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Risk factors of *tympanoplasties in* long-term observation

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Objective: The aim of the study was to evaluate risk factors influencing the results of tympanoplasties on the base of material taken from the Department of Otolaryngology and Laryngological Oncology Collegium Medicum of the Nicolaus Copernicus University in Bydgoszcz between 2004-2009. In this period, 98 operations were performed. The time from operations to hearing examination was 3 to 7 years, mean 5,43. Tympanoplastic operations were divided according to Tos classification. Measuring hearing results, tonal audiometry was done and mean air bone gap on four frequencies was assessed (500, 1000, 2000, 3000 Hz), according to AAO-HNS guidelines (1995). This parameter was compared between groups separated according to risk factors, that could potentially affect the results. Those risk factors were: disfunction of the Eustachian tube, location and size of the perforation of the tympanic membrane, damage of the ossicles, the state of the mastoid process, the number of operations, the presence of the cholesteatoma or granulating tissue, chronic otitis media in the opposite ear, smoking cigarettes, mastoidectomy, canal wall down technique. The results were analyzed using statistical test.

Results: The most important risk factor affecting treatment results (besides discharge from the ear) is damage of the ossicles, especially the malleus and stapes. A properly performed operation ensures good hearing results irrespectively of the presence of cholesteatoma or granulating tissue, and also in case of reoperation. For all types of tympanoplasties neither the location, nor the size of perforation influence the hearing results in long-term observation.

KEYWORDS: tympanoplasty, chronic otitis media, mastoidectomy, canal wall up, canal wall down

INTRODUCTION

Hearing-improving surgery continues to be a huge challenge for otosurgeons. The degree of ossicle destruction is the most frequently mentioned risk factor affecting the results of surgical treatment described in the literature. In the light of contradictory reports, the impact of performing mastoidectomy and ablation of the posterior external ear canal wall remains unclear in terms of worse hearing results after surgery. Auditory tube patency was also considered an aggravating factor in prognosis, however there is also unanimity among researchers in this matter. The features of the tympanic membrane defect, such as size and location of the perforation were also analyzed. A lot of works concern the results following surgical treatment of the ears with cholesteatoma or granulation tissue, which in themselves may be unfavorable prognostic factors. While the hearing test method for postoperative assessment has been unified (AAO-HNS guidelines of 1995), heterogeneous groups of patients and a varying observation time cause the comparison between the results to be difficult. The qualification for the study group varies depending on the clinic or even the study to the extent, that it is difficult to find two analogous studies. This is due to the fact, that a given procedure can be classified differently, e.g., in terms of reconstruction (TORP vs PORP) or resection (canal wall-down vs. canal wall-up).

In the authors' opinion, the factors, that worsen the prognosis are ear discharge, swelling of the mucous membrane and active inflammation, i.e., the symptoms of exacerbation of chronic otitis media. Therefore, patients with ear discharge were tem-

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porarily disqualified from surgery and initially treated conservatively. In the literature, opinions on this subject vary. Older publications definitely qualify ear discharge as a factor worsening hearing following surgery. In the latest reports, there exist opinions about the lack of impact of wet ear on the results of tympanoplasties

Other risk factors were included in the statistical analysis broken down by the scope of resection (mastoidectomy or lack thereof, canal wall-up or canal wall-down) and reconstruction technique (type of tympanoplasty according to Tos classification).

AIM OF PAPER

The aim of the study was to analyze and review the factors used in literature, that influence the long-term results of tympanoplasties in relation to the material of the Department of Otolaryngology and Laryngological Oncology of the CM UMK in Bydgoszcz.

MATERIAL AND METHOD

The material was collected among patients treated for chronic otitis media in the Department of Otolaryngology and Laryngological Oncology of the Nicolaus Copernicus University Collegium Medicum in Bydgoszcz, in 2004-2009.

The approval of the Bioethical Commission of Collegium Medicum named after Ludwik Rydygier in Bydgoszcz of the Nicolaus Copernicus University in Toruń was obtained for the performance of research, reference number: KB 588/2011.

The analysis included a selected group of 86 patients undergoing tone audiometry examination (46 women and 40 men). The mean age of the respondents was 40.5 years (in the range of 18-72 years). A total of 98 tympanoplasties was performed (6 patients had their right and left ears operated). The time elapsed from surgery to the time of the study ranged from 3 to 7 years, an average of 5.43 years. Patients were operated by two experienced otosurgeons. The performed tympanoplasties were divided according to Tos classification [1]. In the evaluation of functional results, a tonal audiometry test was used, calculating the average cochlear reserve from four frequencies (500, 1000, 2000, 3000 Hz), according to the AAO-HNS guidelines from 1995 [2,3]. This parameter was compared between groups separated for factors, that could potentially affect the outcome of treatment. Among these factors, the following were taken into account: obstruction of the Eustachian tube, location and size of eardrum cavity, damage to the ossicles, degree of mastoid aeration, number of operations performed, presence of granulation tissue or cholesteatoma, performance of mastoidectomy, ablation of the posterior external ear canal wall, the condition of the second ear, smoking cigarettes. The obtained results were subjected to statistical analysis.

RESULTS

The results of tonal audiometry were divided into groups depending on the type of surgery performed according to Tos classification as well as the presence of the examined risk factor.

Table 1 presents the value of statistical significance coefficient p for each of the above-mentioned risk factors comparing the mean cochlear reserve before and after the surgery with a breakdown into tympanoplasty type according to Tos.

Table 2 presents p-factor values comparing the average cochlear reserve before and after the operation in the case of damage to individual ossicles in relation to the absence of damage.

DISCUSSION

Prognostic factors, that affect the cochlear reserve after tympanoplastic operations were determined by means of numerous classification systems. The Belucci classification [4] encompasses the division into four groups based on the presence of ear discharge and craniofacial malformations with good or poor surgical treatment effect. Black [5] divides prognostic factors into surgical, prosthetic, infectious, tissue and connected with the auditory tube. Austin [6] bases on the condition of the ossicular chain (the presence or absence of the malleus handle and/or stapes superstructure) as the most important determinant of surgical success. The Kartoush system [7] is a compilation of factors from the above classifications. Dornhoffer [8] created his own risk factor assessment system, among which he distinguished as significant ear drainage, presence of adhesions in the middle ear, lack of a malleus handle, mastoidectomy, ablation of the posterior external ear canal wall and reoperation [4,5,6,7, 8].

The factors most frequently analyzed in the literature were taken into account in the material of the Otolaryngology Clinic of CM UMK in Bydgoszcz.

This study did not assess the effect of the presence of ear drainage and middle ear mucosal edema on the operating results. According to the authors' belief, operating the ear during exacerbation of inflammation reduces the rate of graft healing

Tab. I. Analysis of risk factors for particular types of tympanoplasties

	TYMPANO PLASTY TYPE I	TYMPANO PLASTY TYPE 2	TYMPANO PLASTY TYPE 3	TYMPANO PLASTY TYPE 4
Patency of the Eustachian tube - patent vs blocked	p=0.6472	p=0.8351	p=0.5476	p=0.4000
Eardrum cavity - marginal vs central	p =0.0675	p=0.7088		
Eardrum cavity – in the tense part vs in the flaccid part	p=0.6634	p=0.9759	p=0.8000	
Location of cavity – front vs rear vs rear-upper	p=0.0608	p=0.2474	p=0.5714	
Cavity of eardrum - small (<50% of the membrane area) vs average (= 50%) vs large (> 50%)	p =0.3720	p=0.0482	p =0.7390	
Operation - first vs next	p =0.5498	p=0.9684	p=0.9046	p=0.5333
Cholesteatoma vs no cholesteatoma	p=0.5476	p=0.4711	p=0.0625	p=0.2667
Granulation vs no granulation	p=0.4663	p=0.1398	p=1.0000	p=0.5333
Mastoid - solid vs aerial	p=0.0159	p=0.7094		
Condition of second ear - chronic inflammation vs healthy	p=0.9180	p=0.7070	p=0.5476	p=1.0000
Smoking vs non-smoking	p=0.7311	p=0.2813	p=0.5556	
Mastoidectomy vs no mastoidectomy	p=1.000			
Ablation of the posterior external ear canal wall vs lack of ablation		p=0.940		

Tab. II. Analysis of ossicle damage for all types of tympanoplasties.

OSSICLES - PRESERVED VS DAMAGED	P-VALUE
Malleus	p=0.0057
Incus	P=0.0753
Stapes	p=0.0512

[4, 9, 15-15]. Therefore, the qualification for surgery included only patients without exacerbation markers, and if they were present, the procedure was postponed, blood was drawn and local antibiotic therapy was included, aimed at the resignation of active infection. The latest reports on this topic show, that there is no effect of drainage on wound healing [60,61,62].

Patency of the Eustachian tube is a key element of correct aeration of the middle ear, both in childhood and in adulthood. Enlarged pharyngeal tonsils in children cause a chronic negative pressure in the middle ear, which in turn results in decreased pneumatization of the mastoid, the occurrence of drainage with destructive properties to bone tissue and tympanic membrane and eventually to its perforation [16-18]. If the medialization and destruction of the tympanic membrane relate more to the flaccid part, the accumulated masses of exfoliated epidermis in the retraction pocket of the epitympanum may turn into a cholesteatoma [17]. The literature underlines the huge role of abnormal ventilation of the middle ear not only in the pathogenesis of chronic otitis media, but also in the postoperative period as an element hindering the proper healing of the graft. Avoidance of neo-tympanum medialization and reperforation translate into good and very good auditory results and reduction of cochlear reserve [5, 8, 19-22]. However, some authors report, that there is no effect of an obstructed or poorly patented eustachian tube on postoperative cochlear reserve, primarily in the context of the lack of credibility and reflection of the actual functional status of the trumpet by applied tests [9, 23-25]. In the material under study, this type of dependency was also not found.

Smoking tobacco may have a potentially twofold effect on the healing of the middle ear following surgery. The first mechanism is associated with obstruction of the auditory tube due to chronic rhinitis and nasal as well as nasopharyngeal mucosal edema caused by tobacco smoke. In addition, many years of nicotinism cause atherosclerosis of the blood vessels, which in turn results in ischemia and hypoxia of the healing tissues, and thus hinders, for example, graft healing, revascularization of tissue fragments used for tympanoplasty, delayed healing of the respiratory tissues and aggravates the tendency to infections [26]. However, in the study material no deterioration of long-term auditory results was found for individual types of tympanoplasties in smokers compared to non-smokers, which is confirmed in the literature [27].

The location of the eardrum defect does not affect the size of the cochlear reserve if we take into account the front or rear quadrants of the tensed eardrum [28]. However, in the case of damage to the central area of the membrane conductive hearing loss is greater than in the case of perforation of marginal regions. Thus, the reconstruction of the eardrum depending on the location may also potentially give different results [14, 22]. The analysis compares losses in front, posterior, frontal--posterior quadrants, and those including or not including the tendinous ring. In this study, there was no relationship betwe-

en the location of the defect and the size of the cochlear reserve in the distant observation, which coincides with reports in the literature [27].

An analysis of cavities in the flaccid part and the stretched tympanic membrane was also performed. The loss of the eardrum in the flaccid part occurs in chronic otitis media, sometimes referred to in the literature as the Attico antral type. It is usually associated with the presence of a cholesteatoma in an epitympanum, a retraction pocket formed on the substrate. The presence of cholesteatoma, according to some authors, has a poorer prognosis, both in terms of functional results, i.e., the obtained cochlear reserve, as well as structural results, measured by the percentage of graft healing. The loss in the strained part, however, occurs in chronic tubo-tympanular otitis media and is usually not associated with the risk of coexistence of other pathologies, nor with worse operating results. In the proprietary material for type 1, 2 and 3 tympanoplasties, there was no statistically significant difference between the results of the mean cochlear reserve in patients with tympanic membrane defect in the stretched and flaccid part in long-term observation.

Assessing **the size of the tympanic membrane defect** for type 1, 3 and 4 tympanoplasties, it was found, that it is irrelevant to the auditory effect after surgical treatment, which is confirmed in the literature [20, 25]. Only for type 2 tympanoplasty, a large defect in the tympanic membrane correlates with worse results of the average cochlear reserve. This fact may result from the variation within this type of surgery into two subgroups: canal wall-up and canal wall-down, depending on the behavior or ablation of the posterior wall of the external auditory canal. The Technique wall-down technique is used in the case of additional pathology in the middle ear or in the mastoid (cholesteatoma, granulation tissue). The larger destruction of the membrane is accompanied by greater destruction within the structures of the middle ear and the need to extend resection procedures. The combination of the above circumstances may influence the increase in the mean cochlear reserve after surgery, although according to the literature, analyzing the wall-up and wall-down subgroups separately, the size of the cavity does not matter. Some of the papers show worse results after surgical treatment for subtotal perforations, but the study group included all types of tympanoplasties, which could affect the statistical significance achieved [9]. In addition, the results presented in the articles relate to the short observation time (1 year) [8,9].

Mastoid aeration is one of the anatomical exponents of the duration of the disease and the obstruction of the auditory tube. The presence of a dense, shaded appendix in the imaging study according to some authors, worsens postoperative results [15]. For type 1 tympanoplasty, the presence of an aerated appendage was associated with obtaining a smaller cochlear reserve after the procedure. However, in the group of patients who underwent type 2 tympanoplasty, statistical significance was not demonstrated and the condition of the appendage did not influence long-term operational results. Thus, the presence of a solid appendage is important for long-term results only in type 1 tympanoplasty, which may be related to the impaired patency of the auditory tube before and during the postoperative period in this group of patients. The condition of aeration of the middle ear is not important for surgical results after type 2 tympanoplasty, as it is probably in this group, that the degree of destruction of the ossicles is decisive.

The presence of **cholesteatoma** and **granulation tissue** in the airspaces of the middle ear is associated with increased bone destruction with severity correlated with the duration of the disease. In the first place, delicate auditory ossicles are destroyed, in particular the long leg of the incus. In addition, the need to lift the back wall of the external auditory canal appears more often. The question then arises whether the above pathologies influence the achievement of poorer postoperative results. In the examined material, for all types of tympanoplasties, the presence of a cholesteatoma or granulation tissue does not worsen the long-term results of the mean cochlear reserve. According to the literature, the authors' opinions are divided, but the prevailing view is that this type of pathology is not affected by post-operative results [8]. A properly performed procedure gives the same chance to improve hearing after surgery in patients with chronic otitis media with cholesteatoma and / or granulation tissue as well as in patients diagnosed with chronic simple inflammation.

There is a view in the literature, that **reoperation** gives worse auditory results compared to the first surgery [34]. This analysis did not confirm this thesis. Repeated treatment gives the same chances of hearing improvement as the original procedure.

Some authors report worse post-operative results if chronic otitis media occurs on both sides [20,35]. This situation often occurs in children due to additional aggravating factors, such as vegetationes adenoidales, OMS. In the above material, this type of relationship was not shown, but only adults over 18 years of age were included in the study group.

The most important, and according to some authors, the only factor influencing the results after tympanoplasties is the **condition of the ossicles** [5,6,8,9,15,36]. In the examined material, the damage to the malleus has the greatest impact on the average cochlear reserve in long-term observation. In addi-

tion, better results were obtained for the group with preserved stapes superstructure, than in the group with its damage, however, no statistical significance was obtained in this case (p = 0.0512). The obtained results are consistent with reports in the literature. Many authors point to the greater importance of the presence of a fully preserved malleus than the stapes for the results of the treatment [8,37,38], and even the lack of influence of the preserved superstructure of the third ossicle on postoperative results [8,38,39]. In order to obtain better results, it is important to closely match the formed ossicle to the malleus handle if it is present [37, 40]. Therefore, the optimal execution of Tos's type 3 tympanoplasty in the presence of a handle may give better hearing results than type 2 tympanoplasty in its absence. In addition, the short columella using the auricular cartilage becomes unstable over time due to resorption or dislocation in the case of artificial prostheses, which is why Vincent reconstructs the osseous chain with a TORP prosthesis despite the presence of stapes superstructure *(silastic banding technique)* [41].

Assessing the effect of **mastoidectomy** and **removal of the posterior wall of the external auditory canal** on the operation of the auditory system, an analysis of the results of the average cochlear reserve with the division into the type of surgery was performed.

The results of type 1 tympanoplasty with mastoidectomy (canal wall-up) and myringoplasty alone (procedure without mastoidectomy) were compared. In the long-term observation, the examined material did not show a statistically significant difference between the groups, despite the larger mean cochlear reserve after the procedure for type 1 tympanoplasty with mastoidectomy as compared to type 1 tympanoplasty without mastoidectomy. The obtained results prove, that mastoidectomy does not worsen the long-term results of the mean cochlear reserve by comparing homogeneous groups of patients in terms of existing pathology and the degree of ossicular chain behavior in which tympanoplasty type 1 was performed. In the literature, the authors' opinions are divided on this topic. Some authors report, that better results can be obtained without performing any surgery on the mastoid [9,15, 21, 40, 42-44]. However, worse results after surgical treatment with mastoidectomy were obtained when the study group included all types of tympanoplasty [9], but then other postoperative factors besides mastoidectomy also influenced postoperative results. In addition, the results presented in the articles refer to a short observation time (several months to a year) [9,21]. Regarding literature reports within homogeneous groups of patients, they testify to a larger cochlear reserve after tympanoplasty with mastoidectomy, but without statistical significance [29, 30-33]. A similar result was obtained in this study.

Subsequently, type 2 open tympanoplasty was compared to closed tympanoplasty, assessing the effect of abolishing the posterior wall of the external auditory canal on the obtained average cochlear reserve after surgery. In the analyzed period there was no statistically significant difference between the groups, despite the higher mean of the cochlear reserve for type 2 open tympanoplasty in comparison with type 2 closed tympanoplasty. The above results are confirmed in the literature: better results are obtained for the closed technique, but without statistical significance [45]. Many authors compare the results of hearing between operations performed with the open and closed technique, in favor of the latter [8, 9, 39, 46, 47]. However, these authors compared all types of tympanoplasties together, so for this reason postoperative results may have been influenced by other factors (e.g., condition of the ossicles) [8,9]. Most publications, however, testify to the lack of both the abolition of the posterior wall of the external auditory canal and the performance of mastoidectomy on the results of the mean cochlear reserve after tympanoplasty [1,48-59]. American textbooks also do not report deterioration of the cochlear reserve after the removal of the posterior wall of the external auditory canal provided there is an airspace of the tympanic cavity with a volume of at least 0.5 cm^3 [28]. In the study material, comparing the results of treatment between an open and closed technique within a homogeneous group of patients with preserved stapes superstructure, in which Tos type 2 tympanoplasty was performed, there were no statistically significant differences in long-term follow-up.

Factors affecting post-operative results in the light of contradictory reports are difficult to determine [8,27]. An element perhaps the most important, and always overlooked due to the lack of objectivity, is the ability of middle ear tissues to normal healing without fibrosis, granulation and chronic inflammatory response [8,34]. Therefore, despite proceeding in accordance with the guidelines and avoiding any risk factors, the prognosis may be uncertain.

CONCLUSIONS

1. The most important factor influencing long-term results after tympanoplasties is the **condition of the ossicles**, in particular, the malleus and stapes.

2. A properly performed treatment guarantees good auditory effects regardless of the presence of cholesteatoma and granulation tissue, as well as in the case of reoperation.

3. For all tympanoplasty types, the location and size of the tympanic membrane defect do not affect the results of treatment in long-term observation.

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