

Original Research Article

## A PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE PROGNOSTIC FACTORS AND EARLY OUTCOMES OF PAEDIATRIC TYMPANOPLASTY

Received : 26/11/2025  
Received in revised form : 05/01/2026  
Accepted : 21/01/2026

**Keywords:**  
Child; Hearing Loss; Otitis Media,  
Suppurative; Treatment Outcome;  
Tympanoplasty.

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DOI: 10.47009/jamp.2026.8.1.88

Source of Support: Nil,  
Conflict of Interest: None declared

*Int J Acad Med Pharm*  
2026; 8 (1); 465-469

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### ABSTRACT

**Background:** Chronic otitis media (COM) is a major cause of preventable conductive hearing loss in children. Tympanoplasty aims to achieve tympanic membrane perforation closure and hearing restoration, but outcomes in children remain variable. This study aimed to evaluate the early anatomical and functional outcomes of paediatric tympanoplasty and to analyse factors associated with these outcomes. **Materials and Methods:** This prospective observational cohort study was conducted in the Department of ENT, Government Vellore Medical College Hospital, Vellore, from August 2024 to October 2025. Forty-two children below 18 years of age with mucosal type chronic otitis media underwent tympanoplasty. Demographic profile, clinical characteristics, intraoperative findings, and postoperative outcomes were analysed. The primary outcomes were graft uptake and hearing improvement were assessed at three months postoperatively. **Result:** 61.9% were males and aged 3–17 years; 66.7% belonged to low socioeconomic groups, 64.3% had adenoid hypertrophy and bilateral disease, and 47.6% had recurrent respiratory infections. Large perforations were most common (59.5%). The ossicular chain was normal in 81%; incus erosion was seen in 14.3%. A postaural approach was used in 97.6%, and tympanoplasty alone was performed in 66.7%, with adenoidectomy/adenotonsillectomy added in 23.8%. No facial nerve palsy or nystagmus occurred; wound complications were seen in 2.4%. At 3 months, graft uptake was 97.1%. Hearing improved significantly in small/moderate perforations (33 to 22 dB;  $p=0.016$ ) and in large/subtotal perforations (39 to 23 dB;  $p=0.001$ ), with an overall air–bone gap improvement of 73.5%.

**Conclusion:** Paediatric tympanoplasty demonstrates excellent early outcomes with high graft uptake rates and significant hearing improvement. Early surgical intervention is recommended to prevent long-term hearing impairment and its impact on speech and academic development.



### INTRODUCTION

Chronic otitis media (COM) is defined as a chronic suppurative inflammation of the middle ear cleft structures and is one of the main causes of persistent ear discharge and hearing impairment in paediatrics.

It is broadly categorised into mucosal disease, which usually presents with a perforation in the pars tensa of the tympanic membrane, and squamous disease, which presents with cholesteatoma or a retraction pocket of the tympanic membrane.<sup>[1,2]</sup> COM usually causes mild to moderate conductive hearing loss if

left untreated, which then contributes to communicative and developmental deficits in children. In India, up to 77% of COM cases have been reported to have hearing impairment, suggesting limited access to proper treatment.<sup>[3]</sup>

Tympanoplasty is one of the main surgical treatment option for tubotympanic type COM, particularly aiming for anatomical closure of the tympanic membrane perforation and functional improvement in hearing.<sup>[4]</sup> In children, the outcomes of tympanoplasty have been considered less predictable compared with adults. This is due to the unique anatomical and physiological factors, such as immature Eustachian tube function, frequent upper respiratory tract infections, and variable middle ear aeration. The success rates of tympanoplasty in paediatric populations range from 35 to 94%, and the outcomes depend on a combination of patient-, disease-, and surgery-related factors.<sup>[5]</sup>

The early outcomes of tympanoplasty, such as graft uptake and hearing improvement, assessed in the post-operative period, are main markers in paediatrics, as they help in analysing the effectiveness of surgery and can predict longer-term outcomes. Successful graft merging restores tympanic membrane integrity, reduces the risk of recurrent infections, and improves conductive hearing pathways, thereby providing both disease eradication and functional rehabilitation.<sup>[6]</sup> Though commonly used, factors that influence surgical success, such as age and Eustachian tube function, perforation size and site, contralateral ear status, presence of adenoid hypertrophy, and status of the middle ear at the time of surgery, have different results across the studies. The age and size of perforation, condition of the opposite ear, and surgeon experience are considered to affect tympanoplasty outcomes, whereas other factors such as adenoidectomy and perforation site have shown inconsistent effects.<sup>[5,6]</sup> Even with this incomplete knowledge, the early tympanoplasty was considered in children, as the prolonged disease duration and recurrent discharge increase the risk of persistent perforation and ossicular chain damage, leading to irreversible conductive hearing loss. Early surgical repair supports children's cochlear reserve and reduces the adverse developmental effects of hearing loss, including delayed speech and language acquisition, reduced academic achievement, and impaired social integration.<sup>[7]</sup>

The identification and stratification of prognostic factors influencing early success helps clinicians to better understand which patient- and disease-related factors could possibly impact surgical outcomes in the paediatric population. However, the data about the prognostic factors provided in the previous studies have a heterogeneous nature. Hence, this study aims to evaluate the early outcomes of paediatric tympanoplasty and to analyse the various factors that may contribute to these early outcomes.

## MATERIALS AND METHODS

This prospective observational cohort study was conducted in the Department of Otorhinolaryngology at Government Vellore Medical College Hospital, Vellore, from August 2024 to October 2025, after obtaining approval from the Institutional Review Board of Government Vellore Medical College Hospital, Vellore.

### Inclusion and exclusion criteria

Children aged < 18 years presenting to the ENT outpatient department with chronic otitis media of the mucosal type were included. Children with revision tympanoplasty, cholesteatoma, only hearing ear, or those not willing to undergo surgery were excluded.

### Methods

Written informed consent was obtained from parents or legal guardians, and assent was obtained from the children wherever applicable. Detailed demographic data, clinical history, and otorhinolaryngological examination were performed. Otoscopic evaluation was carried out to assess the tympanic membrane and document the characteristics of the perforation. Hearing assessment was performed using pure tone audiometry to determine the presence, type, and severity of hearing loss. The status of the contralateral ear was assessed using tympanometry, and evaluation of adenoid hypertrophy, Eustachian tube function, and paranasal sinus pathology was also undertaken as part of the preoperative assessment. All the children included had normal external ears, and no one had active ear discharge at the time of surgery. All children underwent tympanoplasty, and intraoperative findings were documented. Clinical and audiological assessments were performed preoperatively and during follow-up using standardised instruments. All evaluations were conducted by trained personnel following uniform assessment protocols.

Postoperatively, all children were discharged on the second postoperative day. Follow-up assessments were conducted on the 8th postoperative day and at three months postoperatively in the ENT outpatient department, during which postauricular wound status, presence of ear discharge or bleeding, and suture site were evaluated, and sutures were removed during the first follow-up visit. Improvement in hearing was assessed using pure tone audiometry at three months post-surgery.

### Statistical Analysis

Data were analysed using SPSS version 29. Continuous variables were summarised as mean  $\pm$  standard deviation and categorical variables as frequencies and percentages. Pre- and postoperative hearing levels were compared using the paired t-test, while categorical variables were analysed using the Chi-square or Fisher's exact test as appropriate. A p-value < 0.05 was considered statistically significant.

## RESULTS

The mean age was 11 years, ranged from 3-17 years, with the majority being males (61.9%). 97.6% of the

children presented with a history of ear discharge, 35.7% had bilateral ear discharge, and 76.2% had a history of hard-of-hearing. [Table 1]

**Table 1: Demographic and baseline clinical characteristics**

Variable	Category	Number	Percentage
Sex	Male	26	61.90%
	Female	16	38.10%
Presenting symptoms	Ear discharge	41	97.60%
	Bilateral ear discharge	15	35.70%
	Hard of hearing	32	76.20%

Low socioeconomic status was present in 66.7% of children, while adenoid hypertrophy and bilateral disease were each observed in 64.3%. Recurrent respiratory tract infections occurred in 47.6%, family smoking exposure in 35.7%, and nasal allergy in 28.6%. Tonsillar enlargement and Eustachian tube dysfunction were noted in 23.8% each, whereas otitis

media with effusion and cleft palate were rare (2.4% each). Regarding the contralateral ear, prior cortical mastoidectomy and adenoidectomy were each reported in 11.9%, previous tympanoplasty in 9.5%, adenotonsillectomy in 7.1%, and myringotomy with grommet insertion in 2.4% of cases. [Table 2]

**Table 2: Clinical risk factors and contralateral ear status**

Variables		Number	Percentage
Associated risk factors	Adenoid hypertrophy	27	64.30%
	Tonsillar enlargement	10	23.80%
	Eustachian tube dysfunction	10	23.80%
	Otitis media with effusion	1	2.40%
	Cleft palate	1	2.40%
	Bilaterality	27	64.30%
	Nasal allergy	12	28.60%
	Recurrent respiratory tract infection	20	47.60%
	Low socioeconomic status	28	66.70%
	Smoking habit in family	15	35.70%
Contralateral ear history	Previous cortical mastoidectomy	5	11.90%
	Previous tympanoplasty	4	9.50%
	Myringotomy with grommet insertion	1	2.40%
	Previous adenoidectomy	5	11.90%
	Previous adenotonsillectomy	3	7.10%

Large perforations were seen in 59.5% of cases, followed by moderate perforations in 28.6%, while small and subtotal perforations were uncommon (4.8% each). The middle ear mucosa was normal in 76.2% of children, with polypoidal changes in 19% and oedematous mucosa in 4.8%. Tympanosclerosis was present in 35.7% of cases. The ossicular chain

was normal and mobile in 81% of patients. Incus erosion was observed in 14.3%, and partial malleus erosion in 7.1%. A foreshortened handle of the malleus was noted in 52.4% of cases. The stapes suprastructure was normal in all patients (100%), while stapes head granulations were seen in 4.8% of cases. [Table 3]

**Table 3: Tympanic membrane, middle ear, and ossicular findings**

Variable	Category	Number	Percentage
Perforation size	Small	2	4.80%
	Moderate	12	28.60%
	Large	25	59.50%
	Subtotal	2	4.80%
Middle ear mucosa	Normal	32	76.20%
	Polypoidal	8	19%
	Oedematous	2	4.80%
Tympanosclerosis	Present	15	35.70%
Ossicular chain	Normal and mobile	34	81%
Incus erosion	Present	6	14.30%
Partial malleus erosion	Present	3	7.10%
Foreshortened handle of malleus*	Present	22	52.40%
Stapes suprastructure	Normal	42	100%
Stapes head granulations	Present	2	4.80%

Surgery was performed more frequently on the left ear (54.8%) than the right (45.2%). A postaural approach was used in the vast majority of cases

(97.6%), with a transcanal approach employed in 2.4%. Tympanoplasty alone was the most common procedure (66.7%), followed by tympanoplasty with

adenoidectomy (19%) and tympanoplasty with adenotonsillectomy (4.8%); cortical mastoidectomy was performed in 7.1% of patients. Canal overhang

removal was required in 28.6% of cases. The chorda tympani nerve and facial canal were preserved and normal in all patients (100%), respectively. [Table 4]

**Table 4: Surgical profile of the study population**

Variable	Category	Number	Percentage
Side of surgery	Left ear	23	54.80%
	Right ear	19	45.20%
Surgical approach	Postaural	41	97.60%
	Transcanal	1	2.40%
Type of surgery performed	Tympanoplasty	28	66.70%
	Tympanoplasty + adenoidectomy	8	19%
	Tympanoplasty + adenotonsillectomy	2	4.80%
	Cortical mastoidectomy	3	7.10%
Canal overhang removal	Done	12	28.60%
Chorda tympani	Preserved	42	100%
Facial canal	Normal	42	100%

No immediate postoperative complications such as facial nerve palsy or nystagmus were observed. Unhealthy post-aural wound or wound dehiscence occurred in 2.4% of cases. At 3-month follow-up, 81% of patients were reviewed, all of whom had a healthy post-aural wound (100%). Successful graft

uptake was achieved in 97.1% of patients, while 2.9% showed a residual perforation with a medialised graft. [Table 5] All those children who had a history of surgery in the contralateral ear were asymptomatic in the operated ear.

**Table 5: Early postoperative outcomes and hearing results**

Outcome		Number	Percentage
Immediate postoperative complications	Facial nerve palsy	0	0%
	Nystagmus	0	0%
	Unhealthy post-aural wound/wound dehiscence	1	2.40%
Follow-up at 3 months	Patients reviewed	34	81%
	Healthy post-aural wound	34	100%
Graft uptake status	Successful graft uptake	33	97.10%
	Residual perforation with medialised graft	1	2.90%

Children with small and moderate perforations showed a significant improvement in hearing, with mean hearing levels improving from 33 dB preoperatively to 22 dB postoperatively ( $p = 0.016$ ). Similarly, the large and subtotal perforation group demonstrated a marked hearing gain, with average hearing levels improving from 39 dB to 23 dB ( $p =$

0.001) (Table 6). The corresponding mean hearing gain was 11 dB in the small and moderate perforation group and 16 dB in the large and subtotal perforation group. The overall percentage of hearing improvement in terms of air–bone gap was 73.5%. [Table 6]

**Table 6: Comparison of pre and postoperative average hearing levels according to perforation size**

Perforation size group	Average hearing level (dB)		p value
	Preoperative	Postoperative	
Small and moderate perforation group	33	22	0.016
Large and subtotal perforation group	39	23	0.001

## DISCUSSION

This study evaluated the early anatomical and functional outcomes of tympanoplasty in paediatric patients with mucosal-type COM. There was a predominance of large perforations and associated risk factors, the procedure achieved a high graft uptake rate and significant hearing improvement across all perforation sizes. Both small/moderate and large/subtotal perforation groups showed significant postoperative hearing improvements, and the overall complication rate was minimal.

All the children were aged between 3–17 years, and most of them were males. Ear discharge was the most common presenting symptom, with bilateral involvement in and most children had hearing

difficulty. Most reported with adenoid hypertrophy, bilateral disease, and recurrent respiratory tract infections. Regarding the contralateral ear history, only a few had previous cortical mastoidectomy and adenoidectomy, tympanoplasty, and adenotonsillectomy. Similarly, Collins et al., who evaluated paediatric tympanoplasty in children aged 3–18 years and found that chronic otorrhoea and conductive hearing loss were the most common presenting complaints, with a predominance of bilateral disease and male patients. They emphasised that a stable, dry contralateral ear, whether previously operated or not, often shows better overall middle ear function and may indicate a more favourable environment for tympanic membrane healing.<sup>8</sup> Baklaci et al. reported that the majority of children

undergoing type I tympanoplasty presented with long-standing ear discharge and hearing impairment. Upper respiratory tract infections, adenoid hypertrophy, and poor Eustachian tube function are the main reasons for poorer outcomes in paediatric tympanoplasty.<sup>[5]</sup> Thus, the demographic and clinical characteristics of our study are consistent with previous studies.

In our study, large tympanic membrane perforations were predominant, followed by moderate perforations. The ossicular chain was normal and mobile in most; incus erosion and partial malleus erosion were observed in a few. Surgery was performed predominantly via a post-aural approach. Tympanoplasty alone was commonly performed; the facial canal and chorda tympani were preserved in all patients. Similarly, Collins et al. performed 97% of paediatric tympanoplasties through a postauricular approach and found a normal ossicular chain in 75% of ears, with incus erosion and malleus erosion/foreshortening being the frequent ossicular abnormalities.<sup>[8]</sup>

Mallouk et al. used the retro-auricular approach in 95 children undergoing type I tympanoplasty and found a preserved and intact ossicular chain in all operated ears.<sup>[9]</sup> Thus, our findings and previous studies report that type I tympanoplasty can be performed safely and preserve ossicular integrity in most cases, even with large perforations. The favourable anatomical and functional outcomes observed in this study may be attributed to careful patient selection, exclusion of active infection at the time of surgery, and the use of a standardised surgical technique. The predominance of intact ossicular chains and preserved middle ear mucosa in most patients may have contributed to improved graft uptake and hearing outcomes.

In our study, no facial nerve palsy or nystagmus was observed postoperatively, and wound-related complications occurred in only 2.4% of cases. At three months, the graft uptake rate was 97.1%. Hearing outcomes showed significant improvement in both perforation groups, from 33 dB to 22 dB in small/moderate perforations and from 39 dB to 23 dB in large/subtotal perforations, with an overall air–bone gap improvement of 73.5%. Baklaci et al. observed an overall graft success rate of 86.3% and a functional success rate of 74.5%, with significant postoperative improvement in the air–bone gap.<sup>5</sup> Similarly, Rahaman et al. reported a graft uptake rate of 90.9% at three months and a significant reduction in mean air–bone gap from 24.05 dB preoperatively to 11.64 dB postoperatively ( $p < 0.001$ ). Whereas none of them reported any complications.<sup>[10]</sup> Thus, suggesting that paediatric tympanoplasty not only achieves high early graft uptake rates but also provides hearing improvement, while maintaining a very low rate of major postoperative complications. The results indicate that early tympanoplasty in carefully selected paediatric patients with mucosal-type chronic otitis media can achieve favourable early anatomical and functional outcomes with

minimal complications. Future multicentric studies with larger cohorts and extended follow-up are required to evaluate long-term outcomes and to clarify the effect of patient- and disease-related factors on surgical success.

### Limitations

This study was conducted at a single centre with a relatively small sample size and a short follow-up period, which may limit the generalisability of the findings and precludes assessment of long-term graft integrity and sustained hearing outcomes.

## CONCLUSION

Tympanoplasty in paediatric patients with mucosal-type chronic otitis media is associated with favourable early anatomical and functional outcomes when performed under appropriate clinical conditions. High graft uptake rates and significant hearing improvement were achieved across different perforation sizes, with a low incidence of early postoperative complications. These findings support the role of early surgical intervention in carefully selected children to restore hearing and improve middle ear health.

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