European Archives of Oto-Rhino-Laryngology (2019) 276:2715–2720
https://doi.org/10.1007/s00405-019-05512-7

OTOLOGY

Effect of balloon dilation eustachian tuboplasty combined with tympanic tube insertion in the treatment of chronic recurrent secretory otitis media

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Received: 15 March 2019 / Accepted: 8 June 2019 / Published online: 13 June 2019

Abstract

Purpose To investigate the long-term clinical effect of balloon dilation eustachian tuboplasty (BET) combined with tympanic tube insertion (TTI) in the treatment of chronic recurrent secretory otitis media (CRSOM).

Materials and methods A retrospective study of 30 cases of CRSOM treated with BET combined with TTI under general anesthesia between August 2014 and September 2016. Thirty cases of CRSOM treated with TTI in the same period were taken as the control group. All cases were followed over 24 months. The scores of eustachian tube (ET) function preoperation, 1 month, 6 months, 12 months, and 24 months postoperation were collected and analyzed, respectively. A satisfaction questionnaire was used to evaluate the therapy at 24-months postoperation.

Results The symptoms were significantly improved and the ET score was obviously increased postsurgery in most cases treated with BET plus TTI compared with those treated with TTI alone. The highest ET score was obtained at 6 months post BET. Five (14%) cases (6 ears) of CRSOM recurred. The 24-month postoperation follow-up questionnaire showed that 84.6% of the patients were satisfied with the treatment, while ten cases (25%) in the TTI group recurred.

Conclusion BET combined with TTI surgery is an effective therapy for patients with CRSOM.

Keywords Balloon dilation eustachian tuboplasty · Chronic recurrent secretory otitis media · Eustachian tube function score · Tympanic tube insertion · Treatment

Abbreviations

ET	Eustachian tube
ET score	Eustachian tube function score
BET + TTI	Balloon dilation eustachian tuboplasty combined with tympanic tube insertion
TTI	Tympanic tube insertion
CRSOM	Chronic recurrent secretory otitis media
BET	Balloon dilation eustachian tuboplasty

Introduction

Chronic recurrent secretory otitis media (CRSOM) is a refractory otological disease with a long history, and is characterized by repeated attacks of symptoms, and characterized by prolonged illness [1]. Patients often have a history of several courses of surgical tympanostomy tube insertion (TTI). However, symptoms often recur, seriously affecting patients' quality of life. Otologists usually prefer to repeat TTI, but the recurrent rate is still high [2, 3], and the incidence of middle ear ventilation tube prolapse and middle ear infection also increases [4, 5].

CRSOM is often difficult to cure, usually due to patients' poor eustachian tube (ET) function [5–9]. TTI is used mainly to treat middle ear effusion, not ET dysfunction directly. Theoretically, by improving and restoring ET function, secretory otitis media can be successfully treated.

Balloon dilation eustachian tuboplasty (BET) was first applied clinically in 2009 by Schroder et al.to treat ET dysfunction [9]. After observation, the otitis media patients underwent BET surgery. After 1 year, the authors [5]

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reported that the overall effective rate was about 66%. However, more than 30% of the patients did not show any significant improvement in symptoms.

The reason BET surgery did not achieve significant symptom improvement of chronic secretory otitis media is still unclear. Christov and Gluth [10] studied the histopathology of the eustachian tube orifice mucosa in 23 cases of chronic otitis media with effusion and found that the mucosa of the middle ear was often severely thickened. They thought that this might be one of the reasons for the failure of BET in some patients.

To clarify the role of BET in the treatment of CRSOM, we observed a group of patients who simultaneously underwent BET combined with TTI and compared the effect with a group of patients who had undergone the TTI operation alone.

Methods

Ethics statement

Approval was obtained from the local ethics committee of the Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China. Written informed consent was obtained from all patients before the study.

Study design

A retrospective study was done of 30 CRSOM patients treated with BET combined with the TTI operation (BET + TTI group) under general anesthesia between August 1, 2014, and September 30, 2016. Thirty patients treated with TTI only during the same period acted as the control group (TTI group).

For CRSOM patients, inclusion criteria were as follows: (1) age between 18 and 65 years; (2) symptoms, signs, and audiological findings confirming secretary otitis media; (3) medical history of more than 1 year; (4) recurring symptoms after more than 3 months of drug treatment; and (5) history of more than one TTI.

Patients in the BET + TTI group underwent simultaneous BET and TTI surgery under general anesthesia, while the control group patients underwent TTI only under local anesthesia.

All other medication was the same in the two groups.

BET surgery course

The BET operation was carried out as previously described by Schroder et al. [9]. A specially designed balloon dilation system (Spiggle & Theiss, Overath, Germany) was used to dilate the ET. The operations were performed with nasal endoscopic assistance (0° and 70° view angle) via the ipsilateral or contralateral nostril. A guiding catheter with a tip angle of 45° or 70° was inserted into the ET nasopharyngeal orifice through the nasal cavity. A 3-mm (diameter) and a 20-mm (length) balloon catheter were pushed through the guiding catheter and smoothly led into the ET orifice until reaching the first mild resistance (called the narrowest diameter at the bony–cartilaginous isthmus) and inflated to a pressure of ten bars for 2 min using a water pressure applicator (Spiggle & Theiss).

ET function evaluation

The ET function score (ET score) of each affected ear was evaluated according to the presence of symptoms, signs, and acoustic impedance examination (tympanometry) [5, 9, 11, 12], with a maximum score of two points for each item and total score of ten points. Detailed scoring criteria are shown in Table 1.

Follow-up

All cases were followed over 24 months. The ET scores preoperation and 1 month, 6 months, 12 months, and 24 months postoperation were summarized, respectively, and analyzed.

At 24 months postoperation, a satisfaction questionnaire was used to evaluate the treatment. Recurrence rate and ET function were evaluated at 1, 3, and 6 months and 1 and 2 years postoperation. Recurrence was defined by either a type B tympanogram or the otologic endoscopic findings.

Table 1 Evaluation items of ET function score

Items	0 point	1 point	2 point
Fullness	Always	Infrequent	None
Hearing loss	Severe	Medium	Mild or none
Clicking noise by swallowing	No clicking	Infrequent, slim	Always, obvious
Clicking noise by Vaslva	No clicking	Infrequent, slim	Always, obvious
Pressure change in tympanometry (calm, vaslva, and swallowing)	No change	Change between 5 and 10 dapa	Change over 10 dapa

Statistical analyses

Data were analyzed with GraphPad Prism 5 software. Continuous variables were described as mean ± standard deviation, differences between the two groups were tested by independent sample *t* test, while categorical variables were described as frequency and group differences were evaluated by Chi-square test or Fisher's exact test. All hypotheses were two-sided, and *p* value less than 0.05 were considered as statistical significant.

Results

General characteristics of CRSOM patients

The general characteristics of patients in the BET + TTI group and TTI group are shown in Table 2. There were no significant differences in age, gender, ear sides, or medical duration between the two groups.

Therapy

30 patients (42 ears) underwent BET and TTI surgery successfully under general anesthesia. 18 cases were unilateral and 12 cases, bilateral. All patients underwent the operation with nasal endoscopy. Among them, 36 received 0° nasal endoscopy. The other six ear sides that had narrow nasal cavities due to severe nasal septum deviation underwent the surgery with 70° nasal endoscopy entered through the opposite nasal cavity. The dilation tube was then introduced into the ET from the affected nasal cavity. 38 ear balloon catheters were introduced smoothly on the first trial without any resistance, while four ears associated with narrow nasal cavities were tried twice before the catheter was successfully introduced. The assistant then began to push the pump to raise the pressure to ten bars and hold it at this point for 2 min, at which time the water valve was opened and the catheter was withdrawn from the ET by the surgeon. The balloon was checked for any bending or folding. In 25 ears, some clear liquid was instantly seen flowing out of the nasopharyngeal opening of the ET and some small bubbles were seen flowing out of 15 ears. After withdrawal, the balloon catheter was again injected with water and pressurized to make sure the balloon was in good condition.

30 patients (41 ears) in the control group underwent TTI surgery under local anesthesia using ear endoscopy. All patients in both groups underwent a safe surgical procedure, having no complications such as bleeding or infection.

Table 2 General characteristics of the CRSOM cases in the two groups

	BET + TTI group ($n=30$)	TTI group ($n=30$)	p
Age (year, mean ± SD)	43.8 ± 13.5	44.7 ± 14	0.48
Gender (M/F, no. of patients)	16/14	17/13	0.77
Ear sides (biolateral/unilateral)	12/18	11/19	1.0
Medical duration (m)	2.77 ± 1.3	2.72 ± 1.32	0.88
Allergic rhinitis	5	4	0.72
ET scores pre	2.17 ± 0.38	2.2 ± 0.4	0.80

Outcome of the ET score

The symptoms were significantly improved, and the ET scores had obviously increased postsurgery in most patients in the BET + TTI group compared with the TTI group.

A comparison of ET scores between the two groups at different time points postsurgery is shown in Fig. 1, and the mean values and SD in each group are shown in Table 3.

The average score of ET function in both groups before operating was about two points, which is very low. However, the scores were increased to more than five points in both groups 1 month postoperation. At 6 months postoperation, the ET score in the BET + TTI group increased significantly to about 8, while the ET value in the TTI group increased only slightly. In addition, there was a significant difference in ET value between the two groups. At 12 months postoperation, the ET value in the BET + TTI group was slightly decreased, but it was still higher than that in the TTI group. The ET value at 24 months postoperation was stable in both only slightly lower than at 12 months postoperation and the difference between the two groups was also significant ($p < 0.001$).

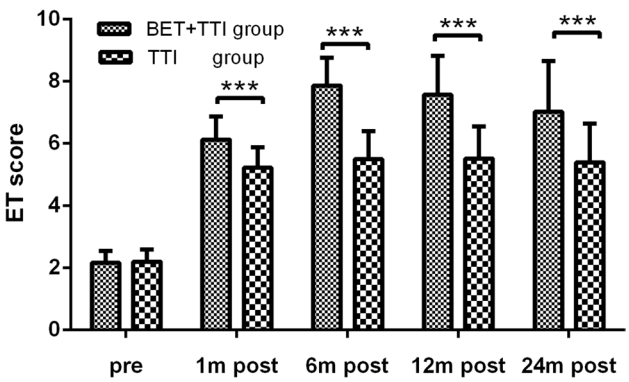

Fig. 1 ET scores at different times postsurgery in the two groups. Note that the ET score in both groups rose significantly at 1 month, 6 months, 12 months, and 24 months postoperation. The ET score in the BET + TTI group was higher than that of the TTI group from 1 month postoperation to 24 months postoperation. ***$p < 0.001$ in *t* test

Table 3 ET scores pre- and postoperation in the two groups (mean ± SD)

	Pre	1 m post	6 m post	12 m post	24 m post
BET + TTI group	2.17 ± 0.38	6.12 ± 0.74	7.86 ± 0.90	7.57 ± 1.25	7.02 ± 1.63
TTI group	2.20 + 0.40	5.22 ± 2.20	5.49 ± 0.90	5.51 + 1.03	5.39 ± 1.24

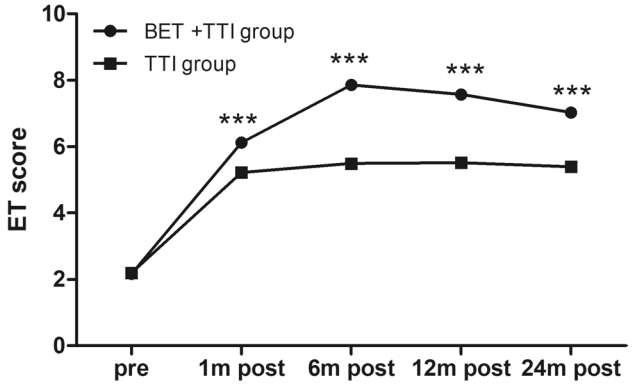

Fig. 2 ET scores mean values at different times postsurgery in the BET + TTI and TTI groups. Note that the ET score improved in both groups postoperation, but the BET + TTI score rose significantly higher than that of the TTI group at 1 month, 6 months, 12 months, and 24 months postoperation. The best ET score in the BET + TTI group was reached 6 months postoperation. ***$p < 0.001$ in t test

Figure 2 shows the changing ET score curve in the two groups at different time points. The ET score of the BET + TTI group reached the highest level at 6 months postsurgery and decreased slightly at 12 months postsurgery, then stabilized at 24 months postsurgery. The difference between the two groups was significant at 1 month, 6 months, 12 months, and 24 months postoperation ($p < 0.001$).

Results of Patients' Satisfaction Questionnaire

All patients were sent a satisfaction questionnaire 24 months postoperation, and more than 85% in each group replied. Six patients in the BET + TTI group reported no improvement as did ten in the TTI group.

The percentage of satisfactory outcomes in the BET + TTI group vs the TTI group were 81% and 70%, respectively.

Discussion

Treating CRSOM in the clinic is challenging. In the past, repeated surgical grommet insertion was the most common method, but the postsurgical outcome of TTI alone was not always satisfactory [2–4].

The purpose of TTI is mainly to drain the effusion from the middle ear and relieve the negative pressure in the tympanic cavity. Since TTI surgery cannot deal directly with ET dysfunction, which may be the main etiological factor in CRSOM, the long outcome is not good in many patients.

From an etiological point of view, a good curative effect was achieved in CRSOM patients by improving and restoring ET function. BET is a new surgical procedure that has shown good results in patients with ET dysfunction. Ockermann et al. [9] in early 2010 studied eight patients (13 ears) having ET dysfunction treated with BET, including six ears with symptomatic ET dysfunction, two with recurrent secretory otitis media, and five with chronic secretory otitis media. 1 week after the operation, the average ET function began to increase. At 2 and 8 weeks postsurgery, the average ET function score was increased significantly, and the symptoms of all affected ears improved satisfactorily. Schröder et al. [5] reported the follow-up results of 72 patients with BET in 2013. The mean score of ET function increased from 2.21 to 5.4, and 12 cases were followed up for 1 year. The mean score of ET function was increased from 1.25 to 6.2. Most patients' symptoms improved. With the increasing number of clinical cases, Schröder et al. [13] retrospectively analyzed the clinical data of 622 patients (1076 ears) who underwent BET from 2009 to 2014. The youngest patient was 7 years old and the oldest was 84. Among them, 50 children were followed up for 3 years. The authors analyzed the follow-up data, including the ET function score at different stages; 188 ears were followed up for 1 year (188/671). The ET function score was increased significantly from 3.13 to 5.75. 34 ears were followed up for 2 years. ET function had increased significantly from 2.65 to 6.26. Only 11 ears were followed up for 3 years, and ET function rose from 2.36 to 5.27. 2 years postsurgery, 80% of patients were satisfied with the treatment.

Singh et al. [14] reported that BET resulted in significant improvement in 11 patients' subjective outcomes such as the seven-item Eustachian Tube Dysfunction Questionnaire symptom scores, but not in objective outcome measures such as tympanometry and pure-tone audiometry. The long-term effect of BET seems satisfactory as 77% of the treated ears were less symptomatic after follow-up than preoperatively.

Si et al. [15] reported that a combination of BET and tympanic paracentesis with methylprednisolone irrigation can significantly decrease the recurrence rate to 20%, and they preferred this technique for treating adult chronic otitis media with effusion, which had a lower recurrence rate and prompt recovery of ET function.

Luukkainen et al. [16] studied the long-term (3 years or more) effect of BET and reported a satisfactory rate

of 77% in the treated ears, which were less symptomatic than preoperatively. The BET best alleviated pain and the feeling of pressure in the ears. Each of these symptoms improved in over 75% of all the affected ears. But the Valsalva maneuver became easier in only 50% of the treated ears.

The mechanism of BET in the treatment of ET dysfunction remains unclear. Most scholars believe that balloon dilatation of the ET is located in the cartilage segment of the ET. The balloon under specific pressure can cause minimal fracture of the cartilage segment. The submucosal epithelial cells of the ET recover quickly after compression, and the inflammatory cells in the balloon are replaced by thin fibrous scars. As a result, the ET cavity is enlarged and ET function is improved.

BET is currently the most effective treatment for cartilage segment stenosis or obstruction of the ET. According to preliminary statistics in the literature, the number of BET operations in Europe has reached 12,000 ears, while there have been over 2000 in China. The short- and long-term effects of some large cases reported in the literature are about 90%–100% and 80%–98% [5, 6, 13, 16–20], respectively.

In our study, the patients treated with BET + TTI had a more satisfying outcome, both in symptom relief and ET score improvement, compared with those treated with TTI alone. The results showed that at 1 month post-BET + TTI operation, symptoms began to improve, the ET function score increased, symptoms had improved significantly at 6 months, ET function score further increased, symptoms of most patients improved satisfactorily 12 months after BET + TTI, and the ET function score was higher than before. The patients' satisfaction rate was 84.6%, which was close to that of most reported articles.

In conclusion, BET + TTI can improve ET function and relieve symptoms in most CRSOM patients. The best therapeutic effect was achieved at 6 months postoperation. But our study had a limited number of patients in each group and the outcomes at > 3 years postoperation need further clinical observation.

Funding This research was supported by a grant from the Guangdong Natural Science Foundation (No. 2015A030313180).

Compliance with ethical standards

Conflict of interest All the authors declare that they have no competing conflict of interest.

Ethical approval All procedures performed in research involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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