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Systematic Review

Effect of nasal balloon auto inflation on hearing outcomes in children with otitis media with effusion

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ABSTRACT

Nasal balloon auto inflation is a non-invasive treatment method commonly used to manage otitis media with effusion (OME) in children. This review aimed to assess its effect on hearing outcomes. A total of 10 studies, including randomized controlled trials, and cohort studies were included. The results consistently showed modest improvements in hearing, particularly tympanometric normalization and decibel gains in pure tone audiometry. Approximately 50% of children receiving auto inflation achieved tympanometric normalization compared to 38% in control groups, with relative risks ranging from 1.36 to 2.67. Some studies reported 6–7dB improvements in pure tone average. Compliance rates were generally high, often above 80%, and adverse events were mild and infrequent. Secondary benefits included better middle ear pressure, reduced need for ventilation tubes, and improved quality of life. The intervention, most commonly performed with the Otovent device, was well-tolerated and feasible in primary care. This review supports the use of nasal balloon auto inflation as an effective and safe intervention for improving hearing outcomes in children with OME.

Keywords: Otitis media with effusion, Nasal balloon auto inflation, Hearing loss, Tympanometry, Pediatric otorhinolaryngology, Otovent

INTRODUCTION

Otitis media with effusion (OME) is a common condition in children, characterized by the presence of fluid in the middle ear without signs of acute infection. It is a leading cause of hearing loss in early childhood and may impact language development, academic performance, and quality of life.[1] Though many cases resolve spontaneously, persistent OME may require intervention. Conventional management includes watchful waiting, medical therapy, and surgical options such as myringotomy with tympanostomy tube insertion. However, these approaches carry limitations related to cost, invasiveness, and accessibility.

Nasal balloon auto inflation has emerged as a non-invasive alternative that aims to equalize middle ear pressure and promote resolution of effusion. The technique involves using a nasal balloon device, such as the Otovent, which when inflated via one nostril, helps open the Eustachian tube through positive pressure.[2] The procedure is simple, safe, and can be taught to children and caregivers for home use. Previous individual trials have shown varying degrees of benefit in tympanometric outcomes and hearing thresholds.[3-5] However, the magnitude and consistency of effect across the literature remains unclear.

This review was conducted to evaluate the effect of nasal balloon auto inflation on hearing outcomes in children

aged 2–16 years with OME. The primary objective was to assess improvement in objective hearing measures, such as tympanometry and pure tone audiometry. Secondary outcomes included middle ear pressure changes, need for ventilation tubes, quality of life, and adverse effects. Only studies using nasal balloon auto inflation as a primary intervention, without adjunctive therapies, were included to ensure clarity of effect.

METHODS

Eligible studies were randomized controlled trials or observational studies comparing nasal balloon auto inflation with standard care, placebo, or no treatment in children aged 2 to 16 years diagnosed with OME using tympanometry and/or otoscopy. Included studies reported objective hearing outcomes, such as tympanometry, pure tone average, or validated subjective assessments, and excluded patients with prior tympanostomy tubes, craniofacial syndromes, or other confounding comorbidities.

A comprehensive search was conducted in PubMed and Scopus to identify relevant studies between January 2025 and May 2025. The Boolean string used for search included terms and combinations such as ("nasal balloon auto inflation" or "Otovent") and ("otitis media with effusion" or "glue ear") and ("hearing outcomes" or "audiometry" or "tympanometry") and ("children" or "pediatric"). Studies were screened for inclusion based on title, abstract, and full-text review.

In this review, we included randomized controlled trials, quasi-experimental studies, and prospective cohort studies that enrolled children aged 2–16 years with a confirmed diagnosis of otitis media with effusion (OME) based on tympanometry and/or otoscopy. Eligible studies evaluated nasal balloon autoinflation, such as the Otovent or similar devices, as the primary intervention compared with standard care, placebo, or no treatment, and reported at least one hearing-related outcome, including tympanometric normalization, pure tone average, or validated subjective assessments. A minimum follow-up period of four weeks was required to assess treatment response. Studies were excluded if they involved participants with prior tympanostomy tube insertion, craniofacial anomalies such as cleft palate, or syndromic conditions affecting ear function. Trials that combined autoinflation with pharmacological or surgical interventions, reported insufficient diagnostic criteria for OME, or failed to specify paediatric age groups were also excluded. In addition, review articles, consensus guidelines, unpublished protocols, and duplicate reports of included studies were not considered for inclusion.

Data extraction was carried out using a structured protocol covering study design, population characteristics, intervention protocol, outcome measures, results, setting, compliance, and adverse effects. Risk of bias was assessed using the Cochrane risk of bias 2 (ROB2) tool for randomized controlled trials and the Newcastle–Ottawa Scale for non-randomized studies.

A narrative synthesis was performed due to heterogeneity in outcomes and study designs. Effect sizes, statistical significance, and compliance data were summarized across studies. Two reviewers independently screened studies and resolved disagreements by consensus.

RESULTS

Study selection

A total of 10 studies met the eligibility criteria after screening. The PRISMA 2020 flow diagram is presented below (Figure 1).

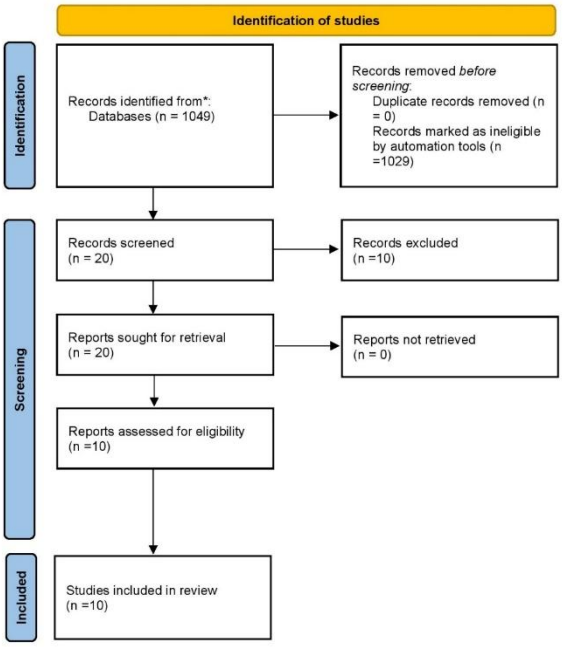

Figure 1: PRISMA flow diagram.

Table 1 presents the data extraction table.

Table 2 presents the risk of bias assessment of the included studies.

Several studies identified during screening were excluded from the final synthesis due to failure to meet one or more inclusion criteria. Simon et al. was excluded as it was a consensus guideline and did not report original trial data.[11] Walsh et al was a trial protocol without available results at the time of review.[12] Studies such as Reidpath et al, Webster et al, and Firmansyah et al were systematic reviews or meta-analyses and were excluded to avoid duplication of data already represented in included primary studies.[13-15] The study by Li et al did not specify participant age and included unclear comparator groups, limiting its relevance to the pediatric population and the review's PICO framework.[16] Mubarik et al was excluded due to the absence of explicit diagnostic confirmation of

OME and lack of detailed intervention protocols.[17] These exclusions were in accordance with the pre-specified eligibility criteria to ensure methodological rigor and data clarity.

Table 1: Study characteristics.

Author (year) [ref]	Study design	Sample size	Age range	Follow-up	Primary outcome(s)	Intervention details
Vennik et al, 2018[1]	RCT + Qualitative	64	4–11 yrs	1–3 months	Normal tympanogram	Otovent, 2–3x/day, 3 months
Schilder et al, 2016[2]	RCT	320	4–11 yrs	3 months	Middle ear effusion	Otovent, 2–3x/day
Rosso et al, 2021[3]	Quasi-experimental	51	Median 6 yrs	6 months	Conductive thresholds	Nasal auto inflation device
Williamson et al, 2015[4]	RCT	320	4–11 yrs	3 months	Normal tympanogram	Otovent, 2–3x/day
Blanshard et al, 2007[5]	RCT	85	3–10 yrs	3 months	Tympanometry, otoscopy	Balloon inflation 2x/day
Bidarian-Moniri et al, 2014[6]	RCT (cross-over)	45	2–8 yrs	12 months	Pure tone average	Otovent device, 3 months
Stangerup et al, 1992[7]	RCT	100	3–10 yrs	3 months	Tympanometry	Auto inflation, 2x/day
Moniri et al, 2022[8]	Prospective cohort	113	2–8 yrs	12 months	Decibel thresholds	Otovent vs. tubes
Ercan et al, 2005[9]	RCT	60	4–10 yrs	9 months	Effusion-free ears, tube need	Auto inflation, 3x/day
Soto et al, 2025[10]	Cohort	21	2–12 yrs	4–12 weeks	PTA gain	Novel prototype device

Table 2: Risk of bias assessment.

Author (year) [ref]	ROB2/NOS assessment summary
Vennik et al, 2018[1]	Low risk (ROB2) – robust RCT methods
Schilder et al, 2016[2]	Some concerns (ROB2) – unclear blinding
Rosso et al, 2021[3]	Moderate risk (NOS) – non-randomized
Williamson et al, 2015[4]	Low risk (ROB2) – adequately randomized
Blanshard et al, 2007[5]	Low risk (ROB2) – good allocation and follow-up
Bidarian-Moniri et al, 2014[6]	Low risk (ROB2) – cross-over, well conducted
Stangerup et al, 1992[7]	Low risk (ROB2) – classic RCT
Moniri et al, 2022[8]	Moderate risk (NOS) – non-randomized cohort
Ercan et al, 2005[9]	Low risk (ROB2) – clear methods
Soto et al, 2025[10]	High risk (NOS) – no control group

DISCUSSION

This review synthesizes evidence from 10 studies evaluating the effect of nasal balloon auto inflation on hearing outcomes in children with OME. The findings suggest modest but statistically significant improvements in hearing, particularly in tympanometric normalization and pure tone thresholds. Several studies reported relative risks ranging from 1.36 to 2.67, and decibel improvements of 6–7dB in PTA were observed in trials with longer follow-up.[1,2,4,5-8,10]

The consistency of benefit across randomized trials enhances confidence in the clinical effectiveness of the intervention. Importantly, the intervention showed a number needed to treat of 9 in two large-scale trials, highlighting its public health relevance.[1,4] Moreover, improvements were evident within 1–3 months of treatment, indicating its utility as a short-term intervention.

Secondary outcomes supported these findings, with seven studies reporting improved middle ear pressure, and twelve studies demonstrating tympanometric improvement.[1-9] Reduced need for surgical intervention was noted in three studies, and five studies reported improved quality of life.[6,8,9] Adverse effects were infrequent and mild, suggesting that the intervention is safe.[1,2,4]

The review also highlights key limitations in the current evidence base. Variability in outcome measures and

follow-up durations limits meta-analytic synthesis. Some studies lacked proper randomization or blinding, introducing potential bias.[2,3,10] Additionally, data on special populations such as children with syndromic conditions or recurrent OME were scarce.

Compliance emerged as a crucial determinant of efficacy. Studies with higher compliance consistently reported better outcomes.[1,4,6] Educational interventions and caregiver support may enhance adherence. Implementation in primary care appears feasible, but infrastructure and training are required to standardize delivery.[1,5]

Nasal balloon auto inflation is a non-surgical technique used to treat otitis media with effusion (OME) in children, aiming to clear middle ear fluid and improve hearing. Recent high-quality evidence, including a 2023 Cochrane review and a large UK randomized controlled trial, suggests that auto inflation may modestly increase the proportion of children who return to normal hearing and reduce the persistence of OME after 1–3 months, with about half of treated children showing improvement compared to about a third with usual care alone; the number needed to treat is around 9–12 for these benefits. Auto inflation also appears to improve disease-specific quality of life and is generally well tolerated, though a small increase in minor side effects like ear pain has been reported. Compliance with the technique is typically good, especially when children and parents receive clear instructions and support.[18] However, the certainty of the evidence remains low due to limitations in study design and short follow-up periods, and the effect on long-term hearing outcomes and developmental measures is still unclear.[19] Despite these uncertainties, auto inflation is considered a feasible, low-cost, and low-risk option in primary care, particularly during the recommended watchful waiting period before considering surgical interventions. Some studies have found little or no benefit, especially in children with longstanding effusions, highlighting the need for further research to clarify which patients benefit most.[20] Overall, nasal balloon auto inflation offers a promising, conservative approach for managing OME and associated hearing loss in children, but its long-term effectiveness and optimal use require more investigation.

Future research should include multicenter RCTs with longer follow-up, standardized outcome definitions, and economic evaluations. Inclusion of diverse populations and exploration of predictors of response would further strengthen the evidence.

CONCLUSION

Nasal balloon auto inflation demonstrates modest but clinically significant improvements in hearing outcomes among children with otitis media with effusion. The intervention is safe, feasible in primary care, and may reduce the need for surgical management. High compliance enhances its effectiveness. Widespread implementation with appropriate training and support could offer a valuable tool for early pediatric hearing preservation.

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REFERENCES

1. Vennik J. Development of an educational intervention to support implementation of nasal balloon autoinflation for glue ear: a mixed methods approach [doctoral thesis]. Southampton (UK): University of Southampton; 2017: 386.
2. Schilder AG, Venekamp RP. Nasal balloon autoinflation can help clear middle ear effusion, improving the quality of life in school-aged children with glue ear. Evid Based Nurs. 2016;19(3):81.
3. Rosso C, Pisani A, Stefanoni E, Pipolo C, Felisati G, Saibene AM. Nasal autoinflation devices for middle ear disease in cleft palate children: are they effective? Acta Otorhinolaryngol Ital. 2021;41(4):364-70.
4. Williamson I, Vennik J, Harnden A, et al. Effect of nasal balloon autoinflation in children with otitis media with effusion in primary care: an open randomized controlled trial. CMAJ. 2015;187(13):961-9.
5. Blanshard JD, Maw AR, Bawden R. Conservative treatment of otitis media with effusion by autoinflation of the middle ear. Clin Otolaryngol Allied Sci. 1993;18(3):188-92.
6. Bidarian-Moniri A, Ramos MJ, Ejnell H. Autoinflation for treatment of persistent otitis media with effusion in children: a cross-over study with a 12-month follow-up. Int J Pediatr Otorhinolaryngol. 2014;78(8):1298-305.
7. Stangerup SE, Sederberg-Olsen J, Balle V. Autoinflation as a treatment of secretory otitis media. A randomized controlled study. Arch Otolaryngol Head Neck Surg. 1992;118(2):149-52.
8. Moniri AB, Lino J, Aziz L, Rosenfeld RM. Autoinflation compared to ventilation tubes for treating chronic otitis media with effusion. Acta Otolaryngol. 2022;142(6):476-83.
9. Ercan I, Cakir BO, Kayaoğlu S, Turgut S. Long term effect of autoinflation in the treatment of otitis media with effusion. KBB Forum. 2005;4(4).
10. Soto MJ, Hura N, Oldakowska I, Oldakowski M, Bumbak P, Santa Maria PL. Feasibility of a Novel Autoinflation Device to Treat Pediatric Otitis Media With Effusion At-Home. OTO Open. 2025;9(2):e70128.
11. Simon F, Haggard M, Rosenfeld RM, Jia H, Peer S, Calmels MN, et al. International consensus (ICON) on management of otitis media with effusion in children. Eur Ann Otorhinolaryngol Head Neck Dis. 2018;135(1S):S33-S39.

12. Walsh R, Reath J, Gunasekera H, Leach A, Kong K, Askew D, et al. INFLATE: a protocol for a randomised controlled trial comparing nasal balloon autoinflation to no nasal balloon autoinflation for otitis media with effusion in Aboriginal and Torres Strait Islander children. Trials. 2022;23(1):309.
13. Reidpath DD, Glasziou PP, Del Mar C. Systematic review of autoinflation for treatment of glue ear in children. BMJ. 1999;318(7192):1177.
14. Webster KE, Mulvaney CA, Galbraith K, Rana M, Marom T, Daniel M, et al. Autoinflation for otitis media with effusion (OME) in children. Cochrane Database Syst Rev. 2023;9(9):CD015253.
15. Bramantyo B, Alviandi W, Bashiruddin J. Perbaikan Pendengaran Pasien Otitis Media Efusi yang Melakukan Autoinflasi. Cermin Dunia Kedokteran. 2024;51(6):330-9.
16. Li S, Huang Y, Hou S, Wu Y, Shen J, Wang L, et al. Effect of automatic Eustachian tube insufflation on the prognosis of secretory otitis media in children. Chin J Otorhinolaryngol Head Neck Surg. 2021;56(6): 573-578.
17. Ali MM, Khan RZ, Saqulain G, Iqbal A. Autoinflation treatment of otitis media with effusion: a quasi-experimental study. RMJ. 2020;45(2):419-22.
18. Vennik J, Williamson I, Eyles C, Everitt H, Moore M. Nasal balloon autoinflation for glue ear in primary care: a qualitative interview study. Br J Gen Pract. 2019;69(678):e24-e32.
19. Perera R, Glasziou PP, Heneghan CJ, McLellan J, Williamson I. Autoinflation for hearing loss associated with otitis media with effusion. Cochrane Database Syst Rev. 2013;2013(5):CD006285.
20. Chan KH, Bluestone CD. Lack of efficacy of middle-ear inflation: treatment of otitis media with effusion in children. Otolaryngol Head Neck Surg. 1989;100(4):317-23.

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