# Intact Canal Wall Mastoidectomy Combined with Balloon Dilation Eustachian Tuboplasty in the Treatment of Middle Ear Cholesterol Granuloma

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To the Editor: Cholesterol granuloma (CG) refers to granulation tissue containing cholesterol crystals and giant cells and is a foreign body response elicited by local tissues. The pathogenesis of middle ear CG can be explained using the classic obstruction-vacuum theory caused by negative middle ear pressure. [1] The Eustachian tube (ET) plays a decisive role in influencing the gas exchange and maintaining the ventilation and pressure of the middle ear. The traditional treatment is mastoidectomy, routinely combined with middle ear ventilation tube insertion or tube insertion during re-examination after operation. [2] Eustachian tuboplasty by balloon dilation can improve the pathological state of ET via specific mechanisms to achieve functional recovery and satisfactory clinical efficacy. [3,4]

In this study, clinical investigations focused on the surgical effect of an intact canal wall mastoidectomy and mastoidectomy combined with tympanostomy tube (TT) or balloon dilation eustachian tuboplasty (BDET). Comparative analysis was performed between the groups of patients to investigate the application value of combined ET in the treatment of middle ear CG.

A total of 49 patients with middle ear CG received surgical treatment between March 2008 and November 2015 in the Department of Otolaryngology, Sun Yat-Sen Memorial Hospital. The study protocol was approved by the institutional review board of the Sun Yat-Sen University. The patients were divided into three groups according to different treatment methods [Table 1]. All patients were followed up for 2 years. In Group B, routine removal of the ventilation tube was performed after 6 months. Evaluation criteria for clinical efficacy are as follows: (1) cured: no feelings of ear fullness, no otorrhea or effusion, and tympanogram converted to Type A or Type As (2) effective: residual feeling of ear fullness, tympanogram converted to Type A or Type C, and tympanocentesis showed no effusion or presence of residual perforation without otorrhea; (3) ineffective: no improvement in feeling of ear fullness or hearing loss, still presenting with a blue eardrum, coffee-colored liquid obtained on tympanocentesis or residual perforation accompanied by otorrhea, and tympanogram was still Type B; (4) recurrence: the symptoms reappeared after the patient was cured or showed improvement for 1 year. The

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cured rate and effective rate were combined to give the total effective rate of the clinical treatment.

The SPSS 20.0 (SPSS, Inc., Chicago, IL, USA) software package was used for data analysis. Comparison of measurement data was performed using analysis of variance and comparison of count data was performed using the Chi-square test. The level of significance was  $\alpha = 0.05$ .

The differences in pretreatment pure tone average (PTA) and airbone gap (ABG) among the three groups were not statistically significant (P>0.05). The posttreatment PTA and ABG for the three groups were significantly lower than the pretreatment values (P<0.05). The total effective rate of Group A, Group B, and Group C was, 37.5% (3 cases), 73.68% (14 cases), and 90.91% (20 cases) respectively [Table 1]. The number of patients who have failed treatment in Group C was significantly less than the other two groups. Patients for whom treatment was not effective or led to recurrence were given middle ear tympanoplasty and TT placement, followed by dexamethasone rinsing of the tympanic cavity via the TT. If the symptom recurred, canal wall down mastoidectomy was performed.

The onset of middle ear CG can be explained by the obstruction of the middle ear ventilation system. At CG onset, various factors can lead to chronic ET dysfunction. When otitis media with effusion, mucosal swelling, and hypertrophy develops into irreversible granulation tissue, it will obstruct the drainage pathway. The air in the mastoid process will be absorbed, thus leading to negative pressure and even potentially to a vacuum. This will cause ischemia and swelling of the air cell mucosa, vascular rupture, and degradation of iron-containing hemoglobin and other substances that can stimulate the foreign body response, which will eventually

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Table 1: Clinical efficacy of surgical treatment in three groups

Items	Group A ( <i>n</i> = 8)	Group B ( <i>n</i> = 19)	Group C ( <i>n</i> = 22)
Age (years)	$42.00 \pm 10.13$	$44.26 \pm 12.63$	$43.83 \pm 9.17$
Sex (male/female)	5/4	12/7	14/8
Disease duration (years)	$3.69 \pm 2.89$	$4.22 \pm 2.98$	$4.01 \pm 2.63$
Clinical efficacy			
Cured	1 (12.50)	10 (52.63)*	14 (63.64)†
Effective	2 (25.00)	4 (21.05)	6 (27.27)
Ineffective	1 (12.50)	2 (10.53)	1 (4.54)†,‡
Recurrence	4 (50.00)	3 (15.79)*	1 (4.54)†,‡
Tympanogram (postoperative)			
Type A	3	10	16
Type As	2	0	2
Type B	2	2	2
Type C	1	1	2
Perforations	0	6	0

All data were shown as mean  $\pm$  standard deviation or n, or n (%). \*Group A versus Group B: P<0.05, ANOVA; \*Group A versus Group C: P<0.05, ANOVA; \*Group B versus Group C: P<0.05, ANOVA. Group A: Patients underwent intact canal wall mastoidectomy; Group B: Patients underwent intact canal wall mastoidectomy combined with middle ear TT placement; Group C: Patients underwent intact canal wall mastoidectomy combined with BDET. BDET: Balloon dilation eustachian tuboplasty; ANOVA: Analysis of variance.

lead to CG. As cholesterol crystals cannot be absorbed by giant cells, they are intractable and irreversible and will repeatedly stimulate the progression of a vicious cycle.<sup>[2]</sup>

The refractory nature of middle ear CG lies with its tendency to recur. Local and conservative methods, such as simple tympanostomy or middle ear TT placement, cannot provide targeted treatment of the underlying cause.

The traditional surgical treatment for middle ear CG is mastoidectomy. Another aspect encouraged in the surgical treatment of middle ear CG is middle ear TT placement. Middle ear TT placement was performed in Group B of this study, which produced good clinical efficacy. However, it is widely known that the damage to the tympanic membrane caused by TT placement can lead to residual perforations, persistent otorrhea, tube rejection or tympanosclerosis, as well as various adverse reactions, including postoperative persistent otorrhea, infection rejection, and replacement of TT, among others.<sup>[2]</sup> Furthermore, TT placement only temporarily replaces the ventilation function of the ET and does not treat the lesions in the ET itself.

Since Ockermann *et al.* reported the use of BDET in the treatment of chronic ET dysfunction, a number of applications and studies have been reported. This technique is simple, noninvasive, and not time consuming. Its short- and long-term efficacy rates reach up to 70–100%, and 45% of retracted tympanic membrane was restored to normal.<sup>[3,4]</sup> We have treated 22 cases of patients using mastoidectomy combined with BDET (Group C). The difference of total effective rates between Group B and Group C was not statistically significant. Moreover, the cure rates did not show statistically significant differences between the two groups. However, the rate of patients whose postoperative tympanogram conversed to Types A, As, and C showed statistically significant

differences between Group B and Group C (57.89% and 90.91%, respectively). This difference was caused by the high postoperative perforation rate of Group B. This indicates that BDET is equally suitable for resolving ETD during the surgical treatment of middle ear CG and will not lead to the sequelae of TT placement, including tympanic membrane perforations. Furthermore, it will not lead to events that will affect quality of life, such as being unable to swim after TT placement.

Histopathology revealed that BDET could reduce the inflammatory epithelial changes of the ET mucosa and submucosal inflammatory infiltrate. Catalano *et al.*<sup>[5]</sup> proposed that the mechanism of action for balloon dilation is based on the multiple microfractures in cartilaginous ET caused by BDET, which changes or relaxes the connected tissue structures. This will reduce the minimum opening pressure of the ET, permitting easier ET opening. Middle ear CG is also a unique type of ETD and its pathological mechanism is amenable to BDET. We combined BDET and TT placement with the same mastoidectomy procedure in order to compare the two treatments, and similar clinical efficacy was obtained overall. Similar studies have not been reported in the literature and its clinical efficacy over a long term warrants further investigation.

In the treatment of middle ear CG, an intact canal wall mastoidectomy combined with BDET achieved similar clinical efficacy compared with mastoidectomy combined with TT placement and avoided the sequelae of TT placement, such as tympanic membrane perforations.

# **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. The patients' guardians have given their consent for reporting their images and other clinical information in the journal. The patients' guardians understand that their names and initials will not be published and due efforts will be made to conceal their identity.

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### **Conflicts of interest**

There are no conflicts of interest.

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