

## Serous otitis media as a cause for language delay following cleft palate repair—A case-control study

### ABSTRACT

**Background and Objectives:** Serous otitis media (SOM), also called otitis media with effusion (OME) or glue ear, is a collection of non-purulent fluid within the middle ear space. Children with cleft palate are more prone to develop this condition. This is caused by impaired eustachian tube function in cleft palate. They may present with hearing loss, delayed speech, and language development or poor social behavior. This is a significant cause of conductive hearing loss in the early speech-forming years of their life. Even after an early surgical repair of palate, speech and language defects are frequently identified during regular postoperative follow-up by speech-language pathologists. When identified, the approach to language delay varies across healthcare systems and includes watchful waiting, providing hearing aids to early otological intervention. The primary objective was to compare the incidence of SOM in children with and without language delay following surgical correction of cleft palate.

**Materials and Methods:** A case-control study involving 63 patients was conducted in a tertiary care hospital with a high-volume cleft lip and palate center from June 2022 to March 2023. Thirty children with language delay were identified and grouped as cases and 33 children without language delay as controls. Tympanogram was conducted after the detailed otoscopic examination. Those with Jerger types B and C were diagnosed with SOM. The incidence of SOM in each group was compared statistically.

**Results:** About 70% of cases and 87.9% of controls had SOM. There is no positive correlation between the incidence of SOM and language delay ( $P$ -value > 0.05).

**Conclusion:** SOM cannot be identified as a causal factor for language delay after cleft palate surgery.

**Keywords:** Cleft palate repair, language delay, otitis media with effusion, serous otitis media, ventilation tube

### BACKGROUND

Serous otitis media (SOM), also known as secretory otitis media, otitis media with effusion (OME) or glue ear, is common in pediatric age-groups and is caused by the collection of non-purulent fluid within the middle ear space. Up to 80% of children are affected by this condition by the age of 4 years, though the majority of it resolve within a few months.<sup>[1]</sup> It is known to be a major cause of acquired hearing loss in preschool children.

Children with cleft palate are more prone to develop SOM due to defective functioning of the Eustachian tube.<sup>[2-4]</sup> Children diagnosed with cleft palate are found to develop significant conductive hearing loss in the early speech-forming years of

their life due to this middle ear pathology.<sup>[5]</sup> This is thought to cause delayed speech and language development and poor social behavior.<sup>[3]</sup> Even after an early surgical repair of cleft palate, speech and language defects are frequently seen to persist. Postoperatively, these children are kept under

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long-term follow-up by speech-language pathologists for identification and assessment of these defects.

Speech problems and language delay are frequently identified during the follow-up period. Though cleft lip and palate do not affect the cognitive development of a child directly, language problems are a common association. Studies have shown that delays in language acquisition can affect receptive as well as productive language skills.<sup>[6]</sup> The contribution of SOM to the development of language delay has not been much studied. We aim to compare the incidence of SOM in children with and without language delay following surgical correction of cleft palate. There are varied opinions regarding the routine tympanostomy and ventilation tube placement following cleft palate repair.<sup>[5]</sup> According to many authors, regular audiological follow-up and surgical intervention if needed, in the early speech-forming years of the child, might reduce the development of language delay in cleft palate children.<sup>[5,7]</sup>

Our primary objective was to compare the incidence of SOM in patients with and without language delay after surgical repair of cleft palate. Our secondary objective was to find any correlation between the incidence of SOM and the presence of associated cleft lip.

## MATERIALS AND METHODS

The study was conducted in a tertiary teaching hospital with a dedicated cleft lip and palate center and a full-fledged audiology unit, from June 2022 to March 2023 after registering in the Clinical Trials Registry of India (CTRI/2022/06/043241). The study was approved to be conducted by the Institutional Ethics Committee. A retrospective pilot study was conducted with 20 cases, and the sample size was calculated.

The children undergoing cleft palate surgery in this center are kept on regular follow-up by a speech and language pathologist to identify the development of speech and language defects. The language development of the postoperative patients was assessed during one of their review visits at least 2 months after surgery. This was conducted using Receptive-Expressive Emergent Language Test (REEL) score,<sup>[8,9]</sup> and language delay was identified, if any.

- Inclusion criteria:
  - History of cleft palate repair
  - Age between 12 and 30 months
- Exclusion criteria:
  - Congenital hearing loss identified on neonatal screening.

- Syndromic association of cleft palate
- Psychomotor development disorders
- History of chronic/recurrent ear discharge
- History of ear surgery

Thirty children who met the inclusion criteria presenting to speech pathologists and diagnosed with language delay were taken as cases. Thirty-three children who met the inclusion criteria presenting to speech pathologists with normal language development on assessment were taken as controls. Informed consent was taken in both the groups.

After otoscopy examination and wax removal in indicated cases, we subjected these children to an audiological assessment by tympanometry. SOM was diagnosed with the presence of Jerger type B or C2 traces on tympanometry.<sup>[10]</sup> The incidence of SOM in children with and without language delay was compared by comparing cases and controls. The statistical analysis was performed using IBM SPSS software. Numerical variables were expressed as mean and standard deviation. Categorical variables were expressed as frequency and percentage.

## RESULTS

We collected data from 30 cases and 33 controls in the age-group of 12 to 33 months. Females were more in the case group (63.3%) when compared to controls (48.5%).

Type B and type C tympanograms are suggestive of SOM. In those with language delay, 70% had bilateral B or C type or unilateral B or C tympanograms. Thirty percent had type A, As, or Ad disease. Among controls, 87.9% had either unilateral or bilateral B or C types, whereas A, As, or Ad types of tympanogram were seen in only 12.1%. This showed that there is no significant increase ( $P$ -value = 0.053) in the presence of SOM among cases [Figure 1].

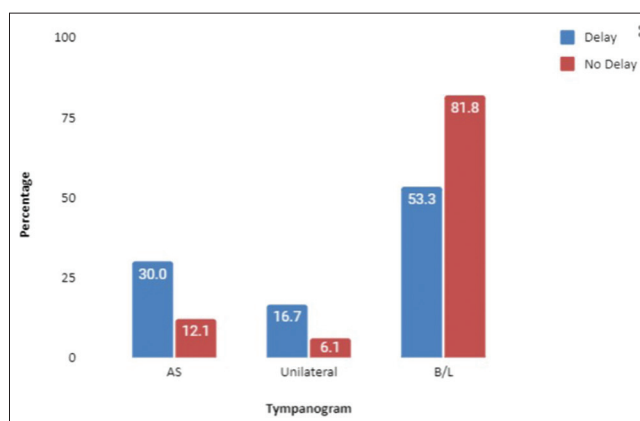


Figure 1: Incidence of serous otitis media in cases and controls

The presence of cleft lip and its association with the incidence of language delay were studied but we could not find any association between the presence of cleft lip and language delay [Figure 2]. Also, there was no significant association between SOM and the cleft lip [Table 1].

The age at which palate repair was conducted was also noted. The majority (76.7%) of children with language delay had undergone surgery at 12–18 months. In the control group, there was almost equal distribution between 6–12 months and 12–18 months of age-groups regarding the timing of surgery. This suggested an association between language delay and the timing of surgery ( $P$ -value 0.021).

## DISCUSSION

Orofacial clefts are one of the most common craniofacial malformations that affect the newborns. They are nonsyndromic in most cases and show variability across geographic origin, race, and ethnic groups. According to Salari *et al.*,<sup>[11]</sup> the global prevalence of cleft palate is 0.33 in every 1000 live births.

SOM is a common pediatric condition leading to mild conductive hearing loss. Children with cleft palate are more susceptible to develop this due to defective functioning of tensor veli palatini and levator veli palatini muscles.<sup>[12]</sup> The literature suggests that SOM occurs at least once before the first birthday in about 90% of children with cleft palate and can be persistent or recurrent and variable in degree, and it

can affect one or both ears.<sup>[6,13]</sup> The hearing loss in the early speech-forming years of life, though mild, is expected to have consequent effects on the child's linguistic and cognitive development as one loses acoustic clues especially those associated with vowel sounds.<sup>[12,13]</sup>

As language acquisition is one of the most important milestones in the development of a child, all factors contributing to language delay become important. There have been studies suggesting SOM as a causative factor for language delay. In our study, we did not find any positive correlation between the presence of SOM and language delay in postoperative children.

There have been varied opinions regarding the management of SOM in cleft palate. Different options, including watchful waiting, prescription of hearing aids, and myringotomy with ventilation tube insertion, have been in practice in different parts of the world. Many studies have been conducted in the past decades to ascertain the most appropriate way to manage SOM in these children. The Management of Otitis Media with Effusion in Children with Cleft Palate (MOMENT) study conducted in the United Kingdom in 2015 called for more research in this regard.<sup>[14]</sup>

According to the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF), clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for 3 months or longer. They have listed cleft palate as an at-risk group for developing speech and language problems due to SOM.<sup>[15,16]</sup> A meta-analysis by Chang *et al.*<sup>[17]</sup> (2022) suggests that ventilation tube insertion (VTI) is an effective procedure to prevent OME in patients with cleft palate and that VTI is beneficial when performed concurrently with palatal repair surgery but there is evidence against routine insertion of ventilation tubes.<sup>[18]</sup>

Updated guidelines by the National Institute of Clinical Excellence (NICE) published in August 2023<sup>[19]</sup> suggest treatment to be based on the needs and desires of children and their parents and that hearing should be reassessed after 3 months of diagnosis of SOM. The child will have check-ups during the 3-month review period during which parents and carers should actively support the child with hearing. During this time, it may resolve on its own, or if it worsens, another management option, such as hearing aids or surgery, may be advised. Autoinflation devices may also be recommended. They prefer the use of hearing aids in SOM children with hearing loss, which allow the child to

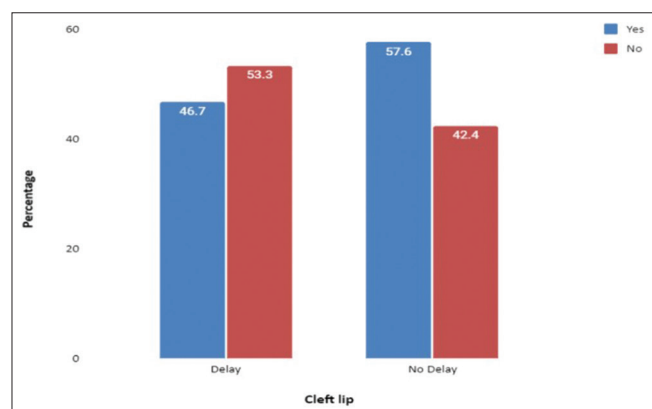


Figure 2: Presence of cleft lip in cases and controls

Table 1: Association between serous otitis media and the presence of cleft lip

Cleft lip	Tympanogram						$P$
	As		U/L		B/L		
	n	%	n	%	n	%	
Yes	7	21.2	3	9.1	23	69.7	0.866
No	6	20.0	4	13.3	20	66.7	

hear quieter speech when set up and used correctly. If the SOM with hearing loss persists after 3 months and the child is not symptomatically supported by conservative methods, tympanostomy and grommet insertion are advised after disk the risk of perforation of the eardrum, atelectasis, tympanosclerosis, and infection associated with grommets.

Recent studies from across the world attribute the language delay in children with cleft palate to multiple factors, such as defective auditory processing and reduced auditory attention skills.<sup>[20,21]</sup> Persistent cognitive linguistic defects and poor academic performance are commonly reported in cleft palate children, though many of them initially catch up with the early language delays. Some studies attribute this to brain abnormalities, mainly volumetric differences in the cerebrum and cerebellum, in the non-syndromic cleft palate. Further research is therefore recommended with multiple linguistic and developmental assessment tools.<sup>[22]</sup>

## CONCLUSION

SOM, though a common occurrence in children with cleft palate, cannot be identified as a cause for language delay in these children. So, routine tympanostomy and ventilation tube insertion during or following cleft palate repair is unlikely to improve this language deficit. Also, there was no association between the presence of cleft lip and SOM.

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## Conflicts of interest

There are no conflicts of interest.

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## PROFORMA

### Serous otitis media as a cause for language delay following cleft palate repair

1. Name and hospital no.
2. Age:
3. Sex:
4. Type of cleft palate:
  - Complete
  - Incomplete
5. Is it associated with cleft lip:
  - Yes.
  - No
6. Age at which palatal surgery was completed
  - Less than 6 months
  - 6–12 months
  - 12–18 months
  - Above 18 months
7. Whether language delay was identified on assessment?
  - Yes
  - No
8. History of earache/ear infections:
  - Yes
  - No
9. Have the parents noticed a hearing loss/lack of attention to sounds?
10. Type of tympanogram
  - A type. As type Ad type
  - B type. C type