of the Eustachian tube reliably and can be applied to assess functional changes of the ET in healthy persons objectively. An optimal and dynamic sonotubometric maneuver is a low volume water swallow test.
2. Sonotubometry using PSEQ stimuli detects fewer ET openings in patients with nasal obstruction than in healthy individuals. The factors that significantly relate with non-openings during the sonotubometry of the ET included the deviation of the nasal septum, edema of the inferior turbinate, oedema and lymphoid hyperplasia of the nasopharynx, oedema and lymphoid hyperplasia of the pharyngeal orifice of ET.
3. In patients with chronic secretory otitis media sonotubometric ET openings were detected for 22,8% of the tested ears. Average of the wave sound amplitude was shorter comparing to healthy individuals ($p<0,001$). Factors, statistically significantly related with not detected openings using sonotubometry were severe hypertrophy of inferior turbinate's, B type tympanogram and the character of the tympanic membrane retraction. More frequent ET dysfunction was found for the patients with retraction of pars tensa of tympanic membrane (0,038).
4. Laser Eustachian tuboplasty is an effective procedure for patients with chronic secretory otitis media when the functional obstruction of the ET pharyngeal orifice is endoscopically detected. After the surgery, full recovery was reported in 37.2% and the condition improved in 31.4% of the patients to whom other treatment methods proved ineffective.

5. Negative treatment results of chronic secretory otitis media using laser Eustachian tuboplasty were related to number of previous operations, smoking, tory of allergies, duration of the disease more than 5 years, retraction of tympanic membrane, nasal polyposis and mucosal edema of the nasopharynx. Better treatment results were obtained in patients with nasopharyngeal lymphoid hyperplasia. Oedema of ET pharyngeal orifice proved a negative prognostic factor of laser Eustachian tuboplasty ($p=0,031$).

5. PUBLICATIONS AND PRESENTATIONS BY THE AUTHOR IN RELATION TO THE TOPIC OF THE THESIS

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SANTRAUKA

Lėtinio sekrecinio vidurinės ausies uždegimo chirurginio gydymo lazerine tuboplastika efektyvumas

Darbo tikslas

Nustatyti lėtinio sekrecinio vidurinės ausies uždegimo chirurginio gydymo ausies trimito lazerine tuboplastika efektyvumą ir ausies trimito funkcijos pokyčius, vertinant objektyviais tyrimo metodais.

Darbo uždaviniai

1. Įvertinti idealios sekos dažnio sonotubometrijos tyrimo duomenis sveikiems suaugusiesiems ir nustatyti optimalų ausies trimito atsidarymą provokuojantį testą.
2. Įvertinti idealios sekos dažnio sonotubometrijos tyrimo duomenis pacientams su apsunkintu kvėpavimu per nosį.
3. Įvertinti ausies trimito funkcijos ir lėtinių vidurinės ausies susirgimų ryšį, atliekant idealios sekos dažnio sonotubometriją.
4. Įvertinti lėtinio sekrecinio otito chirurginio gydymo ausies trimito tuboplastikos lazeriu efektyvumą.
5. Nustatyti veiksnius, turinčius įtakos lėtinio sekrecinio otito chirurginio ATTL gydymo rezultatams.

Tyrimo metodika

Darbą sudarė dvi dalys. Pirmoje tyrimo dalyje, siekiant objektyvizuoti ir įvertinti ausies trimito funkciją, buvo vertinami sonotubometrijos su idealios sekos dažnio garsiniu signalu rezultatai sveikiems ir ausies trimito funkcijos pažeidimą turintiems asmenims. Nustatyti tyrimo parametrai, optimalūs provokacinių mēginiai, normos variantai, bei ypatumai pacientams su nosies obstrukcija ir lėtinėmis vidurinės ausies ligomis. Visiems tiriamiesiems buvo atliekamas kompleksinis tyrimas,

kurį sudarė tiriamojo anamnestinių duomenų rinkimas, otoskopija, rinoskopija, timpanometrija, Valsalvos testas ir sonotubometrija su IS dažnio signalu, o nosies obstrukcijos ir vidurinės ausies patologiją turintiems papildomai atlikta detali nosies ir nosiaryklės videoendoskopija.

Antroje tyrimo dalyje buvo siekiama įvertinti létiniu sekreciniu otitu sergančių pacientų, kurie iki įtraukimo į studiją buvo ilgai ir neefektyviai gydyti kitais metodais, priežastinio chirurginio ligos gydymo ausies trimito toboplastikos lazeriu efektyvumą. Tiriamiesiems buvo atliekamas detalus priešoperacinis ir pooperacinis ištyrimas, įvertintas gydymo efektyvumas ir nustatyti predisponuojantys faktoriai. Kompleksinį tyrimą sudarė anamnestinių duomenų rinkimas, otoskopija, rinoskopija, laringoskopija, timpanometrija, toninė slenkstinė audiometrija, Valsalvos testas, nosiaryklės ir ausies trimito ryklinės angos videoendoskopija, sonotubometrija su idealios sekos dažnių signalu.

Atliekant darbą ištirti 310 asmenų. Pirmoje darbo dalyje sonotubometrijos parametrams įvertinti buvo ištirti 105 sveiki asmenys (33 (31,4 %) moterys ir 72 (68,6%) vyrai). Vertinant apsunkinto kvépavimo per nosį ir idealios sekos dažnių sonotubometrijos rezultatų sasajas ir ypatumus, ištirti 47 pacientai (15 (31,9 %) moterų ir 32 (68,1 %) vyrai), besiskundžiantys nosies obstrukcija. Vertinant létinio sekrecinio otito ir idealios sekos dažnių sonotubometrijos rezultatų sasajas ir ypatumus, ištirti 43 pacientai (28 (65, 1 %) moterys ir 15 (34, 9 %) vyru). Šiame tyrime kontrolinę grupę sudarė 39 asmenys (21 (53, 8 proc.) moteris ir 18 (46, 2 proc.) vyru), kurie nebuvu sirgę ausų ligomis ir neturėjo otologinių nusiskundimų. Antroje darbo dalyje, vertinant ausies trimito lazerio tuboplastikos efektyvumą létiniu sekreciniu otitu sergantiems pacientams, buvo ištirti 37 pacientai, kuriems atlikta vienpusė arba abipusė ATTL operacija (iš viso atlikta 51 ATTL operacija). Kontrolinę grupę šioje tyrimo dalyje sudarė 39 pacientai, kuriems iš viso buvo atliktos 53 timpanostomijos operacijos.

Rezultatai

Ausies trimito funkcijos vertinimas idealios sekos dažnio sonotubometrija

AT funkcijos vertinimas IS dažnio sonotubometrija sveikiems asmenims

Iš viso atlikta 6300 matavimų. Ausies trimito atsidarymas sonotubometriškai užregistruotas visiems tiriamiesiems, bet ne kiekvienam atliktam matavimui. Tyrimo metu iš 6300 matavimų 6180 (98,1 proc.) buvo užregistruoti objektyviai ir vertinti kaip atsidarymai, atitinkantys kriterijus. Vertinant matavimų vidutinę atsidarymo trukmę, didesnė nustatyta atliekant sausą (seilių) rijimo mèginių - 284 ms, trumpesnė vandens rijimo mèginių metu - 263 ms. Skirtumas tarp mèginių nebuvo statistiskai reikšmingas. Vertinant kreivių formas daugiausiai nustatyta smaigalio ir dvigubos viršūnės, mažiau nusileidžiančios ir plokščios formos.

Apsunkinto kvépavimo per nosį ir AT funkcijos ryšys, atliekant idealios sekos sonotubometriją

Ausies trimito atsidarymas sonotubometriškai neužregistruotas 30 (31,9 proc.) atvejų nosies obstrukcijos tiriamųjų grupėje ir 5 (6,4 proc.) sveikų asmenų kontrolinėje grupėje ($p<0,001$). Nustatyta IS sonotubometrijos vidutinė atsidarymo trukmė nosies obstrukcijos grupėje 280 ms, vidutinė garso bangos amplitudė- 10,35($SD\pm 4,86$), kontrolinėje grupėje- 274 ms ir 12,26($SD\pm 5,40$). Skirtumas tarp abiejų grupių statistiskai nereikšmingas. Tyrimo metu nustatyta, kad apsunkintas kvépavimas per nosį ($p= 0,014$), didelio laipsnio nosies pertvaros iškrypimas ($p=0,001$), nosies pertvaros iškrypimas tiriamojoje ausies trimito pusėje ($p<0,001$), apatinį krauklių hipertrofija, obturujanti nosies landas ($p<0,001$), gasterozefaginio refliukso požymiai ($p=0,036$), teigama alergijos anamnezė ($p= 0,013$), nosiaryklės edema ($p<0,001$) ir limfoidinio audinio sankapus ($p<0,001$), videoendoskopiskai fiksuotas neatsidarantis ausies trimi-

to spindis ryjant ($p<0,001$), ausies trimito nosiaryklinės srities edema ($p=0,002$) ar AT limfoidinio audinio sankaupos ($p<0,001$) yra statistiškai patikimai susiję su sonotubometrinio tyrimo idealios sekos dažnio garsiniu signalu tyrimo rezultatais. Rezultatai nepriklausė nuo tiriamujų amžiaus ar lyties.

*Ausies trimito funkcijos vertinimas idealios sekos
dažnio sonotubometrija asmenims su létiniai
vidurinės ausies uždegimais*

Ausies trimito atsidarymas sonotubometriškai neužregistrnuotas 25 (43,9 proc.) tirtų ausų létinių sekrecinių otitų tiriamujų grupėje ir 5 (6,4 proc.) sveikų asmenų kontrolinėje grupėje ($p<0,001$). Nustatyta IS sonotubometrijos vidutinė atsidarymo trukmė létinių vidurinės ausies uždegimui grupėje 261 ms, vidutinė garso bangos amplitudė- 7,41($SD\pm 4,77$), kontrolinėje grupėje- 274 ms ir 12,26($SD\pm 5,40$). Vidutinės garso bangos amplitudės vidurkiai pacientams su létiniu sekreciniu vidurinės ausies uždegimu buvo mažesni, lyginant su kontroline grupe ($p<0,001$). Tyrimo metu nustatyta, kad apsunkintas kvėpavimas per nosį ($p<0,001$), apatinį kriauklių hipertrofija, obturuojanti nosies landas ($p<0,001$), teigiamas "k" mėginys ($p=0,004$), limfoidinis audinys nosiarykleje ($p=0,001$), įtemptosios dalies retrakcija ($p=0,038$), B tipo timpanometrijos kreivė ($p=0,007$) yra statistiškai patikimai susiję su sonotubometrinio tyrimo idealios sekos dažnio garsiniu signalu tyrimo rezultatais.

*Ausies trimito tuboplastikos lazeriu efektyvumas,
gydant létinių sekrecinių vidurinės ausies uždegimą*

Tiriamojoje ATTl grupėje, vertinant operacijos rezultatų efektyvumą objektyviai po 1 mėnesio pasveiko 10 (19,6 proc.), pagerėjo – 25 (49,9 proc.), o jokio pagerėjimo nebuvo gauta 16 (31,4 proc.) atvejų. Vertinant rezultatus po 12 mėnesių, pasveikusiuju buvo 19 (37,2 proc.), būklės pagerėjimas fiksotas 16 (31,4 proc.), o jokios teigiamos dina-

mikos negauta 16 (31,4 proc.) atvejų. Kontrolinėje grupėje rezultatai po mėnesio buvo panašūs į tiriamosios grupės (pasveiko- 10 (18,9 proc.), pagerėjo- 30 (56,6 proc.), nepagerėjo – 13 (24,5 proc.), $p= 0,694$), tačiau po 12 mėnesių gydymo rezultatai jau buvo statistiškai patikimai blogesni (pasveiko- 3 (5,7 proc.), pagerėjo- 19 (35,8 proc.), nepagerėjo – 31 (58,5 proc.) atvejų, ($p<0,001$). Ausies trimito atsidarymas tiriamujų grupėje po 12 mėnesių sonotubometriškai užregistruotas 72,5 proc. atvejų. Nustatyta vidutinės garso bangos amplitudė- $13,11\pm3,98$ dB, atsidarymo trukmė- 256 ± 128 ms. Sonotubometrijos kreivių pasiskirstymas po operacijos pagal formą tiriamojoje grupėje: smaigalio formos – 27 proc., dvigubos viršūnės formos – 38,1 proc., nusileidžiančios kreivės formos – 16,2 proc., plokščios kreivės formos – 24,3 proc., mišrios- 24,3 proc. Vertinant objektyviai fiksuočių atsidarymų rezultatus atlikiems 5 mėginiams nustatyta, kad penki iš penkių atsidarymų fiksuočių 15,7 proc., keturi iš penkių- 17,6 proc., trys iš penkių- 9,8 proc., du iš penkių- 15,7 proc. tiriamų ausų, vienas iš penkių- 13,7 proc. Atsidarymai neužfiksuočių 27,5 proc. tiriamų AT. Skirtumas vidutinės garso bangos amplitudės vidurkio prieš ir po operacijos buvo statistiškai patikimai didesnis po operacijos ($p=0,006$). Sonotubometrijos mėginio metu po operacijos statistiškai patikimai dažniau fiksuočių penki iš penkių ($p=0,003$) ir keturi iš penkių ($p=0,007$) atsidarymai. Kiti skirtumai nebuvo statistiškai reikšmingi. Vertinant klausos pažeidimo lygį tiriamojoje grupėje, vidutinis oro – kaulo intervalas praėjus 1 mėnesiui po operacijos buvo $19,23\pm9,68$ dB (kontrolinėje grupėje $19,56\pm9,34$ dB, $p=0,948$), o paskutinio vizito metu – $15,21\pm11,83$ dB (kontrolinėje grupėje $24,45\pm6,94$ dB, $p<0,001$). Vidutinis klausos pažeidimo lygis praėjus mėnesiui po operacijos tiriamujų grupėje buvo $24,66\pm12,70$ dB, kontrolinėje- $24,11\pm10,45$ dB ($p=0,338$), analogiškai paskutinio vizito metu- $22,50\pm13,45$ dB ir $25,35\pm9,87$ dB ($p= 0,018$). Vidutinis klausos pažeidimas tiriamojoje grupėje tiek praėjus mėnesiui po operacijos ($p<0,001$), tiek po 12 mėnesių ($p<0,001$) buvo mažesnis, lyginant su priešoperacinių tyrimų duomenimis.

mis, tuo tarpu kontrolinėje grupėje po 12 mėnesių klausos vidurkis nesiskyrė nuo priešoperacinių audiometrinių duomenų ($p=0,083$). Po 12 mėnesių AT angos atsidarymas stebėtas 31 (60,8 proc.), provokuojančio atsidarymą "K" testo metu atsidarymas stebėtas 16 (31,4 proc.), AT ryklinės srities edema stebėta 22 (43,1 proc,), limfoidinio audinio sankaus pos AT ryklinės dalies srityje- 11 (21,6 proc.) tiriamų atvejų.

Vertinant nosies ir nosiaryklės videoendokopijos pokyčių ir ATTL gydymo rezultatų sąsajas nustatyta, kad obturuojančios apatinės nosies kriauklės ($p<0,001$) ir limfoidinis audinys nosiaryklėje ($p=0,003$) buvo susiję su geresniais pooperacionais rezultatais, o blogesni operacijos rezultatai gauti pacientams, kuriems prieš operaciją rasti polipai nosies landose ($p= 0,009$), nosiaryklės edema ($p<0,001$) ar AT ryklinės dalies srities edema ($p<0,001$).

ATTL gydymo rezultatai buvo statistiškai patikimai blogesni tiems pacientams, kai iki tol buvo atliktos daugiau nei 3 timpanostomijos operacijos ($p<0,001$), rūkantiems ($p<0,001$), nustačius teigiamą alerginę anamnezę ($p=0,007$), kai sekrecinio otito trukmė buvo daugiau nei 5 metai ($p= 0,043$) ir būgnelio retrakcijos atvejais ($p=0,019$).

Vienaveiksnės logistinės regresijos metodu nustatytais tik vienas statistiškai reikšmingas prognozinis kriterijus – AT ryklinės srities edema leido prognozuoti blogesnius ATTL gydymo rezultatus ($p=0,031$).

IŠVADOS

1. Idealios sekos dažnių sonotubometrija patikimai fiksuoja ausies trimito atsidarymus ir gali būti naudojama objektyviam AT funkcijos vertinimui sveikiems asmenims. Optimalus ir patikimas sonotubometrijos provokacinis mėginyms yra mažo tūrio vandens rijimo testas.
2. Asmenims su apsunkintu kvėpavimu pro nosį idealios sekos dažnių sonotubometrija nustatoma mažiau ausies trimito atsidarymo epizodų nei sveikiesiems, o krievių charakteristikos nesiskyrė. Veiksniai,

statistiškai reikšmingai susiję su sonotubometriškai nefiksuojamais ausies trimito atsidarymais buvo patologinis nosies pertvaros iškry-pimas, apatinį nosies kriauklių edema, nosiaryklės edema ir lim-foidinio audinio hiperplazija, ausies trimito ryklinės angos edema ir limfoidinio audinio hiperplazija.

3. Pacientams su létiniu sekreciniu vidurinės ausies uždegimu sonotubometrijos metu visi provokuoti ausies trimito atsidarymai užfiksuoti 22,8 proc. tirtų ausų, o vidutinė garso bangos amplitudė buvo mažes-nė ($p<0,001$). Veiksnių, statistiškai reikšmingai susiję su sonotubo-metriškai nefiksuojamais ausies trimito atsidarymais buvo obturuo-janti nosies kriauklių hipertrofija, B tipo timpanograma ir būgnelio retrakcijos pobūdis. Įtemptosios būgnelio dalies retrakcijos atvejais sonotubometriškai AT disfunkcija nustatyta dažniau ($p=0,038$).
4. Ausies trimito ryklinės angos tuboplastika lazeriu yra efektyvi pro-cedūra létiniu sekreciniu vidurinės ausies uždegimu sergantiams pa-cientams, kai endoskopiskai nustatoma ausies trimito ryklinės angos funkcinė obstrukcija. Po operacijos visiškai pasveiko 37,2 proc., o bū-klė pagerėjo 31,4 proc. pacientų, kuriems kiti gydymo metodai buvo neefektyvūs.
5. Létinio sekrecinio vidurinės ausies uždegimo gydymas ATTL daž-niau buvo neveiksmingas tiems pacientams, kuriems iki tol buvo atliktos daugiau nei trys timpanostomijos operacijos, rūkaliams, taip pat asmenims, sergantiams ilgiau nei 5 metus, turintiems teigiamą alerginę anamnezę, ausies būgnelio retrakciją, nosies polipozę, no-siaryklės gleivinės edemą ir ausies trimito gleivinės edemą. Gydymo rezultatai gauti geresni, jei iki operacijos buvo limfoidinio audinio hiperplazija nosiaryklėje. Ausies trimito ryklinės srities edema buvo neigiamas prognozinis gydymo ATTL kriterijus ($p=0,031$).