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Research Article

Clinical Analysis of Ear Congestion after Balloon Eustachian Tuboplasty (BET) with or without Tympanostomy Tube Insertion

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Objective. To explore the clinical analysis of ear congestion after balloon Eustachian tuboplasty (BET) with or without tympanostomy tube insertion. *Methods*. A total of 35patients (49 affected ears) with ear congestion following BET with or without tympanostomy tube insertion were recruited from the hospitalized patients from January 2015 to December 2017. The score of Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) 15, visual analogue scale (VAS), and Valsalva scores were recorded before and after operation, and the influencing factors of prognosis were analyzed. The duration of follow-up was 1–4 years. *Results*. All patients showed significantly decreased average preoperative ETDQ-7 score, VAS, and Valsalva score after operation ($p < 0.05$). The significance of the surgery types, course of disease, severity of tympanic membrane retraction, and tympanogram tracings classification as influencing factors of prognosis did not come up to the statistical standard ($p > 0.05$). *Conclusion*. The patients showed relatively stable postoperative conditions after 3 years, and there were variations in the range of ETDQ-7 scores at 5 years postoperatively. Patients with levels I and II tympanic membrane retraction showed more favorable surgical effects. Surgical interventions are required for patients diagnosed with obstructive Eustachian tube dysfunction (ETD) after three months of conservative treatment without satisfactory results.

1. Introduction

The Eustachian tube is an organ connecting the nasopharynx and the middle ear. The prevalence of Eustachian tube dysfunction (ETD) in the adults' population is about 1% [1], which is closely related to the occurrence and development of middle ear diseases and related surgery [2–8]. Balloon Eustachian tuboplasty (BET) is a minimally invasive treatment method for ETD. BET can remove the inflammatory lesions from the temporal bone mastoid intact, repair the tympanic membrane, and reconstruct the auditory chain damaged by the inflammatory lesions, thereby restoring the sound transmission function of the middle ear. It has been first reported [4, 9, 10] in 2010 and has gained wide recognition in clinical settings over the past 10 years. Schröder et al. [11] reported that in a 5-year follow-up, 622 cases of 1076 patients with Eustachian tube balloon dilation (ETBD) had a satisfaction rate of 80%, and 82% of patients improved in terms of Eustachian tuboplasty scores after operation. Of the current 113 publications on BET for ETD, the majority involve patients with recurrent secretory otitis media or those with ETD-related symptoms. There is a dearth of research on relieving ear congestion or tympanic membrane insufficiency after tympanostomy tube insertion. To this end, this study intends to retrospectively analyze the clinical efficacy of BET with or without tympanostomy tube insertion for patients treated in our hospital.

2. Materials and Methods

2.1. Clinical Data. From January 2015 to December 2017, patients with postoperative ear congestion after BET with or without tympanostomy tube insertion who were treated in our hospital were recruited. There were 40 patients, of which

5 were lost to follow-up and 35 patients were finally enrolled including 49 affected ears, with 16 cases of left side lesion, 5 cases of right side lesion, and 14 cases of both sides lesions. The patients, including 20 males and 15 females, were aged 19–63 (38.42 ± 12.62) years, and the interval between middle ear surgery was 0–96 (36.80 ± 2.15) months. Before operation, the tympanic membrane retraction was graded [12] according to the observation results of the ear endoscopy. There were 15 (30.60%) affected ears with level I tympanic membrane retraction, 16 (32.70%) affected ears with level II tympanic membrane retraction, 10 (20.40%) affected ears with level III tympanic membrane retraction, 7 (14.30%) affected ears with level IV tympanic membrane retraction, and 1 (2.04%) affected ear with level III tympanic membrane retraction V. There were also 15 cases of tympanic cavity effusion (TCE). All patients were enrolled in accordance with relevant guidelines and provided written informed consent prior to enrollment. The research was approved by the Ethics Committee of Beijing Friendship Hospital, Capital Medical University (approval no. 9771/63).

2.2. Selection Criteria. Patients with ear congestion as the main complaint after tympanostomy tube insertion, with symptoms persisting for over three months, with poor therapeutic effects after conservative medication, who were diagnosed with ETD confirmed by routine ear and nasopharyngeal endoscopy, pure tone audiometry, and tympanometry before operation [12–14] were included.

2.3. Exclusion Criteria. Patients with patulous ETD, temporomandibular joint pathology, Meniere's disease, sudden sensorineural hearing loss, space-occupying lesions around the Eustachian tube, Eustachian tube malformation, upper semicircular canal dehiscence, type 2 sinusitis or above, cranial malformation, or radiotherapy history in temporal bone before middle ear surgery confirmed by computed tomography (CT) or magnetic resonance imaging (MRI) examination were excluded from this study.

2.4. Follow-Up and Adjuvant Treatment. After BET, the patient received a self-formulated traditional Chinese medicine (TCM) prescription. The ingredients include 10 g of Platycodonis Radix, 20 g of Atractylodis Macrocephalae Rhizoma, 10 g of Poria, 10 g of Puerariae Lobatae Radix, 10 g of Perillae Folium, 15 g of Alismatis Rhizoma, 10 g of Chuanxiong Rhizoma, 10 g of Acori Tatarinowii Rhizoma, 10 g of Angelicae Sinensis Radix, and 5 g of liquorice root, 1 dose daily for 2–4 courses of treatment. Mori Cortex and Semen Plantaginis were added for those with lung heat to relieve pulmonary dampness, tangerine peel and Pinelliae Rhizoma were added for those with phlegm dampness to remove dampness and phlegm, safflower and peach kernel were added for those with severe tinnitus to invigorate blood circulation, and Ephedrae Herba, Schizonepetae Herba, and Saposhnikoviae Radix were added for the acute stage.

The duration of follow-up was 1–4 years, and 35 patients with 49 affected ears completed the follow-up. An acoustic immittance test was performed before surgery. There were 5 (10.20%) cases of type A tympanogram, 9 (18.37%) cases of type B tympanogram, and 35 (71.43%) cases of type C tympanogram.

Pure tone audiometry was performed before surgery. The air conduction threshold was between 12.50 and 76.25 dB·HL, and the air-bone gap was between 0 and 60.00 dB·HL, with the bone conduction of 18.25 ± 12.49 dB·HL, air conduction of 43.63 ± 16.65 dB·HL, and air-bone gap of 25.38 ± 13.08 dB·HL.

The Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) 15, visual analogue scale (VAS), and Valsalva of all patients were recorded before and after surgery, as shown in Figure 1.

2.5. Statistical Analysis. Statistical analysis was performed using SPSS 23.0. ETDQ-7 and VAS scores before and after surgery were expressed as $x \pm s$. The paired t-test was used to compare score differences. Logistic regression analysis was used for multifactor analysis. Statistically significant results were defined as $p < 0.05$.

3. Results

3.1. Surgical Outcomes. The patients were followed up for 1–4 years after surgery, and ETDQ-7, VAS, and Valsalva scores were performed before and after surgery. Table 1 provides the results of postoperative ETDQ-7 and VAS scores, and the data were tested for normality. The Shapiro–Wilk method was used for data analyses as the sample size was $49 < 50$. $P = 0.245 > 0.2$ indicated that the data were considered normally distributed, so the paired t-test was used, and the difference was significant. The ETDQ-7 questionnaire score of 14.5 points was set as the cutoff value between normal and abnormal Eustachian tube function [15]. 39 cases obtained a postoperative ETDQ-7 score of ≤14.5 points, with an overall effective rate of 79.59%, as shown in Figure 2.

Figure 3 shows that the Eustachian tube function score lies in the normal range two years after operation, and the functional status of the Eustachian tube becomes unstable with time. The ETDQ-7 score was decreased at 4 years after operation. However, bias may exist because only 16 ears were followed up for 4 years. Most of the Eustachian tube function scores still remained in the normal range at 3-4 years after surgery.

3.2. Correlation Analysis of Prognostic Factors. Logistic regression analysis was performed on the influencing factors for the postoperative efficacy, and the independent variables included surgery type, course of disease, severity of tympanic membrane retraction, and tympanogram tracings results. The Hosmer–Lemeshow test (HL test) results with $p = 0.364 > 0.2$ revealed that the regression model fits the original data well. The overall classification accuracy rate was 77.6%, which was considered acceptable. However, the significance of surgery type, course of disease, severity of

	No Problem			Moderate Problem			Severe Problem
Pressure in the ears?	1	2	3	4	5	6	7
Pain in the ears?	1	2	3	4	5	6	7
A feeling that your ears are clogged?	1	2	3	4	5	6	7
Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
Cracking or popping sounds in the ears?	1	2	3	4	5	6	7
Ringing in the ears?	1	2	3	4	5	6	7
A feeling that uour hearing is mulffled?	1	2	3	4	5	6	7

Figure 1: The seven-item Eustachian tube dysfunction questionnaire.

Table 1: ETDQ-7 and VAS scores before and after surgery.

Index	Preoperation	Postoperation	t	P
ETDQ-7	26.80 ± 7.28	13.33 ± 6.13	1.345	<0.05
VAS	8.69 ± 0.66	2.51 ± 1.00	2.744	<0.05
Valsalva	8.72 ± 0.71	2.14 ± 0.99	3.048	<0.05

tympanic membrane retraction, and tympanogram tracings as influencing factors of prognosis did not come up to the statistical standard ($p > 0.05$) (Figure 4). Patients with levels I and II tympanic membrane retraction showed more favorable surgical effects. Figure 5 shows that surgical interventions are required for patients diagnosed with obstructive ETD after three months of conservative treatment without satisfactory results.

3.3. Correlation between Preoperative ETDQ-7 and Preoperative Tympanic Diagram and Tympanic Membrane. Figure 6 shows the relationship between the ETDQ-7 score and the preoperative course of disease, severity of tympanic membrane retraction, and tympanogram tracings, suggesting that the ETDQ-7 score is associated with tympanic negative pressure and the severity of tympanic membrane retraction.

3.4. Complications. No patients developed ear canal discharge, earache, and nasal adhesions after operation.

4. Discussion

The results of this study showed that the preoperative tympanogram and ETDQ-7 score analysis showed good consistency and could be used as a follow-up tool to monitor the postoperative curative effect of patients with tympanostomy tube insertion. Anand et al. [9] also mentioned that the changes in the tympanogram after BET are in good agreement with the changes in the ETDQ-7 score. Herein, the ETDQ-7, VAS, and Valsalva scores were significantly ameliorated, suggesting that BET is effective in relieving the ear congestion of patients after tympanostomy tube insertion. According to the consensus on BET, the above observation indicators are recommendable and credible [14]. Si et al. [16] revealed that cartilage tympanoplasty combined with BET yielded a promising result in alleviating the symptoms of ear congestion in patients, and the effect remains stable after 2 years of follow-up. Abdelghany also confirmed that the tympanostomy tube insertion plus BET could relieve negative tympanic pressure after the 12-month follow-up. Research by Chen et al. [17, 18] also supported the above conclusions.

The results of the present study showed that the significance of the surgery types, course of disease, severity of tympanic membrane retraction, and tympanogram tracings classification as influencing factors of prognosis did not come up to the statistical standard. The absence of significance may be attributed to the small sample size included, which, therefore, requires further investigation. Moreover, surgical interventions are required for patients diagnosed with obstructive ETD after three months of conservative treatment without satisfactory results, and patients with levels I and II tympanic membrane retraction showed more favorable surgical effects, which is in line with the surgical standard recommended by the guidelines and related literature [14, 19, 20]: (1) presence of persistent ear congestion that interferes with daily life and cannot be relieved by conservative treatment within three months; levels I and II tympanic membrane retraction; and failure of tympanoplasty, reperforation, or beginning of tympanic membrane invagination. Additionally, as for the choice of surgery type, the patients without ear congestion in this study were treated with balloon dilatation alone, and the postoperative symptoms of the patients were considerably alleviated. Jun and Qin [21] conducted a similar observational study in 2018 and found no statistical disparity in ETDQ-7 scores between the patients with no ear congestion who underwent balloon dilation surgery alone and patients with BET with or without tympanostomy tube insertion. In TCM, clearance of the ears and nose is considered beneficial, while the closure is detrimental. Therefore, the basic treatment of this disease in TCM lies in the promotion of lung fluid and the circulation of Qi and orifices. In TCM, this disease is mostly caused by the upward invasion of wind, heat, dampness, and cold in the ear, resulting in the occlusion of ear Qi and essence [6]. The core of TCM is an evidence-based treatment and features a unique advantage over Western medicine [7]. For example, in the acute stage, the main TCM treatment is to dispel

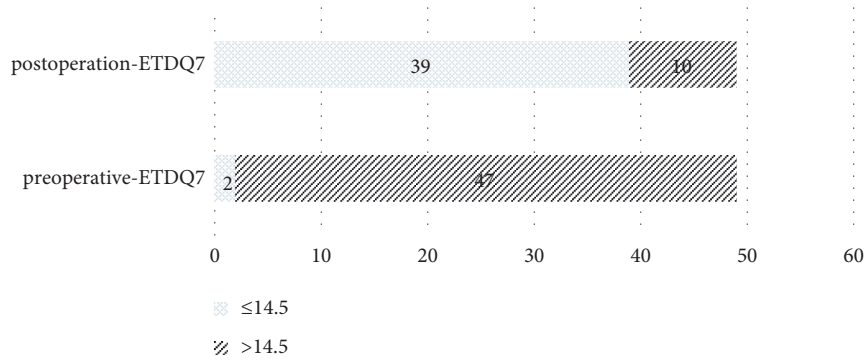

Figure 2: Comparison of the number of patients with normal Eustachian tube function scores before and after surgery.

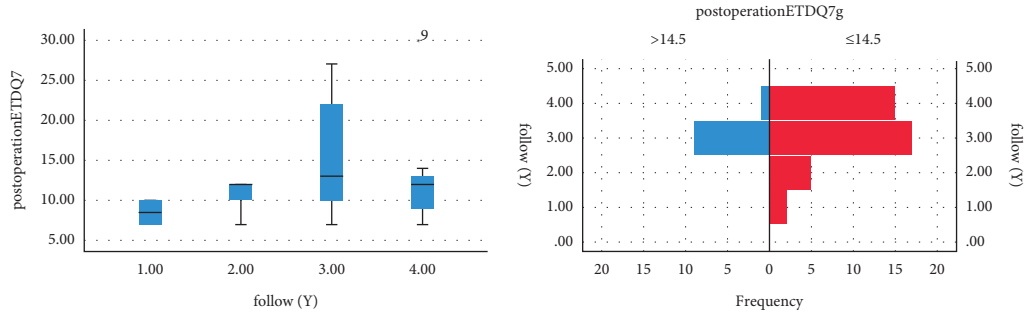

Figure 3: The relationship between postoperative ETDQ-7 score and follow-up years.

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	7.650	7	.364

Classification Table[a]

Observed			Predicted postoperationETDQ7g >14.5	Predicted postoperationETDQ7g ≤14.5	Percentage Correct
Step1	postoperationETDQ7g	>14.5	0	10	0
		≤14.5	1	38	97.4
	Overall Percentage				77.6

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I.for EXP (B) Lower	95% C.I.for EXP (B) Upper
Step 1[a]	Surgery	−.610	.799	.583	1	.445	.543	.114	2.599
	pathogenesis (M)	−.001	.018	.003	1	.957	.999	.964	1.036
	eardrum	−.385	.333	1.333	1	.248	.680	.354	1.308
	tympanogram	.483	.498	.940	1	.332	1.620	.611	4.299
	Constant	1.276	1.660	.591	1	.442	3.583		

a. Variable (s) entered on step 1: surgery, pathogenesis (M) , eardrum, tympanogram.

Figure 4: Logistic regression analysis of factors affecting prognosis.

wind, eliminate mucous membrane edema and congestion in the Eustachian tube and middle ear, and relieve negative pressure. In the case of fluid accumulation, the main focus is to promote drainage, enhance the function of the Eustachian tube, and improve the cilia movement ability. In the later stage, the main purpose is to move Qi and activate blood to arrest the development of the lesion to adhesive otitis media, regulate the function of the internal organs, support the righteous Qi, and reduce the risk of secretory otitis media [8–10].

Therefore, for the diagnosis of obstructive ETD, a comprehensive evaluation of the following aspects is suggested [14, 19]: medical history; otoscopic evaluation of the shape of the tympanic membrane and the tympanic chamber; exclusion of nasopharyngeal occupations and assessment of nasal cavity condition by nasopharyngoscopy (since obstructive ETD has been reported to be associated with sinusitis and allergic rhinitis [22, 23]); an ETDQ-7 score of >14.5 points (it has been demonstrated [24] that the cutoff point for diagnosis of ETD is 14.5 points, with the sensitivity

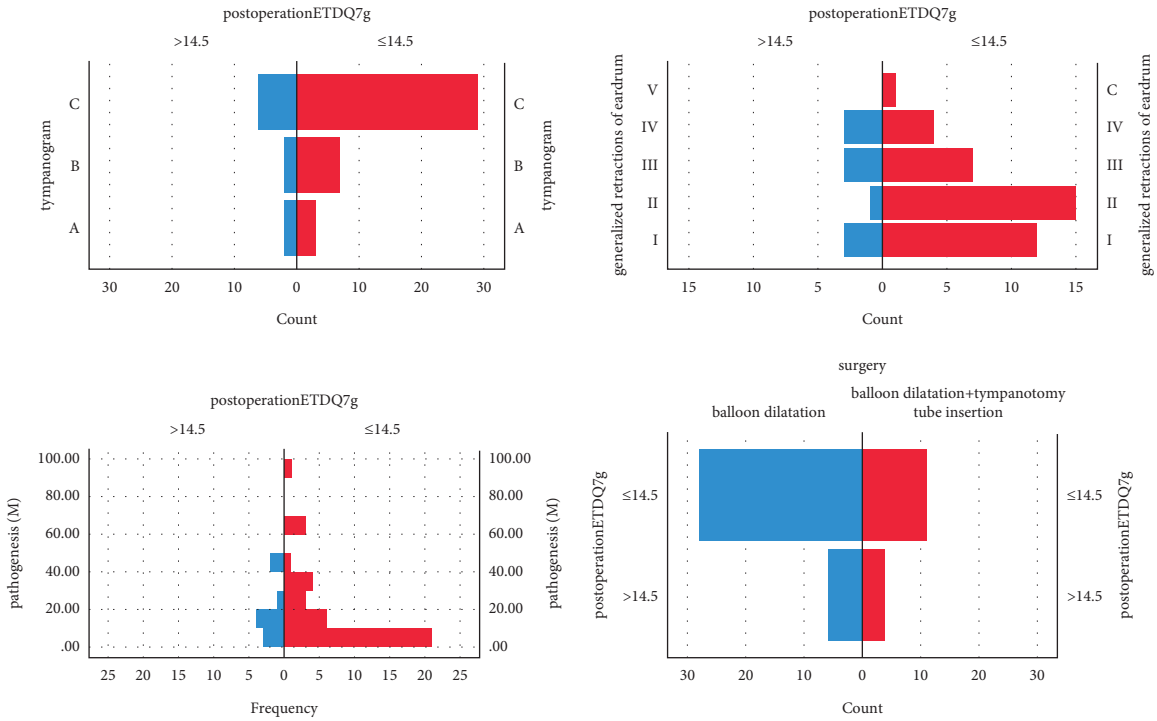

Figure 5: The correlation between postoperative ETDQ-7 scores and preoperative course of disease, degree of tympanic membrane retraction, and tympanogram.

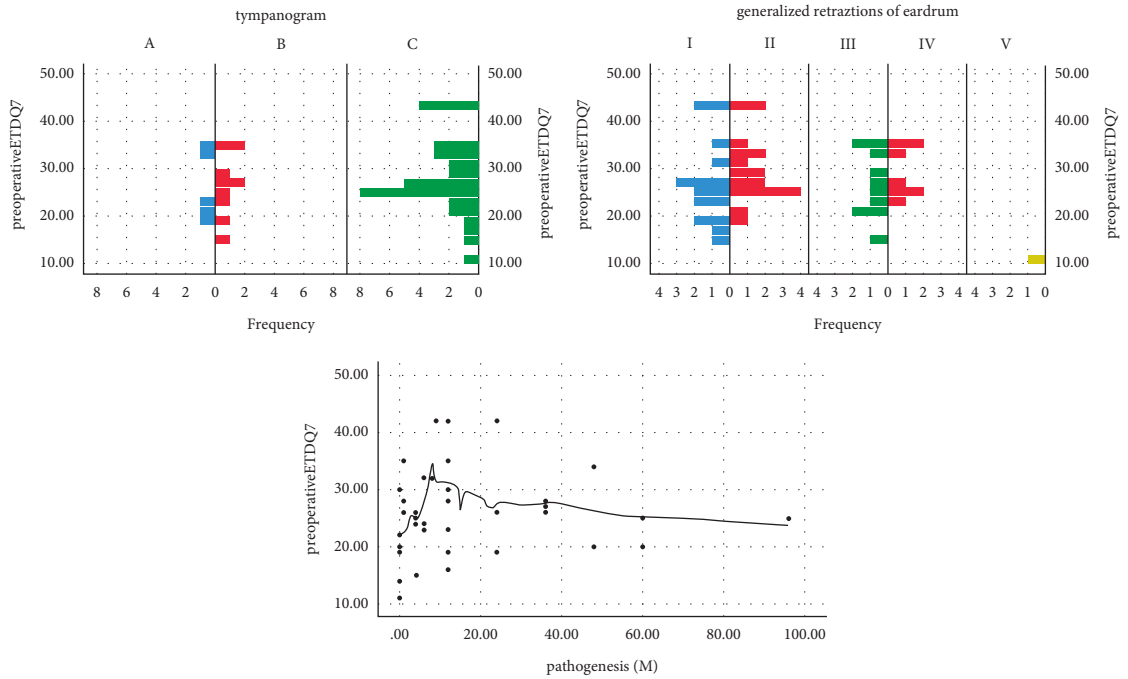

Figure 6: The correlation between the scores of the preoperative ETDQ-7 and the preoperative course of disease, degree of tympanic membrane retraction, and tympanogram.

of 100% and the specificity of 100%); and tympanometry results (Parsel et al. [25] suggested that the sensitivity of the type A curve in diagnosing ETD with mild symptoms is insufficient and ETDQ-7 score >2.1 in the presence of a type B or type C tympanogram could reach 99.0% in predicting ETD).

The ETDQ-7 score was developed by Plaza et al. [14] based on standard methodology and is the only scoring system that has undergone clinical trials and validated for preliminary validity, with good sensitivity and specificity [26, 27], so the use of the ETDQ-7 score for the assessment of patient condition in the present study was reliable.

5. Conclusion

The patients showed relatively stable postoperative conditions after 3 years, and there were variations in the range of ETDQ-7 scores at 5 years postoperatively. Patients with levels I and II tympanic membrane retraction showed more favorable surgical effects. Surgical interventions are required for patients diagnosed with obstructive ETD after three months of conservative treatment without satisfactory results. However, the follow-up examination data were relatively incomplete as most patients failed to regularly perform postoperative otoscope, pure tone audiometry, and acoustic immittance measurement due to geographical factors, which resulted in inaccurate assessment of patient conditions only by telephone follow-up. Although long-term follow-up was conducted in this study to obtain clinical data, independent risk factors were absent in the multifactorial analysis, so future multicenter studies with large samples are required to obtain more clinically reliable data.

Data Availability

The data generated or analyzed during this study are included within the article.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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