An Original Investigation

Tympanoplasty with Eustachian Tube Balloon Dilation for Chronic Inflammatory Middle Ear Disease: A Randomized Clinical Trial

Gey, A., Honeder, C., Reiber, J., Honigmann, R., Zirkler, J., Wienke, A., ... & Plontke, S. K. (2025).
JAMA Otolaryngology – Head & Neck Surgery.

Presenter: Clerk 2 黎芷嘉
Supervisor: VS 吳伯軒醫師
Jan 28, 2026

Introduction

Background

- Eustachian tube dysfunction (ETD) reduces middle ear ventilation and may contribute to chronic inflammatory middle ear disease
- Eustachian tube balloon dilation (ETBD) was introduced in 2010 and approved by the FDA in 2016. It is reported as safe and effective for treating chronic obstructive ETD.

The Clinical Gap

- While effective for ETD alone, data on the efficacy of ETBD **combined with tympanoplasty** are limited.

To compare the effect of **ETBD + Tympanoplasty** vs. **Tympanoplasty alone**
in patients diagnosed with chronic inflammatory middle ear disease and obstructive ET dysfunction

Methods

Participants & Intervention

Inclusion criteria

Chronic Inflammatory middle ear disease

Planned tympanoplasty

Negative result of Valsalva maneuver

ETS <= 5

Age > 18

Jan 2015 - Nov 2019

Exclusion criteria

Previous head & neck radiotherapy

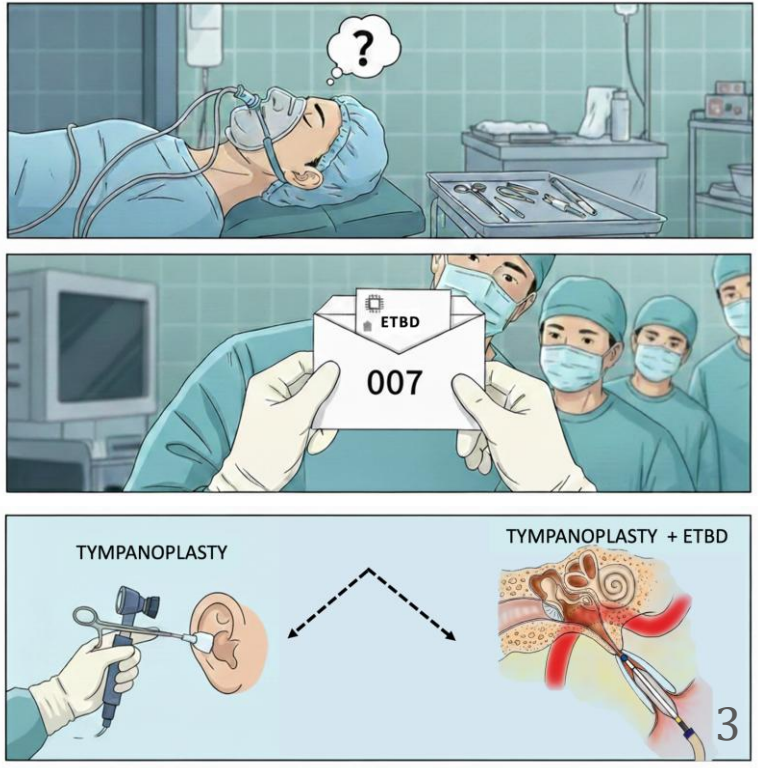
Previous sx for cleft palate

Malformations of the skull/temporal bone

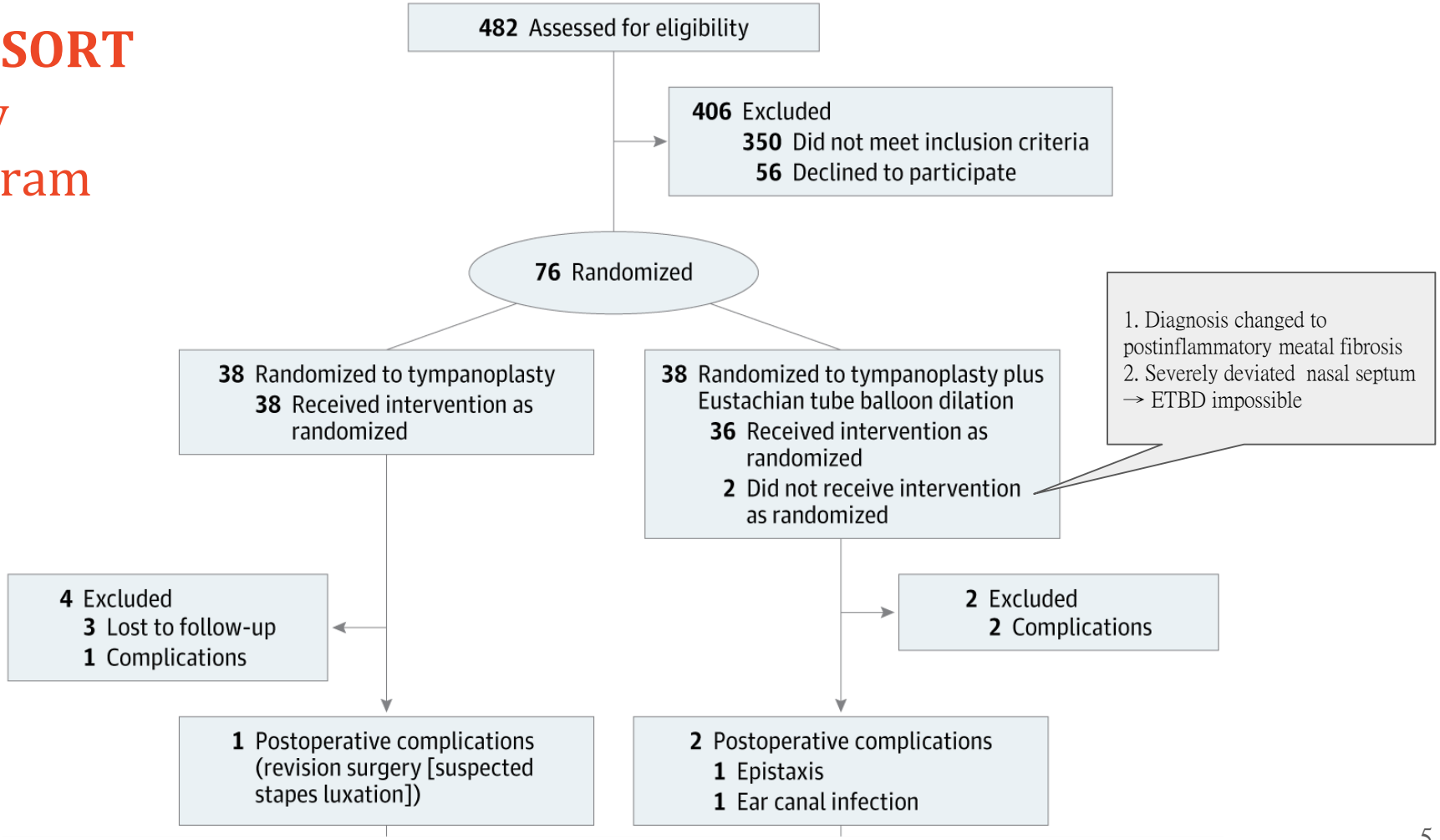
Fx of the skull base

Otitis media with effusion as solitary diagnosis

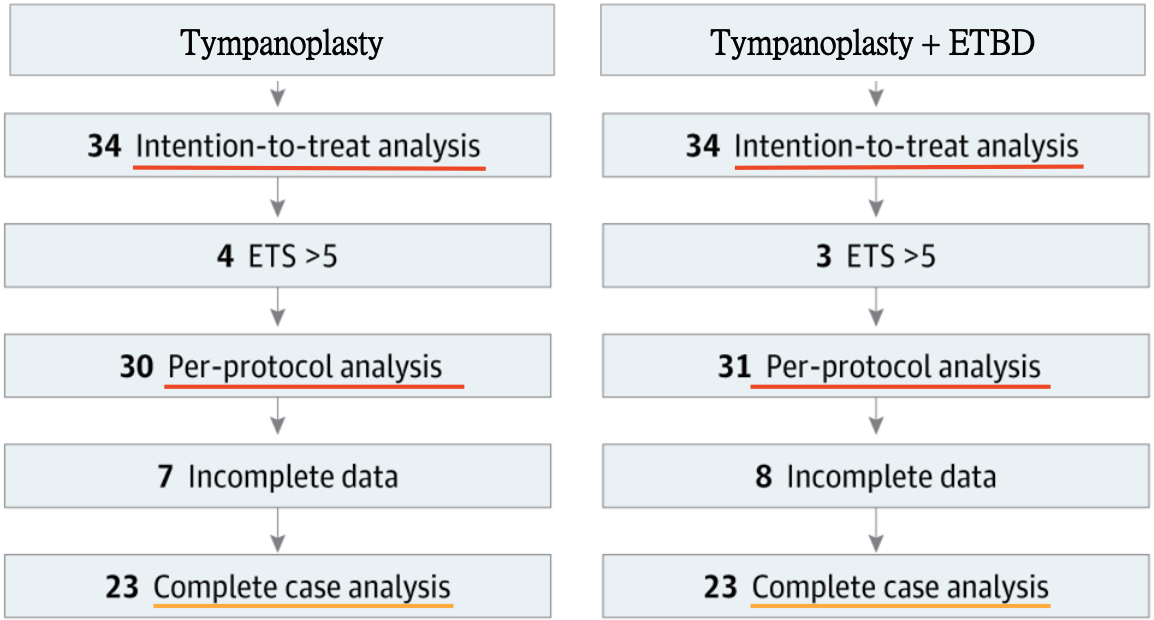
Patulous ETD 、Technical infeasibility



CONSORT Flow Diagram



CONSORT Flow Diagram



Linear mixed model

repeated measures analysis of variance

Table. Patient Demographics and Baseline Data for Intention-to-Treat Analysis[a]

Characteristic	No. (%) Tympanoplasty (n = 34)	Tympanoplasty plus ETBD (n = 34)	*P* value
Sex			
Female	20 (59)	13 (38)	.09
Male	14 (41)	21 (62)	
Age, mean (SD), y	53.4 (12.5)	51.4 (14.5)	.56
Side			
Right	14 (41)	18 (53)	.33
Left	20 (59)	16 (47)	
Diagnosis			
Adhesive otitis media	2 (6)	7 (21)	.30
Chronic suppurative otitis media	17 (50)[b]	12 (35)[b]	
Cholesteatoma	14 (41)	14 (41)	
Other	1 (3)[b]	1 (3)	
No. of previous surgeries			
0	17 (50)	17 (50)	>.99
1	12 (35)	12 (35)	
2	3 (9)	3 (9)	
3	2 (6)	2 (6)	
Eustachian Tube Score, mean (95% CI)	2.48 (1.55-3.41)	2.24 (1.29-3.19)	.71
Air-bone gap (4PTA), mean (95% CI), dB	25.8 (21.1-30.5)	29.1 (25.4-32.8)	.28
Bone conduction threshold (4PTA) mean (95% CI), dB	25.5 (20.1-30.9)	24.6 (19.5-29.7)	.82
Air conduction threshold (4PTA), mean (95% CI), dB	51.3 (44.1-58.5)	53.7 (46.8-60.6)	.63
Tympanogram			
Type A	1 (3)	2 (6)	.61
Type B	13 (38)	18 (53)	
Type C	4 (12)	3 (9)	
TM perforation	13 (38)	10 (29)	
Not possible	3 (9)	1 (3)	
ETDQ-7 score, mean (95% CI)	13.4 (11.6-15.3)	15.15 (13.3-17.0)	.18
Subjective ET function			
Disturbing	6 (18)	10 (30)	.25
Not disturbing	28 (82)	24 (70)	
Valsalva objective			
Positive	0	0	.49
Delayed	4 (12)	6 (18)	
Negative	30 (88)	28 (82)	
Valsalva subjective			
Always possible	2 (6)	1 (3)	.67
Sometimes possible	16 (47)	19 (56)	
Never possible	16 (47)	14 (41)	

Main Outcomes

Primary Outcome

Changes in the ETS during the first year

Secondary Outcome

. Air-Bone Gap after 12 months

. Subjective and objective changes in Valsalva maneuver

. Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores
*The MCID for the ETDQ-7 is 0.5.

Main Outcomes

Primary Outcome

Changes in the ETS during the first year

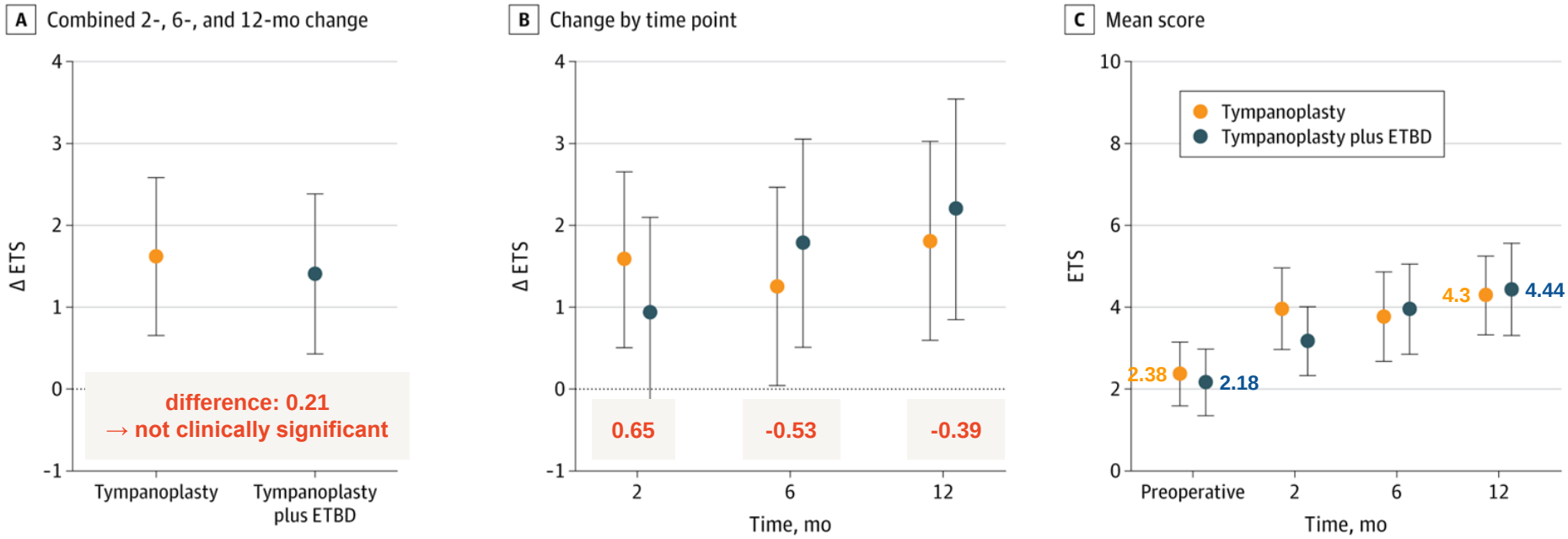
Symptom/Finding	2 Points	1 Point	0 Points
Clicking sound when swallowing	Always	Sometimes	Never
Positive Valsalva's maneuver	Always	Sometimes	Never
TMM at 30 mbar	$R < 1$	$R \geq 1$	No R
TMM at 40 mbar	$R < 1$	$R \geq 1$	No R
TMM at 50 mbar	$R < 1$	$R \geq 1$	No R

TMM: Tubomanometry according to Estève; R indicates opening latency index.
Range of the Eustachian tube score: 0 to 10.

clinically meaningful difference: 3 point

Results

Primary Outcome: ETS score



per-protocol & complete case analysis : no significant difference

Main Outcomes

Primary Outcome

Changes in the ETS d

Over the past month, how much has each of the following been a problem for you?	No problem	Moderate problem	Severe problem
1. Pressure in the ears?	1, 2	3, 4, 5	6, 7
2. Pain in the ears?	1, 2	3, 4, 5	6, 7
3. A feeling that your ears are clogged or "under water"?	1, 2	3, 4, 5	6, 7
4. Ear symptoms when you have a cold or sinusitis?	1, 2	3, 4, 5	6, 7
5. Crackling or popping sounds in the ears?	1, 2	3, 4, 5	6, 7
6. Ringing in the ears?	1, 2	3, 4, 5	6, 7
7. A feeling that your hearing is muffled?	1, 2	3, 4, 5	6, 7

Secondary Outcome

. **Air-Bone Gap after 12 months**

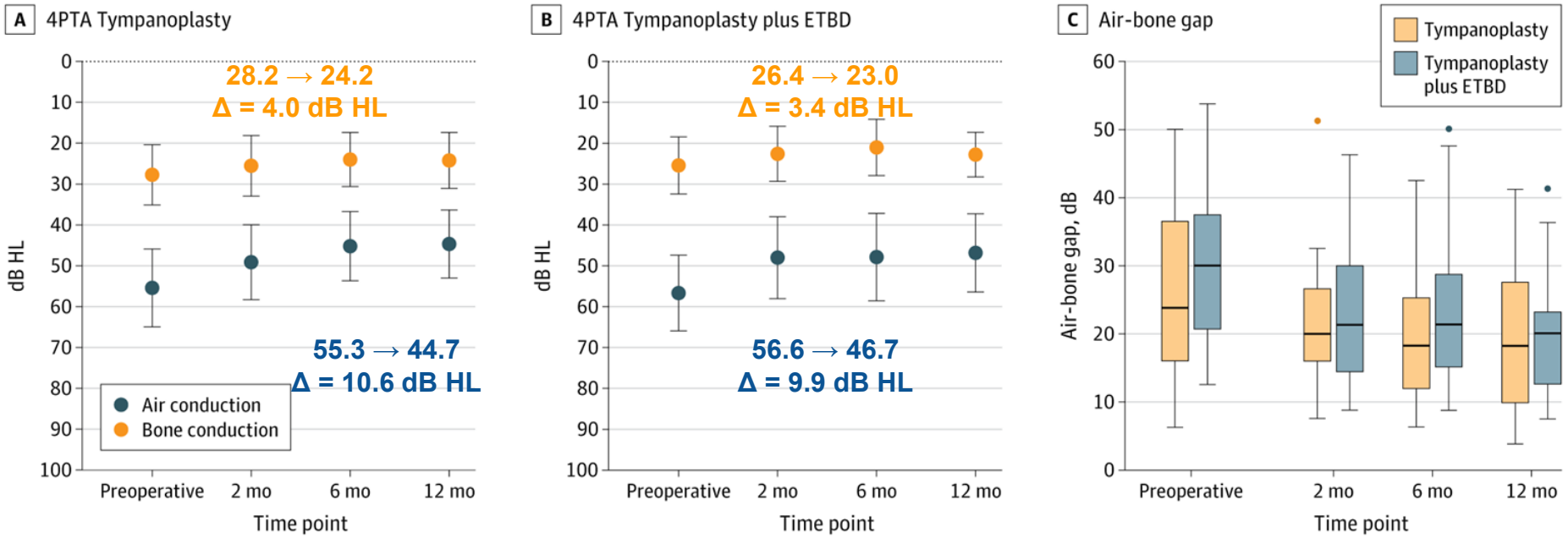
. **Subjective and objective changes in Valsalva maneuver**

. **Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores**
The MCID for the ETDQ-7 is 0.5.

Results

Air-Bone Gap(ABG) → No Clinically Meaningful Difference

difference = 0.6 dB HL (95% CI -3.4 to 4.5)



difference = 0.7 dB HL (95% CI -8.3 to 9.6)

Results

ETDQ-7 scores

Baseline Status

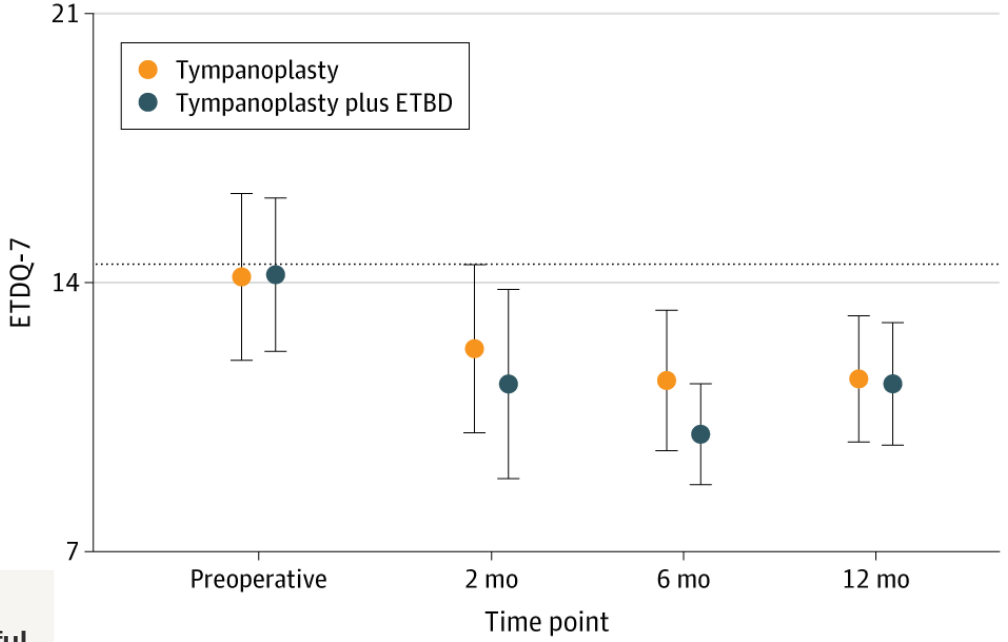
Both groups started with a mean score of **14.2**.(below the diagnostic cutoff of 14.5)

Improvement by Group

Tympanoplasty Only: Score decreased by **2.7 points** (14.2 ⟶ 11.5)
Tympanoplasty + ETBD: Score decreased by **2.8 points** (14.2 ⟶ 11.4)

Between-Group Comparison

Mean difference in change: **-0.2 points** (95% CI, -3.4 to 3.1).



- Difference between groups is negligible.
- Based on the confidence intervals, a **clinically meaningful benefit** from adding ETBD is **extremely unlikely**.

Discussion

Principal Findings

- No significant benefit
  - Eustachian Tube Score (ETS)
  - Air-bone gap (ABG)
  - Subjective ET function (ETDQ-7)
- Routine performance of ETBD as an add-on procedure ?
- Contrast with previous literature
  - Previous trials often focused on single pathologies e.g. adhesive otitis media.
  - This trial included cholesteatoma, chronic suppurative otitis media, adhesive otitis media.
  - In the small subgroup of adhesive otitis media in this study, ETS improved in only 1 of 3 patients receiving ETBD.

*Si Y, Chen Y, Xu G, Chen X, He W, Zhang Z. Cartilage tympanoplasty combined with Eustachian tube balloon dilatation in the treatment of adhesive otitis media. *Laryngoscope*. 2019;129(6):1462-1467.
*Abdel Aziz AAR, Youssef AM, Mostafa MM, Talaat M, Abdelzaher KM, Sadeq AA. Cartilage tympanoplasty in the treatment of adhesive otitis media with and without Eustachian tube balloon dilatation. *J Otol*. 2022;17(4):226-231.

Discussion

Assessment Challenges

- **Lack of Gold Standard**: No widely accepted reference standard for quantifying ETD
- **Why ETS was chosen as Primary Outcome**:
  - A high proportion of patients had tympanic membrane perforations.
  - The ETDQ-7 has reduced reliability in patients with perforations and correlates poorly with objective tests.
  - ETS combines subjective parameters with objective tubomanometry
- **The ETDQ-7 Limitation**
  - Flooring Effect**:**
    - Patients reported minor symptoms pre-operatively. Mean baseline scores were below the diagnostic cutoff (<14.5 points).
    - Tympanic membrane perforations likely masked obstructive symptoms (e.g., ear fullness).

Discussion

Mechanisms of Improvement

Why did both groups improve?

- **Surgical Closure:** Tympanoplasty is a major contributor to improved middle ear mechanics.
- Objective Valsalva success rates improved in ***both*** the control and experimental groups.
  → the benefit came from the **tympanoplasty itself** rather than the balloon dilation

Rethinking the Role of ETD

- **Unexpected Prevalence:** Only **18%** of patients screened for this trial actually met the criteria for ETD
- **Implications for Etiology:** Is ETD the major cause of chronic inflammatory middle ear disease in adults?
- **Potential Explanations:**
  1. Chronic infections or genetic factors may be more significant contributors.
  2. ETD may have been the initiating cause in childhood but resolved by adulthood

Discussion

Study Limitations

Confounding Factors

- Environmental allergies and chronic rhinosinusitis were not analyzed in this trial.

Surgical Timing

- Simultaneous Strategy: ETBD was performed immediately before tympanoplasty to allow for blinding.
  → cannot rule out potential benefits of a staged strategy

Sample Size & Heterogeneity

- **Statistical Power:**
  The number of complete datasets was limited by COVID-19 and strict post-hoc exclusion.

- **Subgroup Analysis:**
  Sample sizes for certain pathologies were too small for subgroup analysis.

Conclusion

Clinical Takeaway

- Simultaneous ETBD did **not** improve outcomes in this randomized cohort.
- Routine performance of ETBD as an add-on to tympanoplasty is **not supported** by these findings.

Future Research Requirements

- **Diagnostic Tools**:

  Novel tools are needed to reliably quantify ETD in the presence of tympanic membrane perforations.
- **Study Design**:
  - Multicentric Trials
  - Specific Phenotypes: Specific types of chronic inflammatory middle ear disease (e.g., pure adhesive otitis media)

Thank you!