

**Otoacoustic Emission and Brainstem Evoked Response Audiometry in Neonates: A Two-Stage Universal Neonatal Hearing Screening Protocol Categories Otolaryngology, Pediatrics, Public Health**

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Abstract

Background: Congenital and early-onset hearing impairment is among the most common neonatal sensory disorders, and undetected loss impairs speech, language, and cognitive development. Otoacoustic emission (OAE) testing offers a rapid, non-invasive first-line screen, while brainstem evoked response audiometry (BERA) provides confirmatory assessment of the auditory pathway. We evaluated a sequential OAE-then-BERA

protocol and compared the incidence of hearing impairment between at-risk and not-at-risk neonates.

Methods: In this prospective observational study, 150 neonates (75 at-risk, 75 not-at-risk) aged 24 hours to four weeks were enrolled at a tertiary-care otorhinolaryngology department. All underwent OAE (Neurosoft, Ivanovo, Russia); those with a “refer” result in either ear underwent a repeat OAE after approximately one month, and persistent “refer” results

were evaluated with diagnostic BERA (Neurosoft, Ivanovo, Russia). Hearing status and severity were determined from BERA thresholds. Proportions were compared using the chi-square test (IBM SPSS Statistics version 26; $p < 0.05$ significant).

Results: The cohort was 49.3% male; 26.7% were preterm and 44.0% had neonatal intensive care unit (NICU) admission. Among at-risk neonates, the commonest risk factors were low birth weight (77.3%), prematurity (53.3%), and hyperbilirubinaemia (48.0%). First OAE referral was 59.3% (at least one ear), falling to 16.0% (24 neonates) after repeat OAE; 16 of these (10.7% of the cohort) had confirmed hearing impairment on BERA, predominantly moderately severe (56–70 dB) and severe (71–90 dB) loss. Impairment occurred in 12.0% of at-risk and 9.3% of not-at-risk neonates, a non-significant difference ($\chi^2 = 0.28$, $p = 0.597$). Low birth weight (88.9%) and prematurity (44.4%) dominated among impaired at-risk neonates.

Conclusions: A two-tier OAE-then-BERA protocol substantially reduced false-positive referrals while reliably identifying hearing impairment. The comparable incidence in at-risk and not-at-risk neonates indicates that risk-based screening alone misses a substantial share of affected infants and supports universal newborn hearing screening.

Keywords: Newborn Hearing Screening, Otoacoustic Emissions, Brainstem Evoked Response Audiometry, Neonatal Hearing Loss, Universal Newborn Screening, At-Risk Neonates, Low Birth Weight, Auditory Brainstem Response

Introduction

Hearing is a fundamental channel for communication, learning, and social belonging, and impairment present at or soon after birth has a disproportionate impact on

development¹. Permanent congenital hearing loss is among the most common birth defects, with a reported prevalence of roughly 2–3 per 1,000 live births, and newborn screening programmes in India have identified permanent bilateral loss in about 1.61 per 1,000 at-risk infants^{2,3}. Because hearing loss is not a visible disability, it typically goes unrecognised until it manifests as delayed speech and language; infants identified and managed within the first six months perform significantly better than those identified later^{4,6}.

Newborn hearing screening enables timely intervention—hearing aids, cochlear implants, and family support—that mitigates these consequences, and national initiatives such as the Rashtriya Bal Swasthya Karyakram have incorporated infant hearing screening in India⁷. Although congenital factors account for most cases, additional contributors include TORCH (toxoplasmosis, other agents, rubella, cytomegalovirus, and herpes simplex) infections, ototoxic exposure, birth asphyxia, low birth weight, and prematurity, reinforcing the need for systematic screening^{8,9}.

Otoacoustic emission (OAE) testing is well suited to first-line screening: it is quick, non-invasive, inexpensive, and highly sensitive to outer hair cell dysfunction, and can be performed at the bedside in sleeping neonates. However, it does not assess the auditory pathway beyond the cochlea and is susceptible to transient outer- and middle-ear factors⁹. Brainstem evoked response audiometry (BERA), also termed the auditory brainstem response, provides an objective measure of auditory nerve and brainstem function, differentiates types and severity of loss, and detects auditory neuropathy that OAE may miss, but requires specialised equipment, trained personnel, and a quiet or sedated infant⁸⁻¹⁰. A sequential strategy—OAE first,

BERA for confirmation—therefore balances feasibility against diagnostic precision.

This study was conducted in a tertiary-care Department of Otorhinolaryngology to evaluate the performance of a two-stage OAE protocol followed by diagnostic BERA, to estimate the incidence of hearing impairment, and to compare that incidence between at-risk and not-at-risk neonates so as to inform whether screening should be targeted or universal.

Materials and Methods

Study design and setting: This prospective observational study was conducted on an outpatient basis in the Department of Otorhinolaryngology of a tertiary-care teaching hospital from May 2025 to April 2026. The study was approved by the Institutional Ethics Committee (approval number IEC/PG/145/MAY/2025), and written informed consent (available in English, Hindi, and Marathi) was obtained from a parent or guardian of each neonate.

Participants: All neonates from 24 hours up to four weeks (28 days) of age presenting during the study period were eligible. Neonates with external- or middle-ear pathology, a fatal event before completion of the study, or whose parents declined participation were excluded. A total of 150 neonates were enrolled and stratified into two equal groups of 75: at-risk neonates (one or more recognised risk factors for hearing loss, e.g. low birth weight, prematurity, hyperbilirubinaemia, birth asphyxia, neonatal intensive care unit (NICU) admission, ototoxic drug exposure, neonatal sepsis, family history of hearing loss, consanguinity, congenital anomalies, or neonatal seizures) and not-at-risk neonates (no identifiable risk factor).

Sample size: The sample was calculated for the comparison of two independent proportions using $Z\alpha/2 =$

1.96 (95% confidence) and $Z\beta = 0.84$ (80% power), yielding 75 per group (150 total). The expected proportions of 21.3% and 6.0% were taken from Pippal et al.¹¹, who reported abnormal otoacoustic emission responses in 16 of 75 premature (21.3%) versus three of 50 full-term infants (6.0%). Two features of this design assumption should be noted: the reference proportions relate to a screening-level outcome (abnormal OAE without confirmatory BERA) rather than to confirmed hearing impairment, and they contrast prematurity with full-term birth rather than a composite at-risk definition with the absence of risk factors. The anticipated between-group difference was therefore larger than that ultimately observed for the present study's outcome of BERA-confirmed impairment.

Procedure: After history-taking and a complete ear, nose, and throat (ENT) examination to confirm eligibility, each neonate underwent OAE testing between 36 hours and 28 days of life using an OAE instrument (Neurosoft, Ivanovo, Russia). A “pass” required a clear response in the ear; a “refer” in either ear prompted a repeat OAE after approximately one month. Neonates with a persistent “refer” on the second OAE underwent diagnostic BERA (Neurosoft, Ivanovo, Russia) in a quiet setting, with severity graded from the wave V threshold as moderate (41–55 dB), moderately severe (56–70 dB), severe (71–90 dB), or profound (>90 dB). Neonates with normal BERA were classified as normal-hearing; abnormal BERA confirmed hearing impairment.

Outcome measures and statistical analysis: Primary outcomes were the prevalence of hearing impairment overall and its comparison between groups; the secondary outcome was the association between risk factors and impairment. Data were entered in Microsoft Excel (Microsoft Corp., Redmond, WA, USA) and

analysed with IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables are summarised as frequencies and percentages and continuous variables as mean $\pm$ standard deviation (SD) and median (interquartile range, IQR). Proportions were compared using the Pearson chi-square test, with $p < 0.05$ considered statistically significant.

Results

Cohort characteristics: Of 150 neonates, 74 (49.3%) were male and 76 (50.7%) female; 110 (73.3%) were term and 40 (26.7%) preterm. Delivery was vaginal in 69 (46.0%), by caesarean section in 68 (45.3%), and instrumental in 13 (8.7%). Sixty-six (44.0%) required NICU admission, and 132 (88.0%) cried immediately at birth. Risk stratification yielded 75 (50.0%) at-risk and 75 (50.0%) not-at-risk neonates (Table 1). Mean birth weight was 2.72 ± 0.78 kg (range 0.93–4.20; median 2.80, IQR 2.30–3.22), and mean age at first OAE was 11.78 ± 8.31 days (range 1–28; median 11, IQR 4.25–17.75) (Table 2).

Table 1: Demographic characteristics of enrolled neonates (n=150)

Variable	Category	Frequency (n)	Percent (%)
Gender	Male	74	49.3
	Female	76	50.7
Gestational age	Term	110	73.3
	Preterm	40	26.7
Mode of delivery	Normal vaginal	69	46.0
	Caesarean section	68	45.3
	Instrumental	13	8.7
NICU	Yes	66	44.0

Variable	Category	Frequency (n)	Percent (%)
admission			
	No	84	56.0
Risk group	At-risk	75	50.0
	Not-at-risk	75	50.0
Cried immediately at birth	Yes	132	88.0
	No	18	12.0

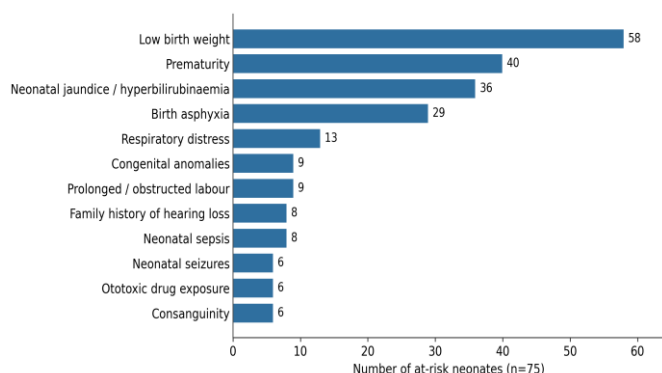
Table 2: Descriptive statistics of birth weight and age at screening

Parameter	Birth weight (kg)	Age at screening (days)
N	150	150
Mean	2.72	11.78
Standard deviation	0.78	8.31
Minimum	0.93	1
Maximum	4.20	28
Median (P50)	2.80	11
25th percentile (P25)	2.30	4.25
75th percentile (P75)	3.22	17.75

Risk-factor profile: Among the 75 at-risk neonates, low birth weight was commonest (58; 77.3%), followed by prematurity (40; 53.3%), hyperbilirubinaemia (36; 48.0%), and birth asphyxia (29; 38.7%); respiratory distress (13; 17.3%), prolonged/obstructed labour and congenital anomalies (nine each; 12.0%), neonatal sepsis and family history of hearing loss (eight each; 10.7%), and consanguinity, ototoxic drug exposure, and neonatal seizures (six each; 8.0%) were less frequent. Many

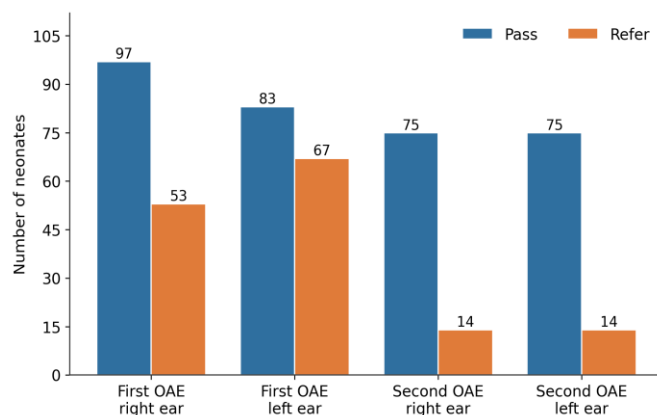
neonates had more than one factor, so percentages exceed 100% (Figure 1).

Figure 1: Distribution of risk factors among at-risk neonates (n=75). As some neonates had more than one risk factor, the total exceeds 75.



OAE screening: On the first OAE, 97 (64.7%) passed in the right ear and 83 (55.3%) in the left; 61 neonates passed bilaterally, while 89 (59.3%) referred in at least one ear and underwent repeat OAE. On the second OAE, the per-ear pass rate rose to 84.3% (75/89), and overall 24 neonates (16.0%) had a persistent “refer” and proceeded to BERA (Figure 2).

Figure 2: Otoacoustic emission (OAE) screening results, first and second screen. The second OAE was performed only on the 89 neonates who referred in at least one ear on the first OAE. Overall, 24 neonates (16.0%) were referred for diagnostic BERA.



BERA and hearing status: Of the 24 neonates assessed by BERA, the right ear was normal in 15 (62.5%) and

abnormal in nine (37.5%), and the left ear normal in 14 (58.3%) and abnormal in 10 (41.7%); the 126 neonates (84.0%) who passed OAE did not require BERA (Table 3). Hearing impairment was confirmed in 16 neonates (19 affected ears): three bilateral and 13 unilateral (six right, seven left). The overall incidence of hearing impairment was 10.7% (16/150): moderately severe loss in six (4.0%), severe in five (3.3%), moderate in three (2.0%), and profound in two (1.3%); the remaining 134 (89.3%) had normal hearing (Table 4).

Table 3: Brainstem evoked response audiometry (BERA) results

BERA result	Right ear, n (%)	Left ear, n (%)
Normal	15 (62.5%)	14 (58.3%)
Abnormal	9 (37.5%)	10 (41.7%)
Total referred for BERA	24	24
Not done (passed OAE)	126 (84.0%)	126 (84.0%)

Table 4: Incidence and severity of hearing impairment among neonates (n=150)

Hearing status	Frequency (n)	Percent (%)
Normal hearing	134	89.3
Moderate hearing loss (41–55 dB)	3	2.0
Moderately severe hearing loss (56–70 dB)	6	4.0
Severe hearing loss (71–90 dB)	5	3.3
Profound hearing loss (>90 dB)	2	1.3
Total with hearing impairment	16	10.7

At-risk vs not-at-risk comparison: Impairment occurred in nine of 75 at-risk neonates (12.0%) and seven of 75 not-at-risk neonates (9.3%), with no statistically significant difference ($\chi^2 = 0.28$, degrees of freedom [df] = 1, $p = 0.597$) (Table 5, Figure 3). First-OAE referral was higher among at-risk (49; 65.3%) than not-at-risk neonates (40; 53.3%) ($\chi^2 = 2.24$, $p = 0.135$), and after two OAE screens final referral was 20.0% (15/75) vs 12.0% (9/75) ($\chi^2 = 1.79$, $p = 0.181$); neither difference was significant (Table 6). Among impaired at-risk neonates, low birth weight (eight; 88.9%) and prematurity (four; 44.4%) were the leading factors, followed by neonatal jaundice (three; 33.3%), ototoxic drug exposure (two; 22.2%), and neonatal sepsis (one; 11.1%) (Table 7).

Table 5: Comparison of hearing impairment between at-risk and not-at-risk neonates

Risk group	Normal hearing, n (%)	Hearing impairment, n (%)	Total
At-risk	66 (88.0%)	9 (12.0%)	75
Not-at-risk	68 (90.7%)	7 (9.3%)	75
Total	134 (89.3%)	16 (10.7%)	150

Pearson chi-square = 0.28, df = 1, $p = 0.597$ (not significant).

Figure 3: Comparison of hearing status between at-risk and not-at-risk neonates. Hearing impairment was comparable between the two groups ($\chi^2 = 0.28$, df = 1, $p = 0.597$).

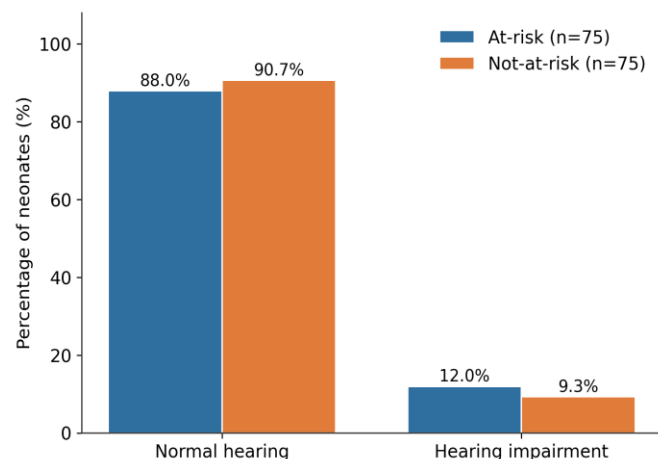


Table 6: Referral rates after otoacoustic emission screening, by risk group

First OAE only	At-risk	Not-at-risk	Total
Passed	26 (34.7%)	35 (46.7%)	61 (40.7%)
Referred	49 (65.3%)	40 (53.3%)	89 (59.3%)
Total	75	75	150

Pearson chi-square = 2.24, df = 1, $p = 0.135$ (not significant).

First + second OAE	At-risk	Not-at-risk	Total
Passed	60 (80.0%)	66 (88.0%)	126 (84.0%)
Referred	15 (20.0%)	9 (12.0%)	24 (16.0%)
Total	75	75	150

Pearson chi-square = 1.79, df = 1, $p = 0.181$ (not significant).

Table 7: Distribution of risk factors among neonates with hearing impairment

Risk factor	At-risk (n=9)	Not-at-risk (n=7)	Total
Low birth weight	8 (88.9%)	0 (0.0%)	8 (50.0%)
Preterm	4 (44.4%)	0 (0.0%)	4

Risk factor	At-risk (n=9)	Not-at-risk (n=7)	Total
			(25.0%)
Neonatal jaundice	3 (33.3%)	0 (0.0%)	3 (18.8%)
Ototoxic drug exposure	2 (22.2%)	0 (0.0%)	2 (12.5%)
Neonatal sepsis	1 (11.1%)	0 (0.0%)	1 (6.3%)

As some infants have multiple risk factors, totals can exceed 100%. By definition, not-at-risk neonates had no identifiable risk factor.

Discussion

Early detection of neonatal hearing impairment is essential for timely intervention and optimal speech, language, and cognitive development, and a sequential OAE-then-BERA strategy combines an efficient cochlear screen with a definitive assessment of the auditory pathway^{9,10}. Our cohort showed a near-equal sex distribution and a high proportion of preterm (26.7%) and NICU (44.0%) neonates, reflecting referral patterns at a tertiary centre and the deliberate inclusion of at-risk infants; comparable enriched high-risk cohorts are described by Aradhana et al. and Gulati et al.^{12,13}. The wide birth-weight range (0.93–4.20 kg) reflects inclusion of low-birth-weight and preterm infants, a group at substantially elevated risk of sensorineural loss⁸.

The risk-factor profile—low birth weight, prematurity, and hyperbilirubinaemia predominating, frequently in combination—mirrors Indian and international screening cohorts^{12,14-16}. Hyperbilirubinaemia (48.0%) is a recognised ototoxic insult to the brainstem pathway, with prolonged BERA latencies documented in icteric neonates¹⁷, and ototoxic exposure and consanguinity (each 8.0%) are established contributors in comparable

populations. The multiplicity of overlapping factors underscores the multifactorial nature of neonatal hearing risk^{16,18}.

The two-stage OAE protocol behaved as expected: a high first-screen referral (59.3%) fell to 16.0% after repeat testing, consistent with reports that early referrals are inflated by vernix, residual amniotic fluid, and immature middle-ear transmission, and decline markedly on rescreening¹⁹⁻²². This reduction in false positives, while retaining true cases for confirmatory BERA, supports the protocol's utility in mixed-risk populations²³. Of the 24 neonates reaching BERA, only a subset (16) had confirmed impairment, again indicating transient causes for many initial referrals and reinforcing BERA's role as the definitive, severity-defining test²⁴⁻²⁷.

The overall incidence of impairment was 10.7%, with moderately severe and severe loss predominating—clinically significant degrees that would jeopardise speech and language if undetected. Reported prevalences vary with population and case mix, but a preponderance of moderate-to-severe loss among confirmed cases is consistent with prior series^{13,28,29}.

The central finding is that impairment was comparable in at-risk (12.0%) and not-at-risk (9.3%) neonates, with no significant difference ($p=0.597$). Seven not-at-risk infants—who would have been missed entirely by a risk-based programme—had confirmed loss, including moderate-to-severe degrees. This aligns with evidence that targeted screening misses an estimated 30–50% of permanent hearing loss and that universal newborn hearing screening identifies loss earlier and improves language outcomes^{22,24,25,30}. Given that identification before three months and intervention before six months are decisive for developmental outcomes⁴, any delay

imposed by risk-based protocols carries lasting cost, strongly favouring universal screening—particularly in tertiary settings with diverse neonatal populations.

Among impaired at-risk neonates, low birth weight (88.9%) and prematurity (44.4%) dominated, consistent with the elevated sensorineural-loss risk of very-low-birth-weight infants and preterm cohorts^{8,11}. The contribution of neonatal jaundice (33.3%) accords with bilirubin-induced auditory neuropathy that OAE alone may not detect, reinforcing BERA's diagnostic value, while ototoxic exposure remains a modifiable target for vigilant aminoglycoside monitoring in the NICU¹⁷.

Limitations. Single-centre design with a modest sample, enrichment for at-risk neonates, and variable timing of screening (median 11 days) limit generalisability; long-term developmental follow-up and audiological confirmation beyond the neonatal period were beyond scope.

Conclusions

A sequential screening strategy that begins with otoacoustic emission testing and confirms persistent referrals with brainstem evoked response audiometry provides an effective and resource-conscious framework for early detection of neonatal hearing impairment. Repeat otoacoustic emission testing markedly reduced false-positive referrals, and brainstem evoked response audiometry reliably confirmed impairment and defined its severity, the majority of cases falling within the moderate-to-severe range that most threatens speech and language development.

Critically, hearing impairment was as common in neonates without recognised risk factors as in those with them, demonstrating that screening confined to high-risk infants would overlook a substantial proportion of affected newborns. These findings support adoption of

universal newborn hearing screening using a combined otoacoustic emission and brainstem evoked response audiometry protocol, so that every affected infant can be identified and referred for timely intervention.

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