

Tympanoplasty With Eustachian Tube Balloon Dilatation for Chronic Inflammatory Middle Ear Disease: A Randomized Clinical Trial

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IMPORTANCE: Eustachian tube balloon dilatation (ETBD) is increasingly used to treat Eustachian tube (ET) dysfunction, but its benefit in patients requiring tympanoplasty for chronic inflammatory middle ear disease is unclear.

OBJECTIVE: To evaluate the efficacy of additional ETBD on the Eustachian Tube Score (ETS), hearing outcomes, and subjective ET function in patients with obstructive ET dysfunction undergoing tympanoplasty.

DESIGN, SETTING, AND PARTICIPANTS: This parallel-group, single-blind, monocentric, randomized clinical trial included patients with chronic inflammatory middle ear disease and ET dysfunction seen at a tertiary referral center and scheduled for tympanoplasty between January 2015 and November 2019. Data were analyzed between June 2022 and December 2023.

INTERVENTION: Patients were randomized to tympanoplasty only or an additional ETBD of the affected side.

MAIN RESULTS AND MEASURES: The main outcome was the change in ETS, and secondary outcome measures were change in the air-bone gap (ABG) and Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores.

RESULTS: From 76 randomized participants, 68 were included in the intention-to-treat analysis. Of the 34 patients in the tympanoplasty group, 20 participants (59%) were female, and the mean (SD) age was 53.4 (12.5) years. Of the 34 patients in the tympanoplasty plus ETBD group, 13 participants (38%) were female, and the mean (SD) age was 51.4 (14.5) years. During the first 12 months after the procedure, the difference in mean ETS changes between the tympanoplasty (1.62 [95% CI, 0.66–2.59]) and the tympanoplasty plus ETBD group (1.41 [95% CI, 0.43–2.39]) was 0.21 (95% CI, –1.17 to 1.59). These results rule out the possibility of a clinically meaningful difference of 3 points or more in ETS. Twelve months after the procedure, ABG improved from 26.1 dB to 19.0 dB hearing loss in the tympanoplasty group and from 30.1 dB to 20.1 dB hearing loss in the tympanoplasty plus ETBD group. The difference in ABG changes between the groups was –2.8 dB (95% CI, –9.1 dB to 3.5 dB), and the difference in mean ETDQ-7 changes was –0.2 (95% CI, –3.4 to 3.1).

CONCLUSIONS AND RELEVANCE: In this randomized clinical trial, the addition of ETBD to tympanoplasty in patients with chronic inflammatory middle ear disease and ET dysfunction did not improve the outcome regarding ETS, ABG, or subjective long-term ET function. ETBD should, therefore, not be routinely performed as an add-on procedure to tympanoplasty for this indication. Larger multicentric randomized trials could provide more insights into the efficacy of ETBD in patients with chronic inflammatory middle ear disease undergoing tympanoplasty and would allow for specific subgroup analyses.

TRIAL REGISTRATION: German Clinical Trials Register Identifier: DRKS000031807

JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2025.0904
Published online May 15, 2025.

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