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Prospective Study on the Results of the Tuboplasty in Rural Region in Germany

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Abstract

1) Introduction: Ventilation disorders of the middle ear play a major role in everyday clinical ENT-practice and sometimes represent a major therapeutic challenge. In addition to the conventional therapy of tympanostomy tube insertion, tuboplasty (TP) offers a less invasive option for treating this problem. The study should examine whether TP can be performed in a rural setting. 2) Material and methods: This is a prospective, monocentric study of patients scheduled for TP because of tubal ventilation disorder (TVD) in a rural region of Germany. The diagnosis was established after a thorough clinical examination and by assessing the possibility of performing the Valsalva maneuver, the tympanogram type, recording the middle ear pressure and air-bone gap. The subjective impairment caused by the TVD was evaluated using the EDTQ-7 questionnaire pre- and approximately 3 months postoperatively. 3) Results: Sixty-two patients with 92 TP were included with a mean age of 44.1 years. The EDTQ-7 score decreased highly significantly from 3.6 to 1.7 ($p < 0.0001$) without correlating with parameters such as age, sex, BMI, allergies or smoking. Middle ear pressure fell in average by −87 daPa, resulting in an improvement of the tympanogram type. The preoperative air-bone gap of 10.2 dB also was reduced significantly in most patients to 8.0 dB after the procedure. No notable complications occurred beside a sore throat due to the use of a laryngeal mask for ventilation during anesthesia in two cases. 4) Conclusion: In our experience, TP represents a less invasive and, in many cases, successful alternative to the established tympanostomy tube insertion with the advantage of an intact eardrum. It can also be offered and successfully performed in a rural setting.

Keywords

Eustachian Tube Dysfunction, Tuboplasty, Eustachian Tube, Valsalva Maneuver, Grommet

1. Introduction

Disturbances in the ventilation of the middle ear spaces are a common, everyday phenomenon for every Otorhinolaryngologist [1] and, more than a century after Joseph Toynbee and Adam Politzer—to name just two historical protagonists - still sometimes represent a therapeutic challenge [2]. If untreated - in addition to the known effects in childhood, which are not the subject of this article - tubal ventilation disorder (TVD) can lead to the development of retractions and thus represent the basis for the development of cholesteatomas. In addition, normal physiology of the auditory tuba is not only a prerequisite for diving, where extreme demands are placed on pressure equalization in the middle ear and disruptions can potentially cause life-threatening situations [3]. Normal tubal function is also desirable in many everyday situations, such as taking elevators, flights or driving in the mountains.

A normal function of the middle ear structures as impedance transducers requires balanced pressure conditions between the external environment and the tympanic cavitiy. Since the atmospheric pressure is subject to considerable fluctuations and, in addition, the mucosa of the pneumatic spaces of the petrous bone absorbs nitrogen in particular, pressure equalization must be ensured via the auditory tube if necessary. However, this seemingly simple structure has a very complex anatomy and physiology in detail [4] [5], which in turn makes it susceptible to functional disorders. The connection between pathological morphology and impaired function becomes obvious, for example in the case of a cleft palate, which is often associated with TVD. However, in the majority of patients with TVD, the underlying cause remains unclear and therapy is based on symptomatic measures. In this context a short overview of the historical development of the treatment of TVD seems to be interesting. In addition to attempts to improve the condition through decongestant nasal drops, the insertion of a tympanostomy tube after paracentesis was the method of choice for many years. This procedure was proposed by Frank Martell from Würzburg in 1845, but was initially unsuccessful [2]. Only later, after the diagnosis could be established more reliably, other otologists such as Schwartze, Politzer and Armstrong defined the indications for such a measure and had therefore more satisfying results than Martell [2].

Another therapeutic approach was proposed earlier, which was based on the anatomical object of TVD: tubal catheterization [2]. However, the condition could not be reliably diagnosed as mentioned before, which was a main problem in those times. Following a suggestion from a medical layman, the French postmaster Guyot, in 1756, Jonathan Wathen, after extensive autopsy studies, described a

technique for intubation the pharyngeal tubal ostium from the nose by Jean Marie Gaspard Itard. He experimented with different media such as: sea water, solutions of iron oxide or ether which were instilled into the middle ear via the catheter.

Another, mostly unsuccessful attempt to improve dysfunctional tubal function was the insertion of a golden tubal catheter, which was usually inserted via the tympanic tube ostium as part of a middle ear operation [4].

In Germany, the Bielefeld group led by Sudhoff developed a transnasal dilatation of the Eustachian tube with a balloon catheter, similar to angioplasty, but without inserting a stent [6]. In the early years of this method, it was common practice to perform a preinterventional CT scan to rule out dehiscences in the osseous part of the tube adjacent to the C3-segment of the internal carotid artery. According to general experience and systematic studies e.g. by Abdel-Aziz and coworkers it has been shown that this radiation-based imaging is usually unnecessary [7].

Nowadays the diagnosis of TVD is based on the typical history of problems with pressure equalization, e.g. while driving in the mountains or when flying (landing approach). The subjective effects can be reliably evaluated using the EDTQ-7 Questionnaire. A precise clinical examination with ear microscopy, Valsalva maneuver, endoscopy of the nasal cavity and nasopharynx is mandatory in order to identify potential obstacles to TP in advance. As a static technique tympanometry is common and ubiquitous available, but cannot rule out TVD, if the findings are normal. Dynamic methods such as tubometry, sonotubometry or, ideally, examination in a pressure chamber, are more suitable for this, but are not generally available [8].

Our goal was to demonstrate, that the procedure of TP can be performed safely and effectively in a municipal hospital in a rural region of Germany, too.

2. Material and Methods

The prospective study ran in an ENT-department in the small town of Bad Hersfeld in a rural region of central Germany from November 2021 to September 2023 and was approved by the Ethics Committee of the Medical School Hanover (reference number 9830_BO_S_2021). The study was performed in accordance to the Declaration of Helsinki. After informed consent, patients between 18 and 80 years of age who suffered from a tubal ventilation disorder and who were scheduled to undergo tuboplasty (TP) were included. The indication for TP arose in the case of a chronic ventilation disorder that has existed for more than 6 months without another cause that can be treated causally. Exclusion criteria were e.g. massive adenoids, nasopharyngeal malignancies, condition after radiotherapy of the region, congenital disorders such as storage diseases, midfacial dysmorphia, palatal cleft or trisomy 21.

As part of the clinical examination including otoscopy and checking the possibility of performing the Valsalva maneuver, an endoscopy of the main nasal cavity and the epipharynx was carried out to assess the feasibility of TP via the transnasal

route. A septoplasty was not performed in this study. The air-bone-gap was measured by pure tone audiometry as the difference of the mean value for bone and air conduction at 0.5 kHz, 1 kHz, 2 kHz and 3 kHz. The type of tympanogram and the middle ear pressure was assessed by tympanometry. The subjective impairment of the TVD was measured by the EDTQ-7 questionnaire in a German translation [9] [10] (**Table 1**: original English version of the ETDQ-7).

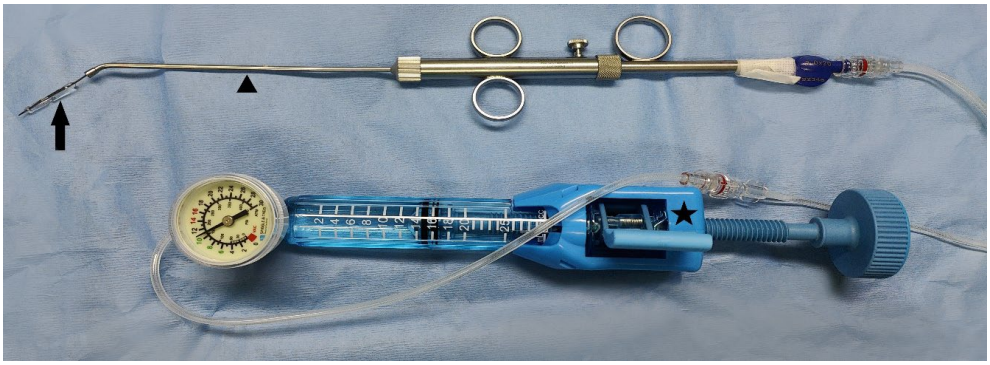
Table 1. Questions of the ETDQ-7 of McCoul *et al.* (Minimum score = 7, maximum = 49, cut-point for the diagnosis is a score of 14.5 [9].

Over the past 1 month, how much has each of the following been a problem for you?	**No Problem**		**Moderate Problem**			**Severe Problem**	
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ear?	1	2	3	4	5	6	7
6. Ringing in the ears	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled?	1	2	3	4	5	6	7

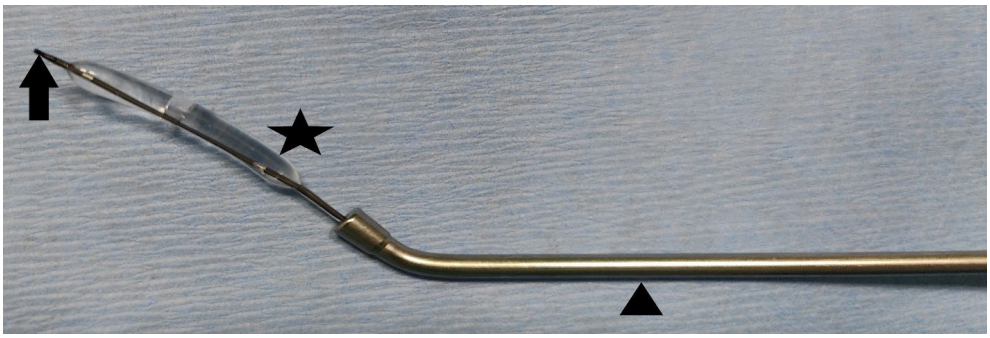
These examinations were repeated three months postoperatively and the data were documented in Excel tables. The audiometric procedure was measured with the audiometers AT900 from Auritec and CA350/450 version 4/2015 R03 from Zeisberg. Both devices were calibrated once a year as part of a maintenance contract. The statistical analysis was carried out using PASW Statistics 18 Version 18.0. Comparison of pre- and postoperative EDTQ-7 scores was performed using paired samples t-test. The Valsalva maneuver, tone audio and tympanograms were analyzed using the McNemar test. Pearson analyses were used to test the correlation. A p-value of 0.05 was defined as evidence of significance. A power-analysis was used to determine a sample size of at least 55 subjects.

The tuboplasty was performed under general anesthesia, usually with a laryngeal mask in the supine position with the head section slightly elevated. The decongestion of the main nasal cavity was provided with neurosurgical gauze soaked with xylometazoline. For endoscopy and documentation Storz Hopkins optics at 0 and 30 degrees and the Storz image documentation AIDA were used. For the TP we utilized the instruments and catheter TubaVent® from Spiggle & Theis (**Figure 1(a)** and **Figure 1(b)**).

After inspecting the pharyngeal tube ostium, intubation was carried out with the catheter and the balloon was advanced. Then it was then inflated to 10 bar for 2 minutes. After this time, the balloon was removed after the pressure was released and the site was checked endoscopically again. In this study, the TP was carried out transnasally without exception (**Figure 2** and **Figure 3**).



(a)



(b)

Figure 1. (a): Overview of the Instruments for tuboplasty: balloon (arrow), insertion tube (arrowtip) and water filled pump (asterisk). (b): Details of the balloon: tip of balloon (arrow), insertion tube (arrowtip) and balloon (asterisk).

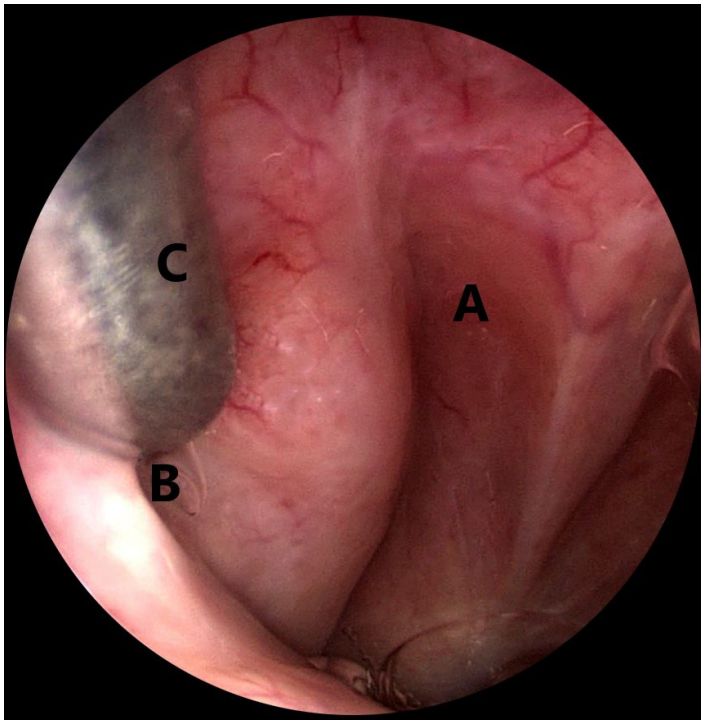


Figure 2. Endoscopic view intraoperatively: right nasopharynx (A), pharyngeal ostium of the Eustachian tube (B) and insertion tube (C).

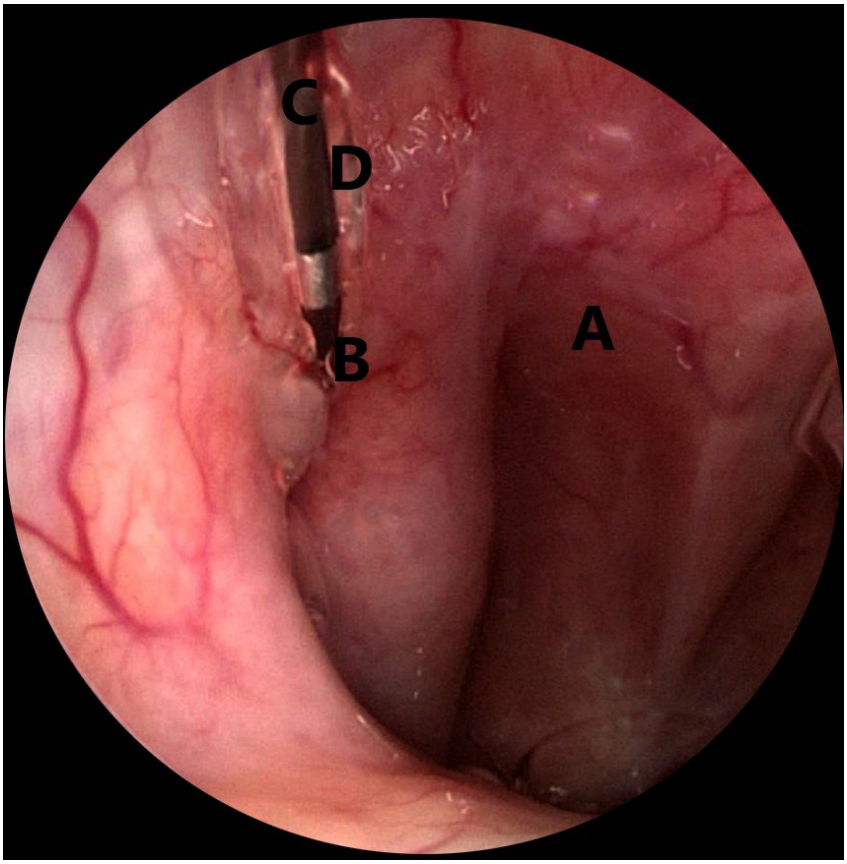


Figure 3. Endoscopic view intraoperatively during the beginning of the balloon's removal: right nasopharynx (A), pharyngeal ostium of the Eustachian tube (B) balloon (C) and mucous leaking out of the Eustachian tube.

To avoid possible emphysema, the patients were instructed not to blow their noses or to refrain from the Valsalva maneuver for 3 days. There was no systematic use of a nasal steroid after this procedure.

3. Results

A total of 62 patients (32 men and 30 women) were recruited for the study. The average age was 44.1 years, with a range of 19 to 74 years. A total of 92 tuboplasties were performed. The body mass index was between 18.4 and 41.5 kg/m^2. Since some of the patients were referred for therapy by ENT colleagues further away, only 30 presented for the planned follow-up examination after three months. The other 32 patients were interviewed by telephone or sent the EDTQ-7 questionnaire by post postoperatively. On the other hand, pure tone audiograms and tympanograms from referring colleagues were used for data analysis. Data from one patient could not be used.

As a primary endpoint, the score of the EDTQ-7 questionnaire (**Figure 4**) decreased statistically significantly ($p < 0.0001$) from 3.6 initially to 1.7 ($n = 61$).

There were no correlations of the improvement of the ETDQ-7score with parameters such as age, BMI, sex, allergies or habit of smoking (**Table 2**).

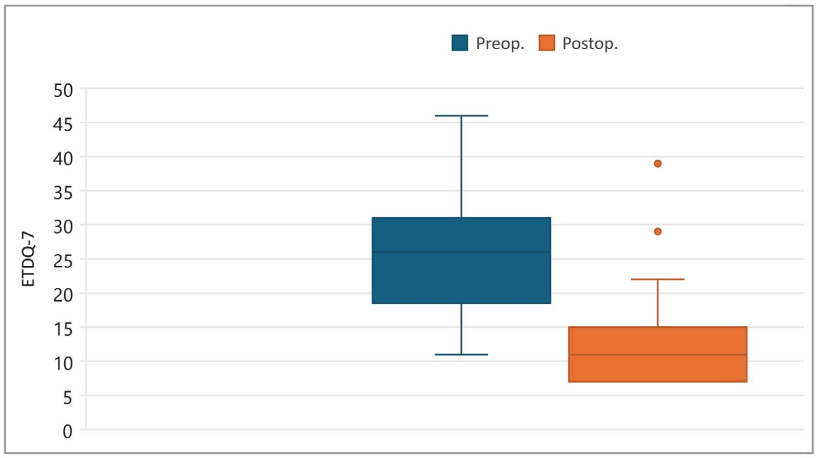


Figure 4. The average change of the Overall-ETDQ-7-Scores (p = 0.0001).

Table 2. Pearson correlation coefficients between the mean change in the total score of the ETDQ-7 questionnaire and various parameters.

Parameter	Coefficient of Correlation r
Age in years	0.037
BMI (kg/m²)	−0.088
Sex (m/w)	−0.129
Allergies (+/−)	−0.089
ASS-Intolerance (+/−)	0.155
Smoking (+/−)	−0.069

The middle ear pressure also decreased significantly by an average of −87 daPa ($p < 0.05$). This is also confirmed by the normalization of the tympanograms: only 2 patients had a tympanogram type B or C post-intervention, while it was observed 14 times preoperatively.

The ability of performing the Valsalva attempt increased from 17 pre- to 29 postoperatively ($p < 0.0001$). In the remaining patients, the test was possible with great effort after the procedure.

The air-bone gap (**Figure 5**) averaged 10.2 dB before the procedure and reduced to 8.0 dB after tuboplasty ($p < 0.05$).

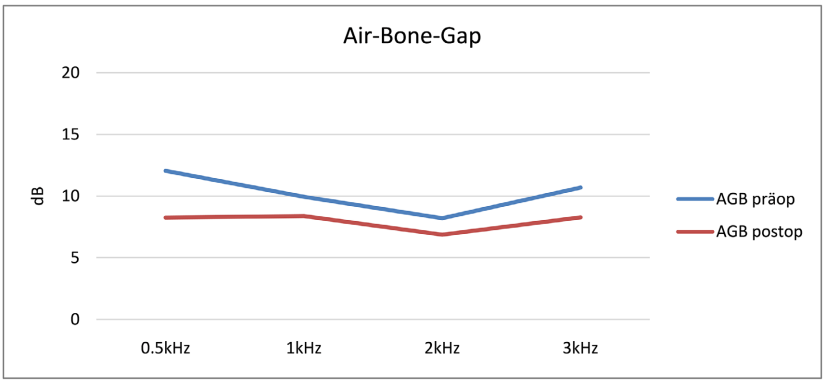


Figure 5. Comparison between the pre- and postoperative air-bone-gap.

Apart from a slight sore throat and two small hematomas of the palatal mucosa as a result of using the laryngeal mask for general anesthesia, we did not observe any significant complications. The minimal bleeding that sometimes occurred from the nasal mucosa due to touching the septal mucosa in case of deviations or spinae always stopped spontaneously. Problems directly associated with TP did not occur. In particular, we were not confronted with a patulous tube.

4. Discussion

Our results regarding treatment success correspond very well with those from studies in an university setting in the literature: Formánek *et al.* demonstrated an improvement in the EDTQ-7 score of more than 20%, with the greatest effect being seen after 6 months [11]. That is the reason we inform our patients not to expect an improvement directly after the intervention.

In the study by Meyer *et al.* there was a reduction in the EDTQ-7 score—2.9 after 6 weeks [12]. Satmis and colleagues found a reduction from 4.10 to 2.96 after three months [13].

With the normalization of the EDTQ-7 score, the above mentioned authors also describe an improvement in the Valsalva function and the tympanogram.

In their studies, Ebmeyer and coworkers used the "Eustachian tube score" they had established to evaluate the subjective disturbance and could see an increase in 2.1 to 6.07 as an expression of improved tube function [14].

The procedure is consistently considered safe and has few side effects—our experience confirms this which is comparable to the results of other centers [15]-[19]. Head and neck emphysema has rarely been described postoperatively in the past [20], which is why we encourage our patients not to blow their nose or perform the Valsalva maneuver for approximately 3 days. Other, more serious complications such as bleeding requiring treatment, inner or middle ear damage with perforation of the eardrum, barotrauma with hematotympanum and pain were also not observed.

Follow-up of our patients in a rural setting was challenging, a problem which colleagues of an ENT-university department observed, too [19]. It is probably easier to motivate patients e.g. after tumor therapy or a cochlear implant with the need for follow-up care.

The mechanism of TP appears to be a long-term stretching of the cartilaginous part of the tube through microfractures, as histological studies have shown, although, in contrast to angioplasty, no stent is used, [21]. There are now also results over a longer period of time that are surprisingly positive: in a prospective, controlled study on 60 patients, the improvements in the EDTQ-7 score remained stable for up to one year post-intervention [18] [22] [23].

This is consistent with our clinical experience. There is also the option of repeat TP if the condition deteriorates again. Like other authors, we also see an indication for re-TP if symptoms reappear that were only temporarily improved by the initial procedure. In these cases, the TubaVent wide can be used, which has an

appromimately 33% larger width 4.94 mm and the same length of 20 mm. However, we do not have special data with this device.

5. Conclusion

According to our results, TP is a safe, often effective and minimally invasive method for improving TVD even in a non-university setting. For suitable patients, it represents a worth mentioning alternative or addition to the traditional tympanostomy tube insertion. In our opinion, particularly promising candidates are patients with difficulty performing the Valsalva maneuver. With our study we were able to prove that this procedure can also be used safely in rural areas. One limitation of the study is the limited number of patients examined postoperatively, which could certainly have something to do with the sometimes long distances to our clinic in the rural surroundings. The restriction of preoperative testing methods without tubometry is also a weakness of our study.

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Conflicts of Interest

The authors declare no conflicts of interest regarding this paper's publication.

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