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A Two-Step Otoacoustic Emission Protocol With Brainstem Evoked Response Audiometry For Universal Newborn Hearing Screening: A Prospective Observational Study Of 500 Neonates

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Abstract

Background: Congenital hearing loss is an important cause of preventable impairment in speech, language, cognitive and social development. Screening restricted to high-risk neonates may fail to identify a substantial proportion of affected infants. Physiological screening using otoacoustic emissions (OAE) is rapid and suitable for universal screening, but early testing can generate transient referrals; a staged protocol may reduce unnecessary diagnostic testing.

Objective: To determine the incidence of congenital hearing loss among newborns using a two-step distortion-product otoacoustic emission (DPOAE) protocol followed by brainstem evoked response audiometry (BERA) in persistent referrals; to identify high-risk neonates, evaluate risk factors associated with hearing loss, and determine the false-positive referral rate.

Methods: This prospective observational study included 500 term and preterm newborns delivered at our hospital, between January and October 2016. After parental informed consent, demographic, antenatal, perinatal, postnatal, family-history and otological data were recorded. Bilateral DPOAE screening was performed at 24–72 hours of age. Newborns with a REFER result in either ear were rescreened by DPOAE at 10–15 days. Persistent REFER results underwent diagnostic BERA at 1 month. Descriptive statistics were calculated using SPSS version 17.0; categorical variables were compared using the chi-square test or Fisher exact test, with $p < 0.05$ considered significant.

Results: At the first DPOAE screen, 453/500 newborns (90.6%) passed bilaterally and 47 (9.4%) had a REFER result: 20 bilaterally, 14 in the left ear only, and 13 in the right ear only. On repeat DPOAE, 43 of 47 referrals passed and 4 remained bilateral REFER. All four persistent referrals had bilateral hearing loss on BERA at 1 month, giving an observed incidence of 0.8% (8 per 1000). The first-stage transient referral/false-positive proportion was 43/500 (8.6%), whereas no additional false-positive referral was observed after the second DPOAE among the four infants sent for BERA. High-risk features were present in 116/500 infants (23.2%); all four BERA-confirmed cases occurred in this group (3.4% vs 0% among infants without identified risk factors; $p < 0.001$). Significant associations were reported for low birth weight ($p < 0.001$), NICU stay with ventilation for > 5 days ($p < 0.001$), birth asphyxia ($p = 0.005$), hyperbilirubinemia ($p = 0.011$), maternal infection ($p = 0.010$), and increasing burden of multiple risk factors ($p < 0.001$).

Conclusion: A two-step DPOAE strategy followed by BERA for persistent referrals was feasible in this hospital cohort and markedly reduced the referral burden between the first and second screens. Universal screening identified an observed congenital hearing-loss incidence of 0.8%, with all confirmed cases occurring among high-risk neonates. Repeating OAE before diagnostic BERA may reduce transient referrals while retaining a structured pathway for early diagnosis.

Keywords: newborn hearing screening; otoacoustic emission; DPOAE; BERA; auditory brainstem response; congenital hearing loss; neonatal risk factors

1. Introduction

Hearing is central to an infant's interaction with the environment and to the acquisition of speech and language. Congenital hearing impairment may remain clinically silent during early infancy, yet deprivation of auditory input during a critical period can adversely affect communication, educational performance and psychosocial development. Historically, behavioral methods were performed only when the infant was developmentally old enough to respond, which delayed diagnosis. Screening programs therefore shifted toward objective physiological methods that can be used soon after birth. Early newborn hearing programs initially focused on infants listed in a high-risk register. This strategy is inherently incomplete because a substantial proportion of congenital hearing loss occurs in infants without recognizable risk factors. Universal newborn hearing screening (UNHS) was developed to overcome this limitation and to facilitate diagnosis and intervention during the period when auditory and language pathways are most plastic. The Joint Committee on Infant Hearing has long advocated early identification and intervention, and the principle underlying such recommendations is that screening should occur sufficiently early to permit confirmatory diagnosis and rehabilitation during infancy.

Newborn hearing screening can be performed with otoacoustic emissions (OAEs), auditory brainstem response (ABR/BERA), or a sequential combination of these techniques. OAE measures cochlear outer-hair-cell responses and is objective, rapid, non-invasive and suitable for bedside screening. Distortion-product OAE (DPOAE) can examine cochlear responses over multiple frequencies. However, OAE can be influenced by transient external- or middle-ear conditions such as vernix, debris, residual amniotic fluid and poor probe fit, particularly during the first days of life. A single early OAE screen may therefore produce a relatively high referral rate.

BERA is an electrophysiological assessment of neural responses generated along the auditory pathway following acoustic stimulation. It is less vulnerable than OAE to transient external-ear factors and can provide threshold-related diagnostic information, but it is more time-consuming, technically demanding and, in diagnostic settings, often requires the infant to be asleep or sedated. A sequential protocol in which OAE is repeated before BERA may therefore combine the practical advantages of OAE with the diagnostic utility of BERA while reducing unnecessary referrals.

The burden of congenital hearing loss and the organization of early hearing-detection services remain especially important in resource-constrained settings. A high birth rate, limited availability of diagnostic audiology, loss to follow-up and the cost of performing BERA in every infant make a staged protocol attractive. At the same time, restricting screening to high-risk infants risks missing affected babies without known risk factors. Hospital-based universal screening using an inexpensive first-line physiological test followed by targeted confirmatory assessment is one pragmatic approach.

Against this background, the present study evaluated a two-step DPOAE protocol followed by BERA in persistent referrals among newborns delivered at a tertiary hospital in New Delhi. In addition to estimating the observed incidence of congenital hearing loss, the study examined neonatal and maternal risk factors and quantified the reduction in referrals achieved by repeating OAE before BERA.

2. AIMS AND OBJECTIVES

- To screen newborns and determine the observed incidence of hearing loss using OAE with BERA in OAE-referred cases at Jaipur Golden Hospital from January 2016 to October 2016.
- To identify neonates with recognized high-risk features and determine the incidence of hearing loss within the high-risk group.
- To evaluate maternal, perinatal and neonatal risk factors associated with hearing loss.
- To determine the number of transient/false-positive referrals generated by the staged OAE protocol.

3. MATERIALS AND METHODS

3.1 Study design and setting

This was a prospective observational study conducted in the Department of Otorhinolaryngology, Jaipur Golden Hospital, Rohini, New Delhi, India. The study period was January 2016 through October 2016.

3.2 Study population and sample size

The study population comprised term and preterm newborns delivered at Jaipur Golden Hospital, irrespective of the presence or absence of recognized risk factors for hearing loss. The thesis sample-size section noted that a larger sample would have been required for a more precise incidence estimate, but because the study was time-bound, 500 neonates were enrolled and screened.

3.3 Inclusion criteria

All term or preterm newborns, with or without risk factors, born at Jaipur Golden Hospital.

For subsequent screening stages, newborns with a previous REFER result.

Newborns able to comply with study procedures.

Written informed consent from the parent/legal representative.

Infants with treatable external/middle-ear problems such as wax, debris, meconium, otitis externa, discharge or otitis

media were treated before screening and then included.

3.4 Exclusion criteria

Age less than 24 hours at first screening.

Obvious congenital aural deformity preventing insertion of the OAE probe.

Absence of parental consent.

Acute illness associated with excessive crying or inability to obtain a reliable recording.

3.5 Clinical data collection and risk assessment

After consent, a structured neonatal hearing-screening proforma was used. Recorded variables included sex, date of birth, gestational age, birth weight, antenatal history, maternal blood group and infections, pregnancy-related conditions, drug exposure, duration and mode of labor and delivery, Apgar score, meconium aspiration, NICU admission and interventions, postnatal sepsis/pneumonia/meningitis, hypoxic-ischemic encephalopathy, intraventricular hemorrhage, seizures, hyperbilirubinemia and its treatment, birth trauma, medications, family history of deafness, consanguinity, craniofacial examination, external-ear findings, external auditory canal patency, and tympanic-membrane examination. Risk-factor analyses in the study focused on low birth weight, NICU stay with ventilation for more than 5 days, birth asphyxia, hyperbilirubinemia, maternal infection, ototoxic medication exposure and cumulative risk-factor burden.

3.6 Equipment

DPOAE screening was performed using a handheld Otoport Lite Audio Screener, version 3.2.1. Distortion-product frequencies from 2000 to 6000 Hz were selected. Diagnostic BERA was performed using a Medicaid AABR/BERA system capable of bilateral waveform recording. Otoscopy was performed with a Riester otoscope and standard ENT instruments.

3.7 Screening protocol

Stage 1: DPOAE at 24–72 hours

The infant was tested during natural sleep in a quiet/sound-controlled room, positioned in the mother's lap with the head turned away from the test ear. A snug probe containing a microphone and loudspeaker was inserted into the external auditory canal. A computerized averaging system generated a PASS or REFER result for each ear. Both ears were tested. A REFER result in three or more tested frequencies in either ear triggered repeat screening.

Stage 2: Repeat DPOAE at 10–15 days

Infants who had REFER on the initial screen returned at 10–15 days of age for repeat DPOAE. Infants who passed on repeat testing exited the diagnostic pathway; those with persistent REFER proceeded to diagnostic BERA.

Stage 3: Diagnostic BERA at 1 month

Persistent OAE referrals underwent BERA at approximately 1 month of age. According to the study protocol, the infant was sedated with triclofos syrup 0.3 mL/kg to minimize movement artifact and was positioned supine. Surface electrodes were placed with the active/non-inverting electrode at the vertex/high forehead, reference/inverting electrodes at the mastoids, and ground on the lower forehead. Both ears were tested with insert earphones. Broadband click stimuli were used, with rarefaction and condensation polarity to assess cochlear microphonic activity. Inter-electrode impedance was maintained below 5 k Ω . Bioelectric activity was amplified at a gain of 150,000 and filtered between 100 and 3000 Hz. At least 1200 sweeps were averaged per trial, depending on signal-to-noise ratio. A 10-dB-up and 5-dB-down threshold-seeking procedure was used. Replications were obtained near threshold; the lowest intensity producing a repeatable wave V was taken as the minimum response level. An absent response was accepted only after three trials at the maximum intensity of 90 dB nHL without a repeatable peak.

Table 1. Diagnostic BERA parameters used in the study

Parameter	Study setting
Stimulus type	Click
Periodic stimulus rate	27.7/second
Stimulus polarity	Rarefaction and condensation
Click duration	0.10 ms
Starting stimulus intensity	60 dB nHL
Maximum intensity for absent response	90 dB nHL
Filter band	100–3000 Hz
Amplifier gain	150,000
Minimum sweeps	1200
Threshold search	10 dB up / 5 dB down
Electrode impedance	<5 k Ω

3.8 Outcome definitions

The primary outcome was BERA-confirmed congenital hearing loss among screened newborns. A first-stage transient referral was defined as an infant who had REFER on OAE-1 but subsequently passed OAE-2. A persistent OAE referral was an infant with REFER on both OAE-1 and OAE-2 and was referred for BERA. The original thesis used the term “false positive” for referrals that resolved on repeat testing. Because the available study documents do not contain diagnostic

middle-ear testing sufficient to prove conductive hearing loss in those infants, this manuscript conservatively describes them as transient OAE referrals rather than confirmed conductive hearing loss.

3.9 Statistical analysis

Data were analyzed using SPSS version 17.0. Continuous variables were summarized as mean and standard deviation, and categorical variables as frequencies and percentages. Nominal categorical variables were compared using the chi-square test or Fisher exact test, as appropriate. A two-sided p value <0.05 was considered statistically significant.

3.10 Ethical considerations

Parents/legal representatives received a patient information sheet and provided written informed consent before enrollment. The study documents also include an investigator declaration regarding confidentiality of participant identity. A formal institutional ethics committee approval number/date was not present in the supplied source documents and should be inserted here before journal submission: [IEC approval number/date to be added].

4. RESULTS

4.1 Screening outcomes

All 500 enrolled newborns underwent the first DPOAE screen at 24–72 hours. A bilateral PASS was obtained in 453 infants (90.6%). Forty-seven infants (9.4%) had at least one REFER result: 20 had bilateral REFER, 14 had left-ear-only REFER, and 13 had right-ear-only REFER. All 47 infants proceeded to the second DPOAE screen at 10–15 days. Forty-three of these infants passed the repeat screen: all 14 left-only referrals, all 13 right-only referrals, and 16 of the 20 bilateral referrals. Four infants remained bilateral REFER and underwent BERA at 1 month. All four had bilateral hearing loss on BERA. Thus, the observed incidence of congenital hearing loss in this cohort was 4/500 (0.8%; 8 per 1000 screened newborns).

Table 2. Sequential newborn hearing-screening outcomes

Screening stage	Bilateral pass	Bilateral refer	Unilateral refer	Total requiring next stage
OAE-1, 24–72 h	453 (90.6%)	20 (4.0%)	27 (5.4%)	47 (9.4%)
OAE-2, 10–15 d (among initial referrals)	43/47 passed overall	4/47 bilateral refer	0 persistent unilateral refer	4/500 (0.8%)
BERA, 1 month	—	4 confirmed bilateral hearing loss	0	—

4.2 Referral reduction and false-positive screening

The referral rate decreased from 9.4% after the first DPOAE to 0.8% after repeat DPOAE, an absolute reduction of 8.6 percentage points. Forty-three of 500 infants (8.6%) had an initial REFER that resolved on repeat screening. All four infants who remained REFER on OAE-2 were confirmed to have hearing loss on BERA; therefore, within this study pathway, there were no second-stage OAE referrals that proved normal on BERA. This finding should be interpreted cautiously because only persistent OAE referrals underwent BERA, so sensitivity, specificity and negative predictive value for the entire screened cohort cannot be calculated from the available verification design.

4.3 Distribution of high-risk infants

One hundred sixteen newborns (23.2%) had at least one recorded risk factor, while 384 (76.8%) had no identified risk factor. All four infants with BERA-confirmed hearing loss were in the high-risk group, corresponding to 3.4% (4/116), compared with 0% (0/384) in infants without identified risk factors ($p < 0.001$).

Table 3. Presence of risk factors and confirmed hearing loss

Risk-factor status	n (%)	Confirmed hearing loss, n (%)	p value
Absent	384 (76.8%)	0 (0%)	<0.001
Present	116 (23.2%)	4 (3.4%)	
Total	500 (100%)	4 (0.8%)	

4.4 Demographic and maternal factors

There were 264 female (52.8%) and 236 male (47.2%) newborns. Two confirmed cases occurred in each sex; sex was not associated with hearing loss ($p = 1.000$). By gestational-age grouping used in the source dataset, 265 infants (53.0%) were classified as <9 months and 235 (47.0%) as >9 months; hearing loss occurred in 1 (0.4%) and 3 (1.3%), respectively ($p = 0.260$). Maternal age averaged 27.98 ± 4.79 years (median 28; range 18–43 years), and maternal age was not significantly associated with hearing loss ($p = 0.435$). Maternal education was recorded as educated in 335 mothers (67.0%) and not educated in 165 (33.0%); corresponding infant hearing-loss rates were 0.3% and 1.8% ($p = 0.107$).

Table 4. Demographic and maternal characteristics in relation to hearing loss

Variable	Category	n (%)	Hearing loss n (%)	p value
Sex	Female	264 (52.8%)	2 (0.75%)	1.000
	Male	236 (47.2%)	2 (0.84%)	
Gestational-age group	<9 months	265 (53.0%)	1 (0.4%)	0.260
	>9 months	235 (47.0%)	3 (1.3%)	
Maternal age	<20 years	36 (7.2%)	0	0.435
	21–30 years	298 (59.6%)	4 (1.3%)	
	31–40 years	164 (32.8%)	0	
	>40 years	2 (0.4%)	0	
Maternal education	No	165 (33.0%)	3 (1.8%)	0.107
	Yes	335 (67.0%)	1 (0.3%)	

4.5 Family history and consanguinity

Twelve infants (2.4%) had a family history of congenital hearing loss, but none of these infants had confirmed hearing loss in the present study ($p=1.000$). Seven infants (1.4%) had a history of consanguineous marriage and none had confirmed hearing loss ($p=1.000$). These null findings are limited by the very small numbers exposed to these factors.

4.6 Birth weight and neonatal risk factors

Birth weight had a mean of 2404.44 ± 594.53 g, median 2500 g, and range 1000–4100 g. The distribution was <2000 g in 96 infants (19.2%), 2000–3000 g in 330 (66.0%), 3001–4000 g in 73 (14.6%), and >4000 g in 1 (0.2%). In the binary low-birth-weight variable used for risk-factor analysis, 61 infants (12.2%) were classified as low birth weight; all four hearing-loss cases occurred in this subgroup (4/61, 6.6%), compared with none among 439 infants without this risk factor ($p<0.001$). Fifty-five infants (11.0%) had NICU admission with ventilation for more than 5 days; four (7.3%) had hearing loss, versus none among the 445 infants without this exposure ($p<0.001$). Birth asphyxia was documented in 15 infants (3.0%), of whom 2 (13.3%) had hearing loss; among infants without birth asphyxia, 2/485 (0.4%) had hearing loss ($p=0.005$). Hyperbilirubinemia occurred in 23 infants (4.6%), with hearing loss in 2 (8.7%) compared with 2/477 (0.4%) without hyperbilirubinemia ($p=0.011$). Maternal infection during pregnancy was recorded for 21 infants (4.2%); 2 (9.5%) had hearing loss compared with 2/479 (0.4%) without this exposure ($p=0.010$). Ototoxic medication exposure was recorded in 9 infants (1.8%); one (11.1%) had hearing loss compared with 3/491 (0.6%) without exposure, but this difference did not reach statistical significance ($p=0.070$).

Table 5. Major neonatal and maternal risk factors associated with hearing loss

Risk factor	Exposed n (%)	Hearing loss among exposed	Hearing loss among unexposed	p value
Low birth weight	61 (12.2%)	4/61 (6.6%)	0/439 (0%)	<0.001
NICU + ventilation >5 days	55 (11.0%)	4/55 (7.3%)	0/445 (0%)	<0.001
Birth asphyxia	15 (3.0%)	2/15 (13.3%)	2/485 (0.4%)	0.005
Hyperbilirubinemia	23 (4.6%)	2/23 (8.7%)	2/477 (0.4%)	0.011
Maternal infection	21 (4.2%)	2/21 (9.5%)	2/479 (0.4%)	0.010
Ototoxic medication exposure	9 (1.8%)	1/9 (11.1%)	3/491 (0.6%)	0.070

4.7 Cumulative risk-factor burden

Of the 500 infants, 384 (76.8%) had no recorded risk factor, 66 (13.2%) had one, 30 (6.0%) had two, 12 (2.4%) had three, 7 (1.4%) had four, and 1 (0.2%) had five. Hearing loss occurred in 0% of infants with zero, one or three risk factors, in 3.3% of infants with two risk factors, and in 28.6% of infants with four risk factors. No hearing loss occurred in the single infant recorded as having five risk factors. The source analysis reported a highly significant relationship between cumulative risk-factor exposure and hearing loss ($p<0.001$).

Table 6. Cumulative number of risk factors and hearing loss

Number of risk factors	n (%)	Hearing-loss incidence	Overall association
0	384 (76.8%)	0%	$p<0.001$
1	66 (13.2%)	0%	
2	30 (6.0%)	3.3%	

3	12 (2.4%)	0%	
4	7 (1.4%)	28.6%	
5	1 (0.2%)	0%	

5. DISCUSSION

The present prospective study evaluated a hospital-based universal newborn hearing-screening pathway in 500 neonates using DPOAE at 24–72 hours, repeat DPOAE at 10–15 days for referred infants, and BERA at 1 month for persistent referrals. The principal findings were an observed congenital hearing-loss incidence of 0.8%, a substantial reduction in referral rate after repeat OAE, and a concentration of confirmed cases among infants with identifiable neonatal or maternal risk factors.

The observed incidence of 0.8% corresponds to 8 per 1000 screened newborns. This lies within the broad range reported across Indian and international hospital-based series, although direct comparison is influenced by population characteristics, screening technology, timing, definitions of hearing loss, and completeness of diagnostic verification. Nagapoornima et al. reported congenital permanent hearing loss in approximately 5.6 per 1000 neonates, while Anil Kumar et al. reported 6.25 per 1000 in a two-stage screening study. Jewel et al. identified four affected infants among 1000 newborns, and Adelola et al. reported approximately 1.21 per 1000 live births in a large regional two-stage program. Differences in baseline risk composition and follow-up pathways likely account for part of this variation.

The most operationally important observation was the decline in referrals from 47 infants (9.4%) after OAE-1 to only four infants (0.8%) after OAE-2. The 43 infants who passed on rescreening demonstrate how a single OAE performed early after birth can generate transient referrals. OAE is sensitive to temporary external- and middle-ear conditions, and referral rates are known to be higher when testing is performed very early. Repeating the test after an interval allows transient obstruction or middle-ear fluid to resolve and can improve the positive predictive value of the screening pathway. Mishra et al. similarly emphasized that repeated OAE before ABR can reduce the economic and referral burden, while Jewel et al. described OAE as a practical nursery-based test that complements rather than replaces BERA.

All four infants who remained REFER on the second OAE also had hearing loss on BERA. Within the verified persistent-referral subgroup, this produced no second-stage false-positive cases. However, this result must not be interpreted as evidence that OAE-2 had 100% sensitivity or specificity, because BERA was not performed in infants who passed screening. A diagnostic-accuracy study requires verification of both screen-positive and an appropriate sample of screen-negative infants; the present study was designed as a staged screening cohort rather than a full test-accuracy study.

High-risk status was strongly associated with confirmed hearing loss. Of 116 infants with one or more risk factors, four (3.4%) were affected, while no confirmed case occurred among the 384 infants without recorded risk factors. This pattern is consistent with reports showing higher rates of hearing loss among high-risk neonates, particularly those requiring intensive neonatal care. Nevertheless, universal screening remains conceptually important because other cohorts have consistently demonstrated that selective high-risk screening alone can miss infants with congenital hearing loss. The absence of cases among low-risk infants in a 500-infant cohort should therefore not be used to justify replacing universal screening with selective screening.

Low birth weight showed a strong association with hearing loss in this cohort. All four affected infants were among the 61 babies classified as low birth weight in the risk-factor analysis. Very low and low birth weight often coexist with prematurity, respiratory support, infection, ototoxic exposure and hyperbilirubinemia; therefore, birth weight may function both as an independent biological marker and as a proxy for neonatal complexity. Cristobal and Oghalai have emphasized that very low birth weight commonly clusters with multiple insults capable of affecting cochlear or neural auditory function.

NICU stay with ventilation for more than 5 days was another prominent risk marker. All four affected infants had this exposure, yielding a hearing-loss rate of 7.3% within the exposed group. Prolonged intensive-care treatment may reflect respiratory failure, hypoxia, sepsis and other systemic illness, and also increases the likelihood of exposure to potentially ototoxic medications. Similar associations between prolonged NICU care and hearing impairment have been reported in Indian and international series.

Birth asphyxia was significantly associated with hearing loss in the study: 2 of 15 infants with asphyxia were affected compared with 2 of 485 infants without documented asphyxia. Hypoxic–ischemic injury can affect the cochlea, eighth nerve and central auditory pathway, and the strength of this association may depend on severity, duration and coexisting neonatal complications. The small number of affected infants means that the magnitude of the risk estimate should nevertheless be interpreted cautiously.

Hyperbilirubinemia was present in 23 infants, of whom two developed hearing loss. Bilirubin neurotoxicity is biologically relevant to the auditory system because brainstem auditory nuclei and neural pathways can be selectively vulnerable. Prior work has shown changes in ABR latency in association with elevated bilirubin levels, particularly in preterm and medically vulnerable neonates. The present association supports close auditory surveillance in jaundiced infants, especially when hyperbilirubinemia occurs alongside other risk factors.

Maternal infection during pregnancy was also significantly associated with neonatal hearing loss. The study grouped

maternal infectious exposures including rubella/hepatitis and used a broader antenatal infection category. Congenital infections, particularly cytomegalovirus and rubella, are established causes of sensorineural hearing loss, and some affected infants may develop delayed or progressive loss. The result reinforces the need for both newborn screening and continued audiological follow-up in infants with relevant congenital-infection risk.

Ototoxic medication exposure showed a numerically higher rate of hearing loss but did not reach conventional statistical significance ($p=0.070$). Only nine infants were recorded as exposed, limiting statistical power. Likewise, family history and consanguinity were not significantly associated with hearing loss in this cohort, but only 12 infants had a positive family history and seven had consanguinity. These negative results should therefore be interpreted as inconclusive rather than as evidence that these established risk domains are unimportant.

The cumulative number of risk factors was significantly related to hearing loss. Particularly notable was the 28.6% hearing-loss rate among the seven infants with four recorded risk factors. This supports the clinical concept that risk factors may act synergistically rather than independently. Because several exposures overlap—such as low birth weight, ventilation, hyperbilirubinemia and asphyxia—multivariable analysis would be required to estimate independent effects. The small number of outcome events (four cases) precluded reliable multivariable modeling in this dataset.

The staged protocol has practical implications for resource-limited settings. Screening every newborn with BERA would be expensive and labor-intensive, whereas a single early OAE may generate avoidable referrals. In the present cohort, repeating OAE reduced the number requiring BERA from a potential 47 to four, a reduction of 91.5% among first-stage referrals. This approach concentrates diagnostic resources on a much smaller group while preserving universal access to an initial physiological screen.

At the same time, the protocol must be interpreted in the context of auditory neuropathy spectrum disorder. OAE primarily evaluates cochlear outer-hair-cell function and may be present despite neural dysfunction. High-risk infants, particularly those with prolonged NICU admission, may therefore warrant ABR-based surveillance even after an OAE pass, depending on the screening guideline used. The source study did not perform BERA in all high-risk OAE-pass infants, so the frequency of auditory neuropathy in the screened cohort cannot be assessed.

The study also demonstrates the value of structured documentation and follow-up. The proforma captured antenatal, perinatal, postnatal, family and otological factors, and the patient information sheet established a clear schedule: OAE at 24–72 hours, repeat OAE at 10–15 days when needed, and BERA at approximately 1 month. Such a defined pathway helps reduce ambiguity for families and clinicians and may improve completion of diagnostic testing.

6. STRENGTHS AND LIMITATIONS

The study used universal first-stage screening rather than restricting enrollment to high-risk infants.

The screening pathway was prospectively defined and used objective physiological tests with a fixed schedule.

The study captured a broad range of maternal, perinatal and neonatal risk factors in a structured proforma.

The sample size was limited to 500 by the study period, and only four infants had the primary outcome; risk-factor estimates are therefore imprecise and vulnerable to sparse-data effects.

BERA verification was performed only in persistent OAE referrals. Consequently, false-negative OAE results, overall sensitivity, specificity and negative predictive value cannot be determined.

The source documents do not provide long-term audiological follow-up, so delayed-onset or progressive hearing loss could not be evaluated.

The source results label initial OAE referrals that later passed as conductive hearing loss; because confirmatory tympanometric or diagnostic middle-ear data were not documented, the present manuscript reports these cases conservatively as transient OAE referrals.

The exact institutional ethics committee approval number/date is absent from the supplied documents and must be added before submission.

The study was performed at a single tertiary hospital, which may limit generalizability to community births and other health-care settings.

7. CONCLUSION

In this cohort of 500 newborns, a staged hearing-screening strategy using DPOAE at 24–72 hours, repeat DPOAE at 10–15 days, and BERA for persistent referrals identified four infants with bilateral congenital hearing loss, corresponding to an observed incidence of 0.8%. Repeating OAE reduced the referral rate from 9.4% to 0.8%, substantially decreasing the number of infants requiring BERA. All confirmed cases occurred among neonates with identified risk factors, and low birth weight, prolonged NICU ventilation, birth asphyxia, hyperbilirubinemia, maternal infection and cumulative risk-factor burden were significantly associated with hearing loss. The findings support universal newborn hearing screening with a structured multistage pathway, while also emphasizing intensified surveillance for high-risk infants.

8. CLINICAL IMPLICATIONS

Universal physiological hearing screening should be offered before or soon after discharge rather than relying solely on a

high-risk register.

A repeat OAE after an initial REFER can markedly reduce transient referrals and unnecessary diagnostic BERA.

Persistent bilateral OAE referrals require prompt diagnostic auditory assessment.

Infants with low birth weight, prolonged NICU ventilation, asphyxia, hyperbilirubinemia or congenital-infection risk require particularly careful audiological follow-up.

OAE-pass results do not exclude neural hearing disorders; ABR-based pathways may be warranted in selected high-risk infants.

9. DECLARATIONS

Ethics approval: Written parental consent and participant-confidentiality documentation were present in the supplied study records. Institutional ethics committee approval number/date: [to be inserted from original IEC approval].

Consent to participate: Written informed consent was obtained from the parent/legal representative before participation.

Consent for publication: Not applicable for individually identifiable data; no participant-identifying information is presented.

Funding: [To be stated by the authors].

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Data availability: The manuscript is based on the study dataset and thesis records from Jaipur Golden Hospital. Availability of de-identified data should be stated according to institutional policy.

Author contributions: R.K.: study conception, data collection, analysis, interpretation and manuscript preparation. Contributions of supervisors/co-authors should be added according to journal authorship criteria.

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APPENDIX: DATA-CONSISTENCY NOTES FOR FINAL SUBMISSION

- The original Results text describes the 43 first-stage referrals that passed OAE-2 as “conductive hearing loss.” The supplied documents do not show tympanometry or another diagnostic test confirming conductive loss; this manuscript therefore reports them as transient OAE referrals/first-stage false positives.
- The source sample-size text contains an internally inconsistent percentage (“4 in 1000” and “0.025%”). The manuscript does not repeat that arithmetic as a calculated estimate; it simply states that the study enrolled 500 because the project was time-bound.
- The thesis uses gestational-age groups “<9 months” and “>9 months,” which are retained when reporting the source data. For journal submission, it would be preferable to re-tabulate gestational age in completed weeks (e.g., <37 vs ≥37 weeks) from the raw dataset if available.
- The institutional ethics committee approval number/date was not found in the supplied documents. This must be inserted before submission.
- The four outcome events are too few for stable multivariable risk-factor modeling. The reported p values are unadjusted bivariate analyses from the source study.
- Because BERA was performed only in persistent OAE referrals, diagnostic sensitivity/specificity for OAE cannot be validly calculated for the entire cohort.