



Cartilage tympanoplasty in the treatment of adhesive otitis media with and without Eustachian tube balloon dilatation

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ABSTRACT

Purpose: To compare cartilage tympanoplasty (CT) combined with eustachian tube balloon dilatation (ETBD) and cartilage tympanoplasty alone as a surgical treatment modality for adhesive otitis media (AdOM) in terms of graft healing, audiological outcomes, and impact on life style, using Chronic Otitis Media Outcome Test 15 (COMOT-15).

Methods: 50 patients with AdOM were randomly classified into 2 groups: 25 patients for cartilage tympanoplasty only (CT group) and 25 patients for cartilage tympanoplasty combined with eustachian tube balloon dilatation (CT + ETBD group). Clinical outcomes in both groups were compared at 3 and 6 months of follow up.

Results: There was no significant difference in graft healing between the two groups. Postoperative COMOT-15 scores significantly decreased in both groups with a significant difference between the groups with regard to the decrease in COMOT-15 scores at 3 and 6 months of follow-up ($P < 0.05$). Hearing improvement was achieved, as the mean preoperative ABG was 26.5 ± 5.4 and 27.1 ± 4.6 dB, and the mean postoperative ABG at 6 months was 19.4 ± 4.4 and 14.6 ± 3.9 dB in the CT and the CT + ETBD groups, respectively. The difference in the magnitude of ABG reduction in the two groups was significant at 3 and 6 months of postoperative follow-up ($P < 0.05$) in favour of the CT + ETBD group.

Conclusion: ETBD can increase the success rate of cartilage tympanoplasty in patients with AdOM by enhancing the audiological outcome and quality of life.

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1. Introduction

Adhesive otitis media (AdOM) is a complication of untreated middle ear effusion caused by long-term eustachian tube dysfunction (ETD). Negative pressure caused by inadequate middle ear ventilation, combined with thinning and atrophy of the eardrum, 'myringomalacia', and inward traction, result in the pathogenesis of AdOM (Mansour et al., 2018).

AdOM is a relatively frequent otologic illness that accounts for

3–5% of operated chronic otitis media cases. AdOM is a crucial ear pathology because of the possible serious complications, such as recurrent infection, ossicular destruction, and the development of cholesteatoma (Mansour et al., 2015).

Drug therapy is not curative in many cases of AdOM, and the use of surgery is controversial. It entails removing the adhering eardrum from the medial wall of the middle ear and reinforcing it after ossicular reconstruction, if necessary, intending to keep the tympanic cavity air-filled (Li et al., 2019).

ETD represents a chronic disorder that is difficult to treat; therefore, the outcome of surgical therapy for AdOM may not be as satisfactory as in other types of otitis media. It has long been believed that surgery to improve hearing can only be considered if the Eustachian tube (ET) function has returned to normal. As a result, most doctors advise that ETD caused by nasal and nasopharyngeal disorders should be treated first before undergoing

Abbreviations: AdOM, Adhesive otitis media; COMOT-15, Chronic Otitis Media Outcome Test-15; ETBD, Eustachian tube balloon dilatation.

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tyimpanoplasty as a second stage surgery (Larem et al., 2016).

Recently, eustachian tube balloon dilatation (ETBD) has been identified by many otologists as an effective and promising treatment for ETD. The aim of the current study was to compare cartilage tympanoplasty (CT) combined with ETBD and cartilage tympanoplasty alone a surgical treatment modality for AdOM in terms of graft healing, audiological outcomes, and impact on lifestyle, using Chronic Otitis Media Outcome Test-15 (COMOT-15).

2. Methods

2.1. Subjects and study design

This was a prospective comparative study involving 50 patients with AdOM who met the inclusion criteria, selected from the ENT clinic of El Minia University Hospital, from November 2019 to September 2021.

Patients were randomly classified into two groups: 25 patients for CT only (CT group) and 25 patients for CT plus ETBD in the same session (CT + ETBD group). Among these, 31 patients were male and 19 female; the age of the patients ranged from 17–52 years, 30 were right-ear cases, and 20 were left-ear cases.

This study was approved by the ethical committee of the Faculty of Medicine, El Minia University (approval number 345:11/2019), and written informed consent was obtained from each participant after a detailed explanation of the study and its purpose.

2.2. Inclusion criteria

- 1) Adhesion of the pars tensa pocket to the medial wall (Tympanic membrane cannot be separated from the promontory). (Grade IV according to Sade's (Sadé and Berco, 1976) classification)
- 2) Manifestations: hearing loss, ear fullness, and tinnitus
- 3) Conductive hearing loss (CHL) with an air-bone gap not more than 35 dB to exclude ossicular erosion in pure tone audiometry (PTA)
- 4) Type B or C tympanometry
- 5) Refusal to use the hearing aid

Exclusion criteria:

- 1) Cholesteatoma diagnosed clinically and/or radiologically
- 2) Sensorineural hearing loss
- 3) Craniofacial anomalies
- 4) Previous tympanoplasty
- 5) Patients with dehiscence in the carotid canal and those with hypertension or cardiac problems were excluded from the CT + ETBD group to avoid the risk of carotid injury and to avoid stimulation of the sympathetic nerves around the ET during dilatation.
- 6) Patients suffering from allergic rhinitis (AR) with uncontrolled clinical manifestations
- 7) Patients with uncorrected nasal or nasopharyngeal diseases which cause ETD

2.3. Assessment methods

All patients were subjected to the following assessments.

- 1) Complete E.N.T. history

Ear symptoms in the form of COMOT-15 were evaluated. This test was proposed by Baumann et al. (2009) to assess the quality of life in individuals with chronic otitis media (COM); lower the

COMOT-15 score, lower the impact of COM on the quality of life.

Nasal symptoms, especially nasal obstruction, and allergic rhinitis (itching, sneezing, and runny nose), gastro-oesophageal reflux disease (GERD) and other E.N.T symptoms, history of medical therapy or surgical procedures, especially adenoidectomy and nasal surgery (septoplasty, partial inferior turbinectomy, functional endoscopic sinus surgery (FESS) etc.) and ventilation tube insertion for treatment of otitis media with effusion.

- 2) Complete E.N.T. examination

Otoendoscopy was performed to confirm the diagnosis and to exclude the possibility of cholesteatoma or active infection and a discharging ear. Endoscopic nasal and nasopharyngeal examinations were performed to evaluate the ET opening and check for any pathology. Any nasal or nasopharyngeal pathology was treated either medically (e.g., AR, GERD) or surgically (e.g., deviated septum, chronic hypertrophic rhinitis) before proceeding to the surgical intervention of the current study to achieve long-term success of tympanoplasty. Patients with AR or nasal diseases who required surgery were eligible for the study after their conditions, identified by clinical assessment and thorough examination, were under control; the time interval between nasal surgery and surgery in the current study was 3 months. If there were associated upper respiratory tract infection symptoms, surgery was postponed until the patient's clinical condition improved.

- 3) Audiological evaluation

The function of the ET was evaluated using the Valsalva maneuver (negative in all patients). PTA was performed in sound-treated room amplisilence using a Madsen Astera audiometer. Air conduction thresholds were measured at 0.25, 0.5, 1, 2, 4, and 8 kHz, whereas bone conduction thresholds were recorded at 0.5, 1, 2, and 4 kHz. The mean air-bone gap (ABG) was calculated.

- 4) Radiological assessment by high-resolution computed tomography was performed on the petrous bone with Valsalva as prescribed by Trabichi & Najmi (Tarabichi and Najmi, 2015) to assess the patency of the ET, detect the site of obstruction, evaluate the relationship between the ET and carotid canal (intact or dehiscent canal), and exclude the possibility of cholesteatoma.

2.4. Operative technique

All operations were performed under general anaesthesia using an endoscope (Carl Storz 0, 30° and 45°, 18 cm long and 4 mm in diameter) after fulfilment of laboratory investigations, electrocardiography (ECG), and internal medical fitness.

CT group: Cartilage tympanoplasty was performed using a transcanal approach. Hydrodissection: intratympanic saline injection in the middle ear was performed to detach and separate the tympanic membrane from the ossicular complex and the promontory. This was followed by elevation of the posterior tympanomeatal flap from the 12 o'clock to 6 o'clock position until it reached the tympanic annulus.

Dissection of the adherent drum, different synechiae, and fibrous bands from the promontory was performed, the tympanosclerotic patches were carefully removed, and the flap was carefully and meticulously dissected from the handle of the malleus. Excision of the mucosal bands around the ossicles and clearance of the tympanic isthmus (anterior and posterior) was performed to get a clear view of different compartments of the middle ear. Endoscopic

exploration of the protympanic opening of the ET using a 45° scope, clearance of any obstructing mucosal bands, and injection of a combination of antibiotics (ceftriaxone) and steroids (dexamethasone) was performed using a syringe connected to a curved suction (Fig. 1).

The tragal cartilage and its perichondrium were harvested. If the graft was thick, it was split with a precise mathematical Kurz® *Precise Cartilage Splitter* as prescribed by Khan and Parab (2015), to produce a thin sheet of cartilage adherent to the perichondrium.

Following this, the underlay technique was used to introduce the graft to be lateral to middle ear mucosa as well as under and medial to the handle of the malleus and tympanic membrane remnant with the perichondrium toward the external auditory canal (EAC). The tympanomeatal flap was repositioned and the EAC was packed using gelfoam and Aural pack was used for 5 days.

CT + ETBD dilatation of the cartilaginous part of the ET through the nasopharyngeal approach was performed, followed by cartilage tympanoplasty, as in the CT group, in the same session. Dilatation was performed using an ETBD set as shown in Fig. (2).

The nasal cavities and nasopharynx were packed with cottonoids soaked in 2% xylocaine and 1:100000 adrenaline to decongest and widen the nasal cavities for easy access to the instruments.

Using an angled endoscope (30° and 45° Karl Storz), the nasal cavities and nasopharynx were inspected to localise the tubal nasopharyngeal ostium. The endoscopes were inserted into the nasal cavity from either the ipsilateral or contralateral side. The catheter was carefully inserted with the appropriate instrument from the contralateral side or parallel to the endoscope through the same nostril and placed at the tubal ostium (Fig. 3).

The catheter was advanced without resistance, and the instrument was not inserted too far to avoid dilatation of the bony part. An inflation pump was connected. The balloon was then inflated to 10 bar (working pressure). The pressure was maintained for 2 min. The pump lock was then released and the balloon was removed.

Clinical outcomes in both groups were compared in terms of graft healing by otoscopy examination, audiological outcomes by PTA, symptomatic improvement, and impact on lifestyle by COMOT-15 at 3 and 6 months of follow-up.

3. Results

No significant difference was observed between the two groups with regard to history as either clinical presentation in the form of COMOT-15, dizziness, risk factors of ETD in the form of smoking, allergic symptoms, nasal obstruction and GERD or the previous surgeries the patient underwent before the current surgery in this study Table 1

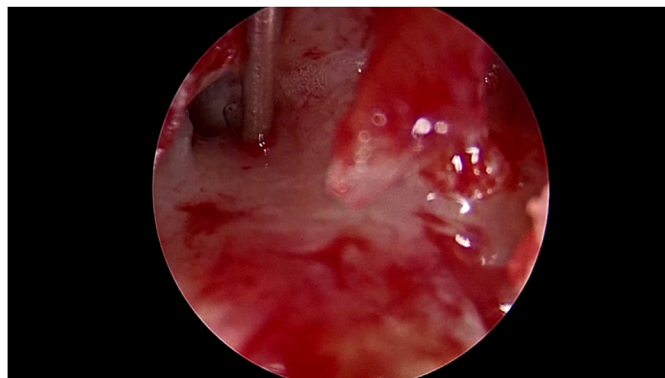


Fig (1). Endoscopic view of right ear showing cleared protympanic ET opening before injection of the antibiotic-steroid combination.



Fig (2). Spiggle and Thesis ETBD system. From left to right: combined insertion instrument, three attachments, inflation pump with extension tube and the sterile catheter in a protective tube.



Fig (3). Insertion of the catheter within the insertion instrument in the ET nasopharyngeal ostium at the right side.

The obstruction of the ET affected the distal cartilaginous part (the lumen could not be visualised) in 41(82%) patients and both the cartilaginous and bony parts in 9 (18%) patients [Fig. (4)]. There was no significant difference between the two groups; thus, the cartilaginous part was the main site of obstruction in the studied cases. The percentage of carotid canal dehiscence among the studied cases was 8% (four cases) (Fig. 5). These patients were excluded from the CT + ETBD group to avoid the risk of carotid injury and were candidates for the CT group.

3.1. Postoperative assessment parameters

3.1.1. Graft uptake

There was no significant difference in graft healing between the two groups. Healing of the tympanic membrane was achieved in all ears except for three ears in the CT group and one ear in the CT + ETBD group which had a small residual perforation after 6 months.

3.1.2. PTA

There was no significant difference in preoperative ABC

Table 1
Comparison of symptoms and previous surgeries between the two groups.

| | | CT | CT + ETBD | P Value |
|-------------------|-----------|------------|------------|---------|
| | | N = 25 | N = 25 | |
| COMT15 | Range | (18–42) | (24–43) | 0.254 |
| | Mean ± SD | 31.8 ± 6.6 | 33.8 ± 5.7 | |
| Smoking | No | 17(68%) | 13(52%) | 0.248 |
| | Yes | 8(32%) | 12(48%) | |
| Dizziness | No | 21(84%) | 20(80%) | 0.713 |
| | Yes | 4(16%) | 5(20%) | |
| Allergic symptoms | No | 15(60%) | 14(56%) | 0.774 |
| | Yes | 10(40%) | 11(44%) | |
| Nasal obstruction | No | 6(24%) | 8(32%) | 0.529 |
| | Yes | 19(76%) | 17(68%) | |
| GERD symptoms | No | 16(64%) | 15(60%) | 0.771 |
| | Yes | 9(36%) | 10(40%) | |
| Adenoidectomy | No | 12(48%) | 8(32%) | 0.248 |
| | Yes | 13(52%) | 17(68%) | |
| Septoplasty | No | 22(88%) | 20(80%) | 0.702 |
| | Yes | 3(12%) | 5(20%) | |
| BPIT | No | 20(80%) | 18(72%) | 0.508 |
| | Yes | 5(20%) | 7(28%) | |
| FESS | No | 24(96%) | 23(92%) | 0.552 |
| | Yes | 1(4%) | 2(8%) | |
| Ventilation tubes | No | 18(72%) | 17(68%) | 0.758 |
| | Yes | 7(28%) | 8(32%) | |

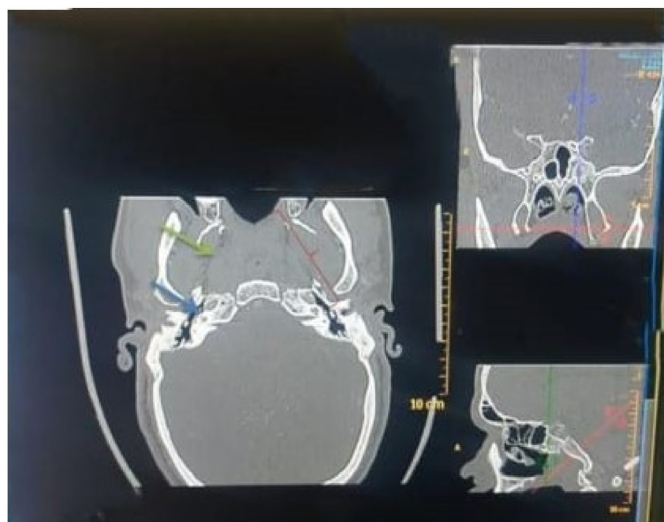


Fig (4). Multiplanar reconstruction to show the whole length of the ET (red line) with patent bony part (blue arrow) and obstructed (non-visualised lumen or not patent) cartilaginous part (green arrow).

between the two groups. Postoperative ABG was significantly reduced in the two groups ($P < 0.05$) after 3 and 6 months (Table 2). The difference in the magnitude of reduction in ABG between the two groups was significant at 3 and 6 months of postoperative follow-up ($P < 0.05$) and is listed in Table 3. Hearing improvement was better in the CT + ETBD group than in the CT group.

3.1.3. COMOT-15

There was no significant difference in the preoperative COMOT-15 scores between both groups ($p = 0.254$), whereas postoperative COMOT-15 scores significantly decreased in both groups after 3 and 6 months of follow-up ($P < 0.05$) (Table 4). There was a significant difference between the groups with regard to the decrease in COMOT-15 scores at 3 and 6 months of follow-up (Table 5). This implies that patients in the CT + ETBD group had a significantly

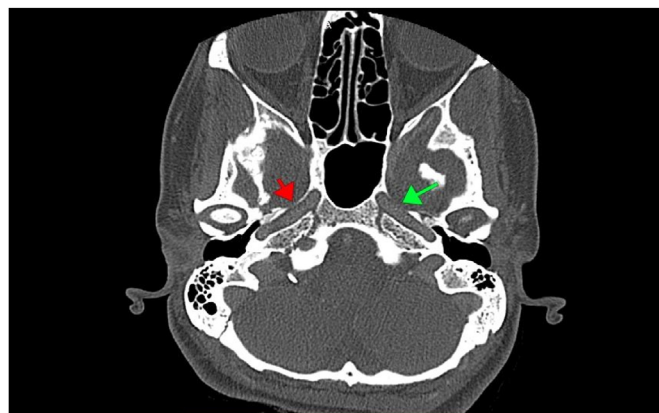


Fig (5). Axial view showing intact right carotid canal (red arrow) and dehiscence in left carotid canal (green arrow).

better postoperative quality of life than those in the CT group. ($P < 0.05$).

4. Discussion

The management of AdOM is controversial. Many otologists prefer conservative treatment in patients with significant CHL with a hearing aid than with surgery due to the poor outcome and unexpected results, and consider surgical intervention in cases of recurrent otorrhea, which represents a sign of growing cholesteatoma (Mansour et al., 2018).

In the current study, otorrhea was not among the indications, and the patients refused to use hearing aids for their conductive hearing loss. Patients in the current study were evaluated using CT petrous bone with Valsalva to assess the patency of the ET and to detect the site of obstruction. The obstruction of the ET affected the distal cartilaginous part (the lumen could not be visualised) in 41(82%) patients and both cartilaginous and bony parts in 9 (18%) patients; thus, the cartilaginous part was the main site of obstruction in the studied cases, and it was the target for dilatation in the CT + ETBD group.

This technique was recently reported by Trabichi & Najmi (Tarabichi and Najmi, 2015) in 2015. This study included 38 patients with no ear disorders and normal para-nasal sinuses on CT. The Valsalva maneuver allowed visualisation of the distal one-third of the cartilaginous tube in 71/76 (94%) ears. The ET paradoxically collapsed in three ears, accompanied by evidence of inadequate Valsalva technique. They concluded that this technique might help localise the site of ET pathology in patients with obstructive ETD.

On the other hand, Diletta et al. (Angeletti et al., 2021) attempted to evaluate the outcomes of ET Score 7 (ETS-7) which is a method for evaluating ET function by questionnaire and CT with Valsalva in 12 patients affected by middle ear atelectasis with a strong suspicion of ETD. They found that the visualisation of the ET before and after the Valsalva maneuver did not present a statistical difference, and no correlation emerged between CT with the Valsalva and ETS-7 score.

Lee et al. (2020) agreed with the current study when they used Valsalva CT in 12 patients with obstructive ETD. They found that the cartilaginous part was obstructed more than other parts of the ET. Sixteen ears were included in their study, and the obstructed area was clearly identified in the cartilaginous portion of 14 ears.

In the current study, the percentage of patients with carotid canal dehiscence was 8% ($n = 4$). Tisch et al. (2013) reported the results of temporal bone CT of 1000 patients and found no

Table 2
Pre- and post-operative ABG.

| Air Bone Gap | | CT | CT + ETBD | P Value |
|------------------------|-----------|------------|------------|-------------------|
| | | N = 25 | N = 25 | |
| Preoperative | Range | (18–35) | (19.5–35) | 0.688 |
| | Mean ± SD | 26.5 ± 5.4 | 27.1 ± 4.6 | |
| 3 months postoperative | Range | (15.8–31) | (11–26) | 0.001* |
| | Mean ± SD | 23.3 ± 4.9 | 18.8 ± 3.9 | |
| 6 months postoperative | Range | (12–28) | (8–22) | <0.001* |
| | Mean ± SD | 19.4 ± 4.4 | 14.6 ± 3.9 | |

Table 3
Comparison of decrease in ABG between both groups.

| Decrease in Air Bone Gap | | CT | CT + ETBD | P Value |
|--------------------------|-----------|-----------|-------------|-------------------|
| | | N = 25 | N = 25 | |
| 3 months postoperative | Range | (1–6.5) | (6.5–9.5) | <0.001* |
| | Mean ± SD | 3.3 ± 1.5 | 8.3 ± 0.9 | |
| 6 months postoperative | Range | (1–12.5) | (10.5–13.5) | <0.001* |
| | Mean ± SD | 7 ± 3.4 | 12.4 ± 1 | |

Table 4
Pre- and post-operative COMOT-15 scores.

| COMT-15 | | CT | CT + ETBD | P Value |
|------------------------|-----------|------------|------------|-------------------|
| | | N = 25 | N = 25 | |
| Preoperative | Range | (18–42) | (24–43) | 0.254 |
| | Mean ± SD | 31.8 ± 6.6 | 33.8 ± 5.7 | |
| 3 months postoperative | Range | (16–36) | (13–32) | <0.001* |
| | Mean ± SD | 26.1 ± 6 | 19.9 ± 5.3 | |
| 6 months postoperative | Range | (14–32) | (8–26) | <0.001* |
| | Mean ± SD | 23.2 ± 5.7 | 15.6 ± 5.2 | |

Table 5
Comparison of decrease in COMOT-15 scores between both groups.

| Decrease in COMT-15 | | CT | CT + ETBD | P Value |
|------------------------|-----------|-----------|------------|-------------------|
| | | N = 25 | N = 25 | |
| 3 months postoperative | Range | (2–9) | (11–15) | <0.001* |
| | Mean ± SD | 5.7 ± 1.3 | 14 ± 1.2 | |
| 6 months postoperative | Range | (4–10) | (16–20) | <0.001* |
| | Mean ± SD | 8.6 ± 1.3 | 18.3 ± 1.1 | |

dehiscence of the carotid canal and an average thickness of 1.02 mm. Moreano et al. (1994) also provided an assessment of 1000 cases and found carotid canal dehiscence in 7.7% and micro-dehiscence in 7.4%. A total of 15.5% of the carotid canals only had thin bone coverage. Schröder et al. (2015) studied 284 preoperative high-resolution CT scans of the temporal bone before unilateral or bilateral ETBD. They found minor dehiscence in 18 patients (6.3%).

In the current study, patients with carotid canal dehiscence were excluded from the CT + ETBD group to avoid the risk of carotid injury; however, Abdel-Aziz et al. (2014) and Schröder et al. (2015) stated that a preoperative CT scan is unnecessary and could be avoided to protect the patients, especially children, from unwarranted radiation exposure, as it does not predict intra- or post-operative difficulties in balloon dilation, and the procedure is intended to only treat the cartilaginous part of the ET; therefore, the fear of carotid injury might be disproportionate.

Avoiding a relapse of AdOM requires the use of rigid grafts that can better resist negative middle ear (ME) pressure and prevent the recurrence of retraction; therefore, cartilage is preferred in the treatment of AdOM than temporalis fascia. Furthermore, at a thickness of 0.5 mm, it has a better sound-conducting capability

(Iacovou et al., 2013). Therefore, a thinned tragus cartilage/perichondrium graft, which was prepared using the cartilage splitter, was used for tympanoplasty in the current study, with the cartilage surface toward the promontory to prevent recurrent adhesions.

Chronic uncomfortable ETD symptoms, ETD-related symptoms when pressure varies quickly, or recurrent OME that can develop into middle ear atelectasis or AdOM, are all considered indications for ETBD by the Finnish Otolaryngological Society. They recommend treating only adults with BET based on the present evidence (Luukkainen et al., 2018).

ETBD was used in the current study in the CT + ETBD group in an attempt to restore the aeration of the middle ear by improving the function of the ET which is necessary for successful surgical treatment of AdOM; the clinical outcome was compared to that of the CT group. There was no significant difference in graft healing between the two groups. There was a significant decrease in COMOT-15 scores in both groups, with a significant difference between the groups after 3 and 6 months (P < 0.05). Hearing improvement was achieved, as the mean preoperative ABG was 26.5 ± 5.4 and 27.1 ± 4.6 dB, and the mean postoperative ABG at 6 months was 19.4 ± 4.4 and 14.6 ± 3.9 dB in the CT and the CT + ETBD groups, respectively. The difference in the magnitude of ABG reduction in the two groups was significant at 3 and 6 months of postoperative follow-up (P < 0.05) in favour of the CT + ETBD group.

Schröder et al. (2015) observed 622 patients treated with ETBD. ETD symptoms, chronic secretory otitis media (SOM), AdOM, and TM retraction after ME surgery were indications of ETBD. The ET score improved significantly in 82% of individuals after 5 years. Nearly 80% of the patients were satisfied. They concluded that ETBD is a safe and effective treatment for chronic obstructive ETD, with a success rate of more than 70%.

A total of 120 patients with AdOM were randomly assigned to one of four groups by Si et al. (2019): control group (conservative treatment), ETBD group, CT group, and ETBD + CT group. Patients were evaluated using the Tinnitus Handicap Inventory (THI), visual analogue scale (VAS), COMOT-15, and ETS at 3 months, 6 months, 1 year, and 2 years after otoendoscopy and PTA. They found no improvement in TM morphology and mean ABG after treatment in the control and ETBD groups.

Their results were in line with the current study regarding postoperative tympanic membrane healing in the CT and CT + ETBD groups. Although retraction recurred in two patients (out of 40) in the CT group, postoperative TM morphology improved in both groups, with no significant difference. However, they disagree with the current study regarding the magnitude of reduction in the ABG between both groups. They found that reduced ABG was achieved in the two groups, but the difference was not significant; however, in the current study, the difference was statistically significant. However, we should consider that cases with suspected ossicular erosion, more severe hearing loss, and cases with infection and granulation tissue formation were included in their study, while such cases were excluded from the current study.

Their results also matched our results with regard to post-operative symptomatic improvement and quality of life. They observed improvements in ETS, THI, VAS, and COMOT-15 in the two groups, and the difference in reduction was significant in favour of the ETBD + CT group.

Huisman et al. (2018) performed a comprehensive systematic review to assess the effectiveness of ETBD in relieving symptoms in adult patients with ETD. There were 15 studies in total, all of which were case series. All studies demonstrated a short-term improvement in symptoms, with some showing even more improvement over time. The follow-up duration ranged from a few weeks to 50 months.

The long-term outcome of ETBD was also studied by Luukkainen et al. (2018) in a systematic review. Five articles were included in their study with a follow-up time of one year or more. Another five articles with follow-up times less than 1 year (6–11 months) were evaluated to obtain supportive data. The revised studies suggest that the long-term outcome of ETBD is promising: Valsalva improved in 80%–98%, symptoms in 73%–98%, and otoscopic findings in 90% of patients. Moreover, the ETS improved for up to three years after ETBD.

Conclusion ETBD can increase the success rate of cartilage tympanoplasty in patients with AdOM by enhancing the audiological outcome and quality of life; however, more research with long-term observation data, universally accepted methods for diagnosis of ETBD, further investigations about the efficacy of ETBD, and the need for long-term repetition are required on the long run.

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Conflict-of-interest statement

The authors hereby declare that they have no competing interest.

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