

Tympanoplasty With or Without Balloon Eustachian Tuboplasty for Chronic Suppurative Otitis Media With Obstructive Eustachian Tube Dysfunction

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Objective: To further elucidate the role of balloon Eustachian tuboplasty (BET) in tympanoplasty, we conducted a study to compare the outcomes of tympanoplasty with and without BET for the treatment of chronic suppurative otitis media (CSOM) with obstructive Eustachian tube dysfunction (OETD).

Study Design: Case control study.

Setting: Tertiary referral center.

Patients: A total of 70 ears diagnosed with CSOM (tubotympanic type) and OETD were included in this study. Thirty-five patients were prospectively enrolled for BET and tympanomastoidectomy between February 2018 and June 2019. Thirty-five control subjects were matched by sex and age and retrospectively enrolled for tympanomastoidectomy between July 2016 and January 2018.

Interventions: BET, tympanomastoidectomy.

Main Outcome Measures: The graft take rate, hearing levels, and Eustachian tube function test results.

Results: The graft take success rate was higher in the BET group (80.0%; 28/35) than in the control group (68.6%; 24/35). However, the difference was not statistically significant. The average air-bone gap (ABG) improvement was 10.93 ± 7.70 dB in the BET group and 7.11 ± 8.08 dB in the control group, with a statistically significant between-group difference ($p = 0.033$).

Conclusions: Our findings suggest that BET can objectively and subjectively improve the Eustachian tube function, with a slight but significant improvement in ABG despite the lack of a clinically significant improvement overall. However, it does not affect the graft take rate. In summary, BET could be used as an adjunctive procedure in the treatment of CSOM with OETD. **Key Words:** Balloon Eustachian tuboplasty—Chronic suppurative otitis media—Eustachian tube dysfunction—Tympanoplasty.

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Tympanoplasty is a standard surgical treatment for perforated chronic suppurative otitis media (CSOM). The overall success rate is approximately 65 to 95% (1–4). Factors such as the site and size of the perforation, graft material, ossicular chain status, and Eustachian tube function (ETF) may influence the graft take rate and hearing improvement following tympanoplasty (5,6).

Some reports have suggested that ETF is a major determinant of surgical outcome (1–4). A lower graft take rate and relatively poor hearing improvement after

tympanoplasty are likely to occur in patients with poor ETF. The success rate of tympanoplasty in patients with normal ETF is approximately 87 to 95% (2,4–6,7,9) while it is much lower, at approximately 65 to 70% (1–4,7–10), in patients with chronic suppurative otitis media (CSOM) and impaired ETF.

The Eustachian tube regulates middle ear ventilation. For patients with obstructive Eustachian tube dysfunction (OETD), both ventilatory and clearance functions are impaired, which commonly result in fluid retention and subsequent infection. OETD may also lead to negative middle ear pressure, followed by a poor healing outcome after tympanoplasty (8,11).

Balloon Eustachian tuboplasty (BET) has recently been introduced as an effective technique for treating OETD (12,13). BET improves ventilation and clearance of the middle ear by dilating the cartilaginous part of the Eustachian tube.

To further elucidate the role of BET in tympanoplasty, we conducted a study to compare the outcomes of

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tympanoplasty with and without BET for the treatment of CSOM with OETD.

achieve a pressure of 10 bars, which was maintained for 2 minutes.

MATERIALS AND METHODS

Ethical Consideration

This case–control study was conducted in tertiary referral centers after obtaining appropriate approvals from the research ethics committee (REC107-03). The authors abided by the guidelines of the Helsinki Declaration of the World Medical Association in conducting this study. Written informed consent was obtained from all prospectively enrolled patients with a protocol approved by the Research Ethics Committee of Tai-chung Tzu Chi Hospital.

Experimental Design

A total of 70 ears diagnosed with CSOM (tubotympanic type) and OETD were included in this study. Thirty-five patients were prospectively enrolled for BET and tympanomastoidectomy between February 2018 and June 2019. Thirty-five control subjects were matched by sex and age and retrospectively enrolled between July 2016 and January 2018. This control group included patients who underwent tympanomastoidectomy only, without BET. All subjects fulfilled the following inclusion criteria: 1) CSOM (tubotympanic type) with an air–bone gap (ABG) of more than 20 dB; and 2) a diagnosis of OETD for at least 3 months. Subjects were excluded if they had any of the following conditions: a congenital ear anomaly, a history of ear surgery within the past 6 months, a history of head and neck cancer, acute otitis media, refractory chronic rhinosinusitis, recent use of ototoxic medications, and pregnancy. All subjects underwent high-resolution computed tomography scans of the temporal bone. Audiological examinations, laboratory examinations, and a series of ETF tests were carried out. All surgeries were video recorded.

Currently, there is no golden standard for diagnosing OETD. In our study, OETD was diagnosed using the following criteria: 1) a poor result on the modified inflation–deflation test (14–16) (objective); 2) a score on the traditional Chinese version of the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) higher than 14 (subjective) (17); and 3) symptoms lasting more than 3 months (subjective).

Modified Inflation–Deflation Test

This test was performed by fitting a probe into the external auditory canal and administering varying pressures exceeding ± 400 daPa after the patient was asked to swallow three times with the nose and mouth closed. The pressure remaining at the end of each swallow was recorded as the residual negative pressure. In this study, a poor result in the modified inflation–deflation test (7,16,18) was defined as a residual pressure exceeding 10 daPa or no change in pressure following the swallow.

Balloon Eustachian Tuboplasty

BET is a minimally invasive technique used to treat chronic OETD. BET was performed on the operated side before tympanomastoidectomy in the BET group. A balloon catheter was introduced into the cartilaginous part of the Eustachian tube endoscopically through the nasal cavity. The balloon measured 20 mm in length and 3 mm in width. Once the insertion was confirmed, the balloon was inflated with distilled water to

Data Collection and Analysis

Subjects and Variables

All patients were followed up for at least 6 months. Demographic information on the subjects, including their age, sex, current medical status, hearing levels, tympanic membrane status, mastoid pneumatization grading determined by high resolution computed tomography, and serial ETF test results were obtained before surgery. Hearing levels, the status of the tympanic membrane, and the ETF test results were collected at 6 months after surgery.

Hearing Measurements

Non-aided pure tone audiometry thresholds (250, 500, 1000, 2000, 4000, and 8000 Hz) were collected before and 6 months after the surgery. The four-frequency air conduction (AC) and bone conduction pure tone audiometry averages (250, 500, 1000, and 2000 Hz) were derived. Low- (250 and 500 Hz), mid- (1000 and 2000 Hz), and high- (4000 and 8000 Hz) tone thresholds were also computed.

Eustachian Tube Function

ETF was evaluated using the modified inflation–deflation test, the traditional Chinese version of the ETDQ-7 (17), the Eustachian tube mucosa inflammation scale (19), the Valsalva maneuver, and tympanography. The ETDQ-7 is a validated 7-item patient subjective questionnaire used to evaluate symptom severity associated with OETD (17). Nasal endoscopy was performed to complete the Eustachian tube mucosa inflammation rating scale. A positive Valsalva maneuver indicated that the patient could detect the “pop” sound in their ears when performing the Valsalva maneuver. The tympanograms were classified into three types (A, B, and C) according to the shape.

Outcome Measurements and Statistical Analysis

Graft take rate, hearing levels, and the ETF test results were collected and analyzed. Descriptive statistics were presented as means and standard deviations, and categorical variables were presented as counts and percentages. The study had a statistical power of 80% and an effect size of 70%. The chi-squared (χ^2) test was performed to compare categorical variables between groups. The postoperative ABG gains, ETDQ-7 improvements, average pure tone levels, and the values of the variables were analyzed using the Mann–Whitney *U* test. The criterion for statistical significance was set at $p < 0.05$.

RESULTS

A total of 70 subjects were included in the study. Demographic data for the BET and the control groups are shown in Table 1. Both air and bone conduction hearing levels showed no significant differences before surgery. In addition, the remaining variables such as the pneumatization gradings, tympanic membrane status, perforation size, positive Valsalva maneuver, and scores for the traditional Chinese version of ETDQ-7 showed no significant between-group differences before surgery. Neither complications nor patulous symptoms were noted after performing BET.

TABLE 1. Demographic and baseline characteristics of patients

Variables	BET (n = 35)	Control (n = 35)	p-Value
Age (yr)	50.2 ± 13.4	48.7 ± 14.2	0.65
Sex (female:male)	19:16	19:16	1
DM, No (%)	2/35 (5.7%)	3/35 (8.6%)	0.64
Perforation size (%)	48.3 ± 15.0	51.43 ± 16.8	0.41
Perforation type (central:peripheral)	27:8	24:11	0.42
Pneumatization grade	2.97 ± 0.72	2.80 ± 0.71	0.20
Hearing levels			
Air conduction	55.68 ± 19.43	56.46 ± 19.56	0.30
Bone conduction	30.57 ± 19.03	30.11 ± 16.95	0.30
Air-bone gap	25.11 ± 4.40	26.36 ± 5.97	0.54
Eustachian function			
ETDQ-7	26.46 ± 5.98	25.97 ± 6.55	0.42
E-tube mucosa inflammation scale	2.11 ± 0.72	2.17 ± 0.71	0.72
Positive Valsalva maneuver, No (%)	15 (42.9%)	16 (45.7%)	0.81

The χ^2 test was performed for categorical variables.

The Mann–Whitney *U* test was performed for continuous variables.

BET indicates balloon Eustachian tuboplasty; DM, diabetes mellitus; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7; No, number.

Graft Take

Otoendoscopy and otoscopy were performed to determine the graft take status. Table 2 summarizes these results; the graft take success rate was higher in the BET group (80.0%; 28/35) than in the control group (68.6%; 24/35). However, the difference was not statistically significant.

Hearing Outcome

According to guidelines for evaluation of the treatment response in cases of conductive hearing loss (1995) (20), we determined the postoperative ABG and the improvement in ABG after surgery (Table 2). The preoperative AC in the BET and control groups was 55.68 ± 19.43 and 56.46 ± 19.56 dB, respectively, while the postoperative AC was 46.00 ± 21.87 and 49.54 ± 23.29 dB, respectively. The average preoperative ABG was 25.11 ± 4.40 dB in the

BET group and 26.36 ± 5.97 dB in the control group. The postoperative ABG in the BET group (14.18 ± 8.65 dB) was better than that in the control group (19.25 ± 10.11 dB; $p = 0.028$). The ABG improvement was 10.93 ± 7.70 dB in the BET group and 7.11 ± 8.08 dB in the control group, with a statistically significant between-group difference ($p = 0.033$; Fig. 1).

The proportion of patients who achieved AC hearing thresholds within the normal range (≤ 25 dB) (21) was 22.8% (8/35) in the BET group and 14.2% (5/35) in the control group. Moreover, in accordance with the Japan Clinical Otology Committee (1998) criteria for calculating hearing improvement after tympanoplasty (22), a postoperative ABG of ≤ 20 was observed in 57.1% (20/35) patients in the control group and 74.3% (26/35) patients in the BET group (Table 2); this difference was not statistically significant.

TABLE 2. Postoperative results

Variables	BET (n = 35)	Control (n = 35)	p-Value
Graft take, No (%)	28 (80%)	24 (69%)	0.274
Hearing outcome			
Air conduction	46 ± 21.87	49.54 ± 23.29	0.530
Bone conduction	31.82 ± 19.29	30.29 ± 17.59	0.855
Air-bone gap	14.18 ± 8.65	19.25 ± 10.11	0.028*
Air-bone gap improvement	10.93 ± 7.70	7.11 ± 8.08	0.033*
Air-bone gap ≤ 20 dB, No (%)	26 (74.3%)	20 (57.1%)	0.134
Eustachian tube function			
ETDQ-7	19.66 ± 7.24	21.69 ± 7.30	0.269
ETDQ-7 improvement	6.8 ± 6.6	4.2 ± 6.2	0.042*
Positive Valsalva maneuver, No (%)	28 (80%)	20 (57%)	0.039*
E-tube mucosa inflammation scale	1.57 ± 0.5	1.74 ± 0.61	0.204
Type A tympanogram, No (%)	19 (54%)	13 (37%)	0.15

The χ^2 test was performed for categorical variables.

The Mann–Whitney *U* test was performed for continuous variables.

BET indicates balloon dilation Eustachian tuboplasty; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7; No, number.

* $p < 0.05$.

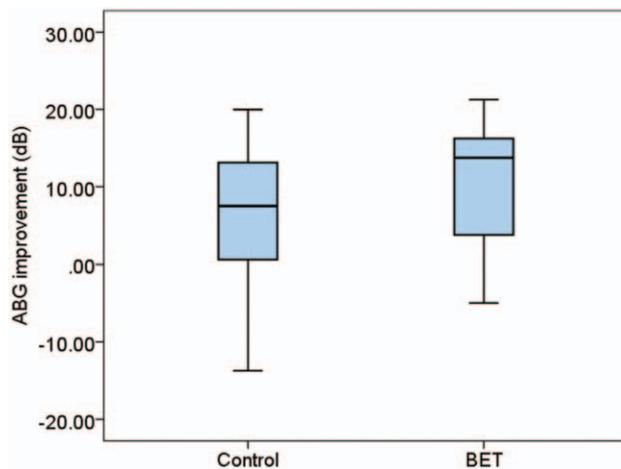


FIG. 1. Comparison of postoperative hearing improvement between the BET group and the control group. The average ABG improvement was 10.93 dB in the BET group and 7.11 dB in the control group, with a statistically significant difference between groups. ABG indicates air-bone gap; BET, balloon Eustachian tuboplasty.

ETDQ-7 Improvement

The postoperative ETDQ-7 scores showed a significant difference between the two groups, as illustrated in Figure 2. The improvement in the ETDQ-7 score was 6.8 ± 6.6 in the BET group, which was significantly higher than that in the control group (4.2 ± 6.2). A total of 87% (30/35) of the patients in the BET group and 68.6% (24/35) of the patients in the control group showed symptom improvement according to the ETDQ-7 scores. It should be mentioned that there was an outlier in the control group, which showed an improvement of 26 points. There was no significant difference in the ratio of patients who achieved a normal ETDQ-7 score of less

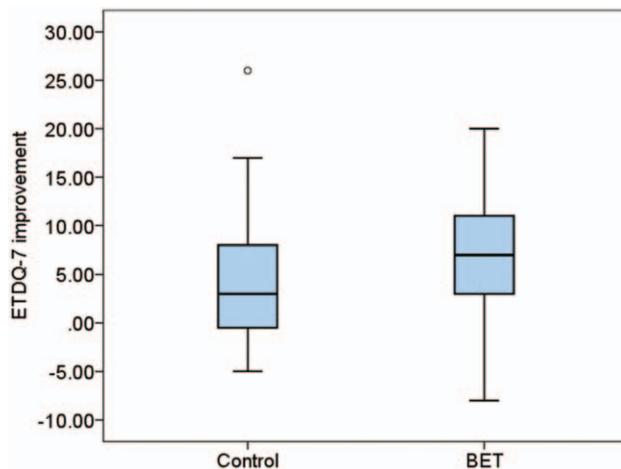


FIG. 2. Comparison of ETDQ-7 score improvement between the BET group and the control group. The mean score improvement was 6.8 in the BET group and 4.2 in the control group, with a statistically significant difference between groups. BET indicates balloon Eustachian tuboplasty; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7.

than or equal to 14 (10 out of 35 [28.6%] patients in the BET group, 6 out of 35 patients [17.1%] in the control group).

Tympanogram

In the BET group, 19 patients (54.3%) exhibited a type A tympanogram after surgery; this number was 13 (37.1%) in the control group (Table 2). There was no statistically significant between-group difference in this regard.

Positive Valsalva Maneuver

The percentage of patients who could perform a positive Valsalva maneuver was significantly higher in the BET group (80.0%) than in the control group (57.1%) at 6 months after surgery (Table 2).

DISCUSSION

Benefit of BET in Tympanoplasty

To our knowledge, this is the first study to explore the role of BET in improving the success rate of tympanoplasty in individuals with CSOM and OETD. The overall success rate of tympanoplasty in individuals with CSOM and ETD was 74.3%. As shown in Table 3, the control group exhibited a success rate (68.6%) comparable with those reported in previous studies (65.6–70%) (1–4). The graft take rate in our BET group reached 80.0%, which was higher than those reported in previous studies where BET was not performed simultaneously with tympanoplasty and mastoidectomy. Although the improvement in the graft take rate was not statistically significant, there was a trend toward greater success in the BET group than in previously reported groups where BET was not performed.

The success rate observed in the present study was slightly lower than those in studies included in recent meta-analyses (23,24). This discrepancy can be attributed to the target patients. While our study included patients with CSOM and OETD, those in the meta-analyses only focused on patients with chronic otitis media, regardless of the ETF. Nevertheless, the success rate with a combination of BET and mastoidectomy does not appear to be significantly superior to that of other published techniques for perforation closure.

Surgery as a treatment for CSOM aims to not only heal the tympanic membrane but also achieve improved hearing. For all patients with successful grafts in the BET and control groups, the ABG improvement was 14.06 and 11.45 dB, respectively, with a statistically significant difference between groups. In both groups, bone conduction did not change after the operation. The ABG improvement in the BET group was 10.93 dB, which was significantly higher than that in the control group (7.11 dB). While the effect size of 3.82 dB for ABG may be significantly different, a change of less than 5 dB does not have any clinical significance. The results of this study are not conclusive and should be interpreted with caution.

TABLE 3. Summary of the graft take rate reported in studies on Eustachian tube dysfunction

Study	Eustachian Tube Function Test	Graft Take Rate
Cohn et al. (4) (1979)	Toynbee's	69%
Sen et al. (10) (1998)	Impedance audiometry	66%
EI-Guindy (9) (1993)	Inflation–deflation and Fluorescein endoscopy	68%
Kurien et al. (7) (2009)	Inflation–deflation	69.5%
Prasad et al. (3) (2009)	Saccharin	68.4%
Srivastava et al. (1) (2014)	Toynbee's	65.6%
Priya et al. (2) (2012)	Toynbee's	76%
Dave and Ruparel (8) (2019)	Swallow equalization and impedance audiometry	70%
Present control group	Modified inflation–deflation	68.5%
Present BET group	Modified inflation–deflation	80%

BET indicates balloon dilation Eustachian tuboplasty.

In a meta-analysis conducted by Tan et al. (25) in 2016, a postoperative ABG of less than or equal to 20 was observed in 68.6% (2,428/3,540) patients who underwent tympanoplasty, regardless of ETF. This proportion was lower than that (74.3%) in the BET group in the present study (Table 2). Choi et al. (16) showed in 2009 that the postoperative ABG after type I tympanoplasty was approximately 18.6 ± 4.5 dB in patients with severe Eustachian tube dysfunction, similar to the results of the control group (19.25 ± 10.11 dB). In our study, the postoperative ABG in the BET group was 14.18 ± 8.65 dB, which was better than that in the control group. Performing BET during tympanoplasty may offer better hearing results by closing the ABG. These results suggest the potential role of BET in treating patients with CSOM and OETD.

Eustachian Tube Function

Bluestone et al. in 1981 suggested that the modified inflation–deflation test was a reasonable method of evaluating the ETF status in a perforated eardrum (14,16,26). In our study, we also used the modified inflation–deflation test to select CSOM patients with OETD. As shown in Table 2, the improvement in the ETDQ-7 score was 6.8 ± 6.6 in the BET group, which was significantly higher than that in the control group (4.2 ± 6.2). In addition, the proportion of individuals with a positive postoperative Valsalva maneuver result was 80.0% in the BET group, which was also significantly higher than that in the control group (57.1%). BET may improve ETF, according to the results of the objective Valsalva maneuver and the subjective EDTQ-7 questionnaire. However, only 28.6% patients achieved normal values ($ETDQ-7 \leq 14$) after surgery. BET appears to relieve certain symptoms but does not yield full subjective satisfaction. In the control group, we still found some postoperative improvement in the ETDQ-7 score (from 25.97 ± 6.55 to 21.69 ± 7.30). This result may be because of the resolution of muffled hearing, which was an item in the ETDQ-7. The proportion of patients with a type A tympanogram after surgery was 54.3% (19/35) in the BET group and 37.1% (13/35) in the control group. This difference was not statistically significant, which may be

attributed to the fact that patients with unhealed drums were not excluded.

If the Eustachian tube is obstructed, both ventilatory and clearance functions may be impaired. For the patients with healed tympanic membrane in the control group, Eustachian tube mucosa inflammation scale (from 2.29 ± 0.62 – 1.88 ± 0.61), improvement of ETDQ-7 score (6.08), and air–bone gap (26.25 ± 6.38 – 14.79 ± 8.56) were all improved following tympanomastoidectomy. These results imply that tympanomastoidectomy may have some benefits in terms of ETF. A comparison of the healed tympanic membrane between BET and control groups revealed that adjunctive therapy with BET may further improve ETF and lead to a better hearing outcome following tympanoplasty.

The role of mastoidectomy in CSOM treatment is controversial. Mastoidectomy is conventionally thought to benefit patients with CSOM, with some studies showing that mastoidectomy may benefit the surgical outcome and eradicate the mastoid source of infection in individuals with CSOM (27,28). However, recent literature, including a randomized study and systematic reviews, propose no additional benefits of mastoidectomy performed with tympanoplasty for CSOM (29–31). In the present study, we performed mastoidectomy for consistency with the procedures used in the control group, which was retrospectively enrolled. On comparison of our success rate with those in existing studies, we found that mastoidectomy probably does not provide additional benefits in tympanoplasty. Therefore, the necessity of mastoidectomy remains to be evaluated.

Size of Perforation and Valsalva Maneuver as Predictor of Successful Outcome

A larger perforation size and failure to perform the Valsalva maneuver before surgery have significant effects on the graft take rate (Table 4). Many studies have been carried out in the past regarding factors related to graft take. Some studies found a significantly higher failure rate in individuals with CSOM and larger perforations (25,32). The major reasons for graft failure in larger perforations may be an increased technical

TABLE 4. Risk factors for graft uptake

Variables	Graft Uptake (n = 52)	No Uptake (n = 18)	p-Value
Perforation type (central:peripheral)	36:16	15:3	0.246
Air-bone gap (dB)	25.63 ± 5.39	26.04 ± 4.95	0.386
Size (%)	47.5%	59.67%	0.037*
ETDQ-7 (7–49)	26.27 ± 6.84	26.06 ± 4.12	0.903
Valsalva maneuver, No (%)	27 (52%)	4 (22%)	0.029*
Mastoid pneumatization (1–4)	2.94 ± 0.73	2.72 ± 0.46	0.168

The chi-squared test was performed for categorical variables.

The Mann–Whitney *U* test was performed for continuous variables.

ETDQ-7 indicates Eustachian Tube Dysfunction Questionnaire-7; No, number.

**p* < 0.05.

difficulty, a reduced graft overlap with the residual tympanic membrane, and poor graft fixation. Additionally, we found that patients who were able to perform the Valsalva maneuver before surgery showed a better graft take rate after tympanoplasty. In our study, the site of perforation, diabetes mellitus (DM), and mastoid pneumatization did not significantly affect the graft take rate. This result implies that the size of perforation and Valsalva maneuver may be a predictor of graft success.

LIMITATIONS

We presume that BET may benefit tympanoplasty performed in individuals with CSOM and OETD, but the number of patients enrolled was too small to draw a definite conclusion regarding the significance of the graft take rate. Thus, the findings of this study are preliminary. Moreover, the groups in this comparative study were only matched by age and sex. The participants were recruited at different time points, and data were collected prospectively and retrospectively for the BET and control groups, respectively. This may have resulted in bias. Further studies should investigate this topic over a longer duration in a prospective, randomized controlled study with a larger set of participants.

CONCLUSIONS

Our findings suggest that BET can objectively and subjectively improve the Eustachian tube function, with a slight but significant improvement in ABG despite the lack of a clinically significant improvement overall. However, it does not affect the graft take rate. In summary, BET could be used as an adjunctive procedure in the treatment of CSOM with OETD.

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