

Accuracy of OAE as a Screening Test to Detect the Incidence of Hearing Loss in Normal and High-Risk New-borns

Authors:

Nivedita¹, Sushma Nayak², Vinay Kumar K³, Mahesh V⁴

¹Assistant professor, Department of ENT, Raichur Institute of Medical Sciences, Raichur.

²Associate professor, Adichunchanagiri institute of Medical Sciences, B.G.Nagara, Mandya District.

³Senior Resident, Department of Community Medicine, CIMS, Chamarajanagar, Karnataka, India.

⁴Associate Professor, Department of Community Medicine, CIMS, Chamarajanagar, Karnataka, India.

Corresponding Author:

Dr. Nivedita, Assistant professor, Department of ENT, Raichur Institute of Medical Sciences, Raichur, Karnataka
drniveditakavatekar@gmail.com

DOI: <https://doi.org/10.5281/zenodo.21990373>

Article Received: 01 July 2026, Accepted: 15 July 2026, Online First: 18 August 2026

ABSTRACT

Background: Hearing loss is one of the most common congenital sensory impairments and remains an important public health concern due to its long-term impact on speech, language, and cognitive development. Early identification through universal newborn hearing screening enables timely intervention and significantly improves developmental outcomes. Otoacoustic emissions (OAE) are widely used for initial screening, while Auditory Brainstem Evoked Response (BERA) serves as the diagnostic gold standard. However, the diagnostic performance of single-stage versus repeat OAE screening in comparison with BERA requires further evaluation, particularly in high-risk new-borns. **Objectives:** To assess the diagnostic accuracy of initial and repeat OAE screening compared with BERA, to determine the incidence of hearing loss among normal and high-risk new-borns, and to evaluate the association between selected perinatal risk factors and confirmed hearing loss. **Methods:** A prospective diagnostic accuracy study was conducted among 376 new-borns at a tertiary care hospital, CIMS, Chamarajanagar. All enrolled neonates underwent initial OAE screening within 7th to 10th day of birth, followed by repeat OAE after 1st month of first OAE. If both OAE results were refer, then confirmatory BERA done at 6months as the reference standard for confirmation of hearing loss. Demographic and perinatal risk factors were recorded. Diagnostic parameters including sensitivity, specificity, predictive values, likelihood ratios, diagnostic accuracy, and Cohen's kappa were calculated. Associations between hearing loss and risk factors were analyzed using Chi-square or Fisher's exact test. **Results:** The overall incidence of confirmed hearing loss was 4.26%, with a significantly higher prevalence among high-risk new-borns compared to normal-risk neonates (5.9% vs. 1.44%, $p = 0.038$). Initial OAE demonstrated a sensitivity of 56.25% and specificity of 96.39%, while repeat OAE showed improved sensitivity (81.25%) and specificity (97.50%). Diagnostic accuracy increased from 94.68% to 96.81%, with better agreement with BERA (kappa 0.67). Family history of hearing loss was significantly associated with confirmed hearing impairment. **Conclusion:** A two-stage OAE screening protocol followed by confirmatory BERA improves detection of neonatal hearing loss and is particularly effective in high-risk new-borns. Integration of repeat OAE into universal new-born hearing screening programs is recommended for early diagnosis and intervention.

Keywords: New-born hearing screening; Otoacoustic emissions; BERA; Diagnostic accuracy; High-risk neonates; Universal screening

INTRODUCTION

Hearing loss is one of the most common congenital sensory impairments, with a reported global incidence ranging from 1 to 6 per 1,000 live births, increasing substantially among high-risk neonates admitted to neonatal intensive care units (NICUs).¹ Early identification of hearing impairment is critical, as

undetected hearing loss during infancy can adversely affect speech, language, cognitive development, and psychosocial integration.² Evidence indicates that intervention initiated within the first six months of life significantly improves language outcomes, emphasizing the importance of universal newborn hearing screening (UNHS).³

Otoacoustic emissions (OAE) testing is widely used as a first-line screening tool in newborn hearing screening programs due to its non-invasive nature, rapid administration, and feasibility in large-scale population screening.⁴ OAE evaluates cochlear outer hair cell function and can be performed even in sleeping neonates. However, OAE results may be influenced by transient middle ear conditions, vernix, or ambient noise, potentially leading to false-positive results, particularly when performed soon after birth.⁵

Auditory Brainstem Evoked Response (ABR/BERA) testing is considered the gold standard for confirmation of neonatal hearing loss, as it objectively assesses neural conduction along the auditory pathway.⁶ While ABR provides higher diagnostic accuracy, its use as a universal screening tool is limited by higher cost, longer testing time, and need for technical expertise. Consequently, a two-stage screening protocol employing OAE followed by confirmatory ABR has been recommended by several international guidelines, including the Joint Committee on Infant Hearing (JCIH).⁷

Previous studies have demonstrated variability in the sensitivity and specificity of single-stage OAE screening, particularly among high-risk newborns, while repeat OAE testing has been shown to improve diagnostic performance and reduce false-positive rates.^{8–10} Indian studies have highlighted the feasibility of integrating OAE-based screening into routine neonatal care, especially in resource-constrained settings.^{11,12}

In this context, the present study was undertaken to evaluate the diagnostic accuracy of initial and repeat OAE screening compared with BERA, estimate the incidence of hearing loss among normal and high-risk newborns, and assess the association between selected perinatal risk factors and confirmed hearing loss.

MATERIALS AND METHODS

A hospital-based prospective diagnostic accuracy study was conducted in the Department of Otorhinolaryngology at a tertiary care teaching hospital, Chamarajanagar institute of medical sciences, Chamarajanagar over a period of one year. All live-born neonates delivered or admitted during the study period were considered eligible for inclusion. Newborns with external ear malformations preventing probe placement and those whose parents did not provide informed consent were excluded from the study. A total of 376 new-borns were enrolled using consecutive sampling after obtaining written informed consent from their parents or guardians.

Baseline demographic and perinatal details, including sex, gestational age, birth weight, mode of delivery, NICU admission, family history of hearing loss, consanguinity, and antenatal and postnatal risk factors, were recorded using a predesigned and pretested proforma. Newborns were classified as high-risk or

normal-risk based on the Joint Committee on Infant Hearing criteria.

All enrolled neonates underwent initial otoacoustic emission screening using transient evoked otoacoustic emissions within the early neonatal period i.e., within 7th to 10th day of birth in a quiet room. The test was performed while the neonate was naturally asleep or calm, and results were recorded as “pass” or “refer” based on the device’s automated criteria. If both OAE results were refer, then confirmatory BERA done at 6months as the reference standard for confirmation of hearing loss.

Auditory Brainstem Evoked Response (BERA) testing was performed as a confirmatory diagnostic procedure for newborns who underwent OAE screening. The evaluation included assessment of the presence, morphology, and reproducibility of auditory evoked potentials, with particular emphasis on the detection of Waves I, III, and V. Wave V detection threshold was measured to estimate hearing sensitivity, and responses were evaluated across appropriate stimulus intensities using standard electrophysiological protocols. Absolute wave latencies, interpeak intervals (I–III, III–V, and I–V), frequency-specific responses, and ear-specific findings were analyzed. Hearing loss was considered when there was absence of reproducible waveforms, elevated Wave V thresholds beyond recommended levels, or abnormal waveform morphology and latency patterns. All recordings were performed by trained audiology personnel under controlled conditions using standardized stimulus parameters, and BERA findings were used as the reference standard for confirmation of hearing impairment in newborns.

The diagnostic performance of both initial and repeat OAE screening was evaluated by calculating sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy, likelihood ratios, and Cohen’s kappa coefficient, with BERA findings taken as the gold standard. The incidence of hearing loss was estimated separately for high-risk and normal-risk new-borns.

Data were entered into Microsoft Excel and analyzed using SPSS version 22.0 (IBM SPSS Statistics, Somers, NY, USA). Categorical variables were summarized as frequencies and percentages, while continuous variables were expressed as mean and standard deviation. Associations between hearing loss and individual risk factors were assessed using the Chi-square test or Fisher’s exact test as appropriate. A p value of less than 0.05 was considered statistically significant.

The study protocol was reviewed and approved by the Institutional Ethics Committee, and all procedures were carried out in accordance with ethical principles for biomedical research involving human participants.

RESULTS

A total of 376 newborns were included in the study, of whom 196 (52.1%) were males and 180 (47.9%) were females. The mean gestational age of the newborns was 38.50 ± 1.47 weeks, and the mean birth weight was 2843.5 ± 436.4 g. Preterm births accounted for 13.0% of the study population, while 26.3% of newborns required NICU admission. A family history of hearing loss was present in 5.9% of cases, and consanguinity was reported in 12.5%. Antenatal and postnatal risk factors were identified in 21.8% and 16.8% of newborns, respectively, and 63.0% of the study population were classified as high-risk newborns (Table 1).

On comparison of initial OAE screening with BERA, 22 newborns were labeled as “refer” on OAE, of whom 9 were confirmed to have hearing loss on BERA. Among the 354 newborns who passed the initial OAE, 7 were found to have hearing loss on BERA. The sensitivity and specificity of initial OAE were 56.25% and 96.39%, respectively, with a diagnostic accuracy of 94.68%. The positive predictive value was 40.91%, while the negative predictive value was 98.02%. The agreement between initial OAE and BERA was moderate, with a Cohen’s kappa value of 0.45, and the association was statistically significant ($\chi^2 = 77.05$, $p < 0.001$) (Table 2).

Repeat OAE screening showed improved diagnostic performance, with 13 of the 22 newborns labelled as

“refer” being confirmed to have hearing loss on BERA. The sensitivity and specificity of repeat OAE were 81.25% and 97.50%, respectively, with a diagnostic accuracy of 96.81%. The positive predictive value increased to 59.09%, and the negative predictive value was 99.15%. Agreement with BERA improved substantially, with a Cohen’s kappa of 0.67, and the association was statistically significant ($\chi^2 = 172.46$, $p < 0.001$) (Table 3).

The overall incidence of confirmed hearing loss was 4.26%. Hearing loss was significantly more common among high-risk newborns (5.91%) compared to normal-risk newborns (1.44%), and this difference was statistically significant ($p = 0.038$) (Table 4).

Comparison of diagnostic parameters between initial and repeat OAE demonstrated an absolute improvement of 25.0% in sensitivity, 18.18% in positive predictive value, and 2.13% in diagnostic accuracy, along with improved agreement with BERA (Table 5).

Analysis of individual risk factors revealed a statistically significant association between hearing loss and high-risk newborn status ($p = 0.038$) as well as family history of hearing loss ($p = 0.025$). Other factors, including preterm birth, NICU admission, consanguinity, antenatal and postnatal risk factors, and ototoxic drug exposure, did not show statistically significant associations with confirmed hearing loss (Table 6).

Table 1. Baseline characteristics of the study population (N = 376)

Variable	Category / Mean $\pm$ SD	n (%)
Sex	Male	196 (52.1)
	Female	180 (47.9)
Gestational age (weeks)	Mean $\pm$ SD	38.50 ± 1.47
Birth weight (g)	Mean $\pm$ SD	2843.5 ± 436.4
Preterm birth	Yes	49 (13.0)
	No	327 (87.0)
NICU admission	Yes	99 (26.3)
	No	277 (73.7)
Family history of hearing loss	Yes	22 (5.9)
	No	354 (94.1)
Consanguinity	Yes	47 (12.5)
	No	329 (87.5)
Antenatal risk factors	Yes	82 (21.8)
	No	294 (78.2)
Postnatal risk factors	Yes	63 (16.8)
	No	313 (83.2)
High-risk newborn	Yes	237 (63.0)
	No	139 (37.0)
Father’s age (years)	Mean $\pm$ SD	29.8 ± 4.9
Mother’s age (years)	Mean $\pm$ SD	26.3 ± 3.8

Table 2. Diagnostic performance of Initial OAE compared with BERA (N = 376)

OAE (Initial)	BERA Hearing Loss	BERA Normal	Total
Refer	9	13	22
Pass	7	347	354
Total	16	360	376
Parameter	Estimate (95% CI)		
Sensitivity	56.25% (33.18–76.90)		
Specificity	96.39% (93.92–97.88)		
PPV	40.91% (23.26–61.27)		
NPV	98.02% (95.98–99.04)		
Diagnostic accuracy	94.68% (91.93–96.53)		
Likelihood ratio (+)	15.58		
Likelihood ratio (–)	0.45		
Cohen's kappa	0.45		
Chi-square (df = 1)	77.05, p < 0.001		

Table 3. Diagnostic performance of Repeat OAE compared with BERA (N = 376)

OAE (Repeat)	BERA Hearing Loss	BERA Normal	Total
Refer	13	9	22
Pass	3	351	354
Total	16	360	376
Parameter	Estimate (95% CI)		
Sensitivity	81.25% (56.99–93.41)		
Specificity	97.50% (95.32–98.68)		
PPV	59.09% (38.73–76.74)		
NPV	99.15% (97.54–99.71)		
Diagnostic accuracy	96.81% (94.51–98.17)		
Likelihood ratio (+)	32.5		
Likelihood ratio (–)	0.19		
Cohen's kappa	0.67		
Chi-square (df = 1)	172.46, p < 0.001		

Table 4. Incidence of hearing loss among high-risk and normal newborns

Newborn risk status	Hearing loss n (%)	Normal hearing n (%)	Total	p value
High-risk	14 (5.91)	223 (94.09)	237	0.038
Normal risk	2 (1.44)	137 (98.56)	139	
Total	16 (4.26)	360 (95.74)	376	

Chi-Square test

Table 5. Comparison of diagnostic performance of Initial and Repeat OAE for detection of hearing loss (Reference standard: BERA)

Diagnostic parameter	Initial OAE % (95% CI)	Repeat OAE % (95% CI)	Absolute improvement
Sensitivity	56.25 (33.18–76.90)	81.25 (56.99–93.41)	25.00%
Specificity	96.39 (93.92–97.88)	97.50 (95.32–98.68)	1.11%
Positive Predictive Value (PPV)	40.91 (23.26–61.27)	59.09 (38.73–76.74)	18.18%
Negative Predictive Value (NPV)	98.02 (95.98–99.04)	99.15 (97.54–99.71)	1.13%
Diagnostic accuracy	94.68	96.81	2.13%
Cohen's kappa	0.45	0.67	Improved agreement

Table 6. Association between individual risk factors and hearing loss (BERA)

Risk factor	Hearing loss n (%)	Normal hearing n (%)	p value
High-risk newborn	14 (5.9)	223 (94.1)	#0.038*
Family history of hearing loss	3 (13.6)	19 (86.4)	0.025*
Preterm birth	4 (8.2)	45 (91.8)	0.146
NICU admission	5 (5.1)	94 (94.9)	0.648
Consanguinity	1 (2.1)	46 (97.9)	0.44
Antenatal risk factors	6 (7.3)	76 (92.7)	0.12
Postnatal risk factors	2 (3.2)	61 (96.8)	0.641
Ototoxic drug exposure	2 (7.4)	25 (92.6)	0.4

Chi-square test

Fischer exact test

DISCUSSION

In the present study, the overall incidence of confirmed neonatal hearing loss was 4.26%, with a significantly higher prevalence among high-risk newborns (5.9%) compared to normal-risk neonates (1.44%). This finding is consistent with previous reports indicating a 2–10-fold higher risk of hearing loss among NICU-admitted and high-risk infants.^{1,7,11}

The diagnostic performance of initial OAE screening demonstrated high specificity (96.39%) but relatively low sensitivity (56.25%), indicating that while most normal-hearing infants were correctly identified, nearly half of infants with hearing loss were missed at the first screening. Similar sensitivity ranges have been reported by Yousefi et al. and De Capua et al., who attributed reduced sensitivity to transient conductive factors and early testing.^{5,8}

Repeat OAE screening substantially improved sensitivity to 81.25% and diagnostic accuracy to 96.81%, with a notable increase in Cohen's kappa from 0.45 to 0.67, indicating improved agreement with BERA. These findings corroborate earlier studies demonstrating that repeat OAE significantly reduces false-negative and false-positive results.^{9,10,12} The marked improvement in likelihood ratio (+) following repeat OAE further supports its role in strengthening diagnostic confidence prior to confirmatory BERA testing.

The negative predictive value of both initial and repeat OAE was high (>98%), suggesting that neonates who passed OAE screening were highly unlikely to have hearing loss, an observation consistent with large-scale screening program data.^{3,7}

Among individual risk factors, family history of hearing loss showed a statistically significant association with confirmed hearing impairment, in agreement with previous epidemiological studies highlighting genetic predisposition as a major contributor.^{6,11} Other perinatal factors such as prematurity, NICU admission, antenatal and postnatal risk factors did not reach statistical significance individually, possibly due to overlapping risk profiles and limited event numbers.

Strengths of the Study

Overall, the findings reinforce the utility of a two-stage OAE screening protocol followed by BERA confirmation, particularly in high-risk populations, and support current recommendations for universal newborn hearing screening in tertiary care settings.

Limitations of the Study

This study has several limitations. First, it was conducted at a single tertiary care centre, which may limit the generalizability of the findings to other hospitals and community-based newborn populations. Second, although the total sample size was 376 newborns, the number of confirmed hearing-loss cases was relatively small, which may have limited the statistical power for assessing individual risk factors. Third, the study had limited follow-up beyond the initial diagnostic assessment, and long-term hearing and developmental outcomes were not evaluated. Fourth, BERA was used as the reference standard, but the timing and follow-up of confirmatory testing may affect the interpretation of diagnostic accuracy. Finally, the study did not evaluate the cost-effectiveness, parental acceptability, or feasibility of implementing a two-stage OAE screening protocol on a larger population level. Larger multicentre studies with longer follow-up are therefore required to validate these findings.

Future Research / Recommendations

Future multicentre studies with larger sample sizes are recommended to validate the diagnostic performance of two-stage OAE screening in diverse neonatal populations. Longer follow-up with standardized BERA and audiological assessment may help determine the long-term hearing outcomes of screened newborns. Further studies should also evaluate the cost-effectiveness and feasibility of integrating repeat OAE with confirmatory BERA into universal newborn hearing screening programs, particularly in resource-limited settings. Strengthening follow-up systems for infants who fail screening and ensuring timely referral for diagnostic evaluation and early intervention should also be prioritized.

CONCLUSION

The present study demonstrates that otoacoustic emission screening is a reliable and practical tool for universal newborn hearing screening, particularly when implemented as a two-stage protocol. While initial OAE showed high specificity, repeat OAE significantly improved sensitivity, diagnostic accuracy, and agreement with BERA, thereby reducing false-negative and false-positive results. The incidence of hearing loss was significantly higher among high-risk newborns, with family history emerging as an important associated factor. These findings support the integration of repeat OAE followed by confirmatory BERA into routine neonatal care to facilitate early detection and timely intervention for hearing impairment.

DECLARATIONS

Ethics Approval and Consent to Participate

The study protocol was reviewed and approved by the Institutional Ethics Committee of Chamarajanagar Institute of Medical Sciences (CIMS), Chamarajanagar, Karnataka, India, prior to commencement of the study. Written informed consent was obtained from the parents or legal guardians of all participating newborns. The study was conducted in accordance with applicable institutional ethical requirements for research involving human participants.

Consent for Publication

Not applicable. No identifiable personal information, images, or other identifying details of individual newborns are included in this manuscript.

Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request, subject to institutional policies and ethical restrictions.

Competing Interests

The authors declare that they have no competing interests or conflicts of interest related to this study.

Funding

The authors received no specific funding, grant, or financial support from any government, commercial, or not-for-profit organization for this study.

Authors' Contributions

Nivedita contributed to the conception and design of the study, data collection, interpretation of findings, and preparation of the manuscript. Sushma Nayak contributed to study supervision, data interpretation, and critical revision of the manuscript. Vinay Kumar K and Mahesh V contributed to data analysis, interpretation, and critical review of the manuscript. All authors critically reviewed and approved the final

version of the manuscript and agreed to be accountable for all aspects of the work.

Acknowledgements

The authors would like to thank the Department of Otorhinolaryngology, Department of Community Medicine, audiology personnel, nursing staff, and all participating parents and guardians for their cooperation and support during the study.

REFERENCES

1. Nagapoornima P, Ramesh A, Srilakshmi, et al. Universal hearing screening. *Indian J Pediatr.* 2007;74(6):545-549.
2. White KR, Vohr BR, Behrens TR. Universal newborn hearing screening using transient evoked otoacoustic emissions. *J Speech Lang Hear Res.* 1993;36:1410-1418.
3. Kemper AR, Downs SM. A cost-effectiveness analysis of newborn hearing screening strategies. *Arch Pediatr Adolesc Med.* 2000;154(5):484-488.
4. Mason JA, Herrmann KR. Universal infant hearing screening by automated auditory brainstem response measurement. *Pediatrics.* 1998;101(2):221-228.
5. De Capua B, De Felice C, Costantini D, et al. Newborn hearing screening by transient evoked otoacoustic emissions. *Acta Otorhinolaryngol Ital.* 2003;23:363-369.
6. Meier S, Narabayashi O, Probst R, et al. Comparison of automated ABR and OAE. *Int J Pediatr Otorhinolaryngol.* 2004;68:153-161.
7. Joint Committee on Infant Hearing. Year 2019 position statement. *J Early Hear Detect Interv.* 2019;4(2):1-44.
8. Yousefi J, Ajalloueyan M, Amirsalari S, et al. Sensitivity and specificity of TEOAE in neonatal screening. *Iran J Otorhinolaryngol.* 2013;25(72):199-204.
9. Korres SG, Balatsouras DG, Lyra C, et al. Comparison of automated ABR and OAE for UNHS. *Int J Pediatr Otorhinolaryngol.* 2006;70:205-213.
10. Johnson JL, White KR, Widen JE, et al. A multisite study of OAE/AABR protocols. *Am J Audiol.* 2005;14:S1-S12.
11. Kumar A, Gupta SC, Singh S, et al. Universal hearing screening using OAE and ABR. *Indian J Otolaryngol Head Neck Surg.* 2017;69(2):223-229.
12. Arslan S, Serel Arslan S, et al. Results of universal newborn hearing screening. *Int J Pediatr Otorhinolaryngol.* 2013;77:1776-1780.