Outcomes of hearing screening in very-low-birthweight infants in a tertiary hospital in South Africa: A cross-sectional study

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Background. In resource-constrained settings, targeted hearing screening is a feasible short-term option to identify infants with hearing loss. The risk factors which guide targeted hearing screening are based on data collected in high-income countries, with very little data available from low- and middle-income countries. Many of these risk factors are associated with very-low-birthweight (VLBW). Similarly, VLBW infants are more likely to experience complications of prematurity.
Objectives. To identify associations between the complications of prematurity and failing hearing screening.
Methods. We conducted a retrospective record review of 508 infants admitted to Tygerberg Hospital during 2022 who underwent hearing screening. Univariate and multivariate logistical regression was used to demonstrate an association with failing the hearing screen. The proportion of hearing screening failures, as well as the frequency of complications of prematurity were also determined.
Results. A total of 508 VLBW were enrolled in the study. The proportion of hearing screening failures was 7% (95% CI 5 - 9). Factors with a statistically significant association with failing the hearing screen included being extremely low-birthweight (ELBW) (p=0.02) and exposure to gentamicin (p=0.04).
Conclusion. We found a significant association between failing the hearing screening, birthweight and exposure to gentamicin. Further research needs to be done to identify other novel risk factors in the South African context.

Keywords. very low birthweight; hearing screening; complications of prematurity; hearing loss; high-risk infants.

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Hearing loss is a silent but increasing global problem, with significant morbidity, economic cost and far-reaching impact. In 2019, the Global Burden of Diseases study found that 70 million children under the age of 15 years had hearing loss and that children under the age of 5 years living in low- and middle-income countries (LMIC) were the most severely affected.[1] Similarly, South Africa (SA), as an upper-middle-income country, carries a high burden of childhood hearing loss, with an estimated hearing loss incidence of 4 - 6 per 1 000 live births.[2] However, hearing loss in SA often goes unaddressed due to delayed diagnosis and intervention. An estimated 90% of children in SA do not have access to hearing screening services, which results in a median age of diagnosis of 3.7 years.[3] This is in stark contrast to the Health Professions Council of SA (HPCSA) and the Joint Committee on Infant Hearing (JCIH) 1-3-6 recommendations, which state that neonatal screening should be done by 1 month of age, diagnostic evaluation made by 3 months and intervention implemented by 6 months.[4]

Unaddressed childhood hearing loss affects all aspects of a child's development, as well as their family and the broader community. The critical phase for speech and language development is between birth and 5 years of age, with the first year being the most crucial.[5] This is due to the early neuroplasticity, which is optimised for language and cognitive development.[6] Affected children have reduced academic performance and a higher unemployment rate as adults. Additionally, social isolation and loneliness are common, as hearing impairment is stigmatised in many communities, which further precipitates the social isolation experienced by affected children.[7] To enable affected children to reach their highest developmental potential, timely diagnosis and intervention are critical. This can be accomplished using universal or targeted hearing screening programmes. In SA, there are many barriers to the implementation of universal screening, making targeted screening the most feasible short-term solution to address infant hearing loss.[8] The HPCSA compiled a list of risk factors for hearing loss based on the JCIH recommendations to guide targeted screening.[4] However, the majority of these factors are based on findings in higher-income countries, and there is a lack of data on relevant risk factors for hearing loss in LMICs, where the social determinants of health are vastly different.[9] Special consideration needs to be given to the most at-risk infant populations and possible novel risk factors for hearing loss that could exist in the SA context.

Very-low-birthweight infants (VLBW; <1 500 g) is a key population to consider. VLBW is often associated with preterm birth (<37 weeks' gestation).[10] These infants are more likely to experience complications of prematurity owing to anatomical and functional immaturity of multiple organ systems. Although improvement in obstetric and neonatal care in recent decades has resulted in greater survival of VLBW infants, the incidence of some complications has not decreased significantly.[11] Long-term neurocognitive disability (including hearing loss) has increased, as preterm infants as young as 20 weeks' gestation may now survive.[12] VLBW has been identified as a major risk factor

for hearing loss owing to its close association with multiple risk factors for hearing loss as listed by the JCIH.[12,13] These risk factors include admission to the neonatal intensive care unit (NICU) for more than 5 days, *in utero* infections, culture-positive meningitis, family history of hearing loss, craniofacial abnormalities and syndromes associated with hearing loss.[4] Other risk factors found to have an association with hearing loss in VLBW infants include aminoglycoside exposure, hyperbilirubinaemia, hypoxia and HIV infection.[14] However, very little research has been done to analyse the association of complications of prematurity and hearing loss, especially in the SA context.

The objective of the present study was to identify context-specific risk factors for hearing screen failures in VLBW infants cared for at a tertiary hospital in SA. Secondary objectives included determining the proportion of hearing screen failures and describing the complications of prematurity which occur in the sample.

Methods

Study design and setting

We conducted a retrospective cross-sectional review of hearing screening outcomes of VLBW infants at TBH, SA, between1 January 2022 and 1 December 2022. TBH is a 1 384-bed tertiary hospital in the Western Cape Province of SA. The 132-bed neonatal unit includes a 12-bed NICU, 3 high-dependency wards and 1 kangaroo mother care ward. Data on VLBW infants admitted in the neonatal unit were extracted from the admission records. Using the TBH Enterprise Content Management electronic patient records and the Vermont Oxford Network database, any VLBW infant that underwent hearing screening was identified. The exclusion criteria included infants identified with factors on the JCIH high-risk register that are not considered complications of prematurity, such as infants with a family history of hearing loss, infants identified with syndromes associated with hearing loss and those born with craniofacial abnormalities or exposed to chemotherapy.

Study procedure

The universal newborn hearing screening programme at TBH was expanded from targeted screening in 2016 by Carel du Toit, a school for hearing-impaired children, and is still managed by this organisation. All infants admitted to the neonatal wards are screened using a three-stage screening protocol. Screening is done by trained hearing screening personnel in a quiet room using automated auditory brainstem response (AABR). Infants are screened once they are stable on room air, and they weigh at least 1 200 g. A minimum threshold of 35 dB for AABR is required for a pass, and those who fail the screen in one or both ears are re-screened. After three failed screening tests the infant is sent to the audiologist for full diagnostic assessment.

Sample size calculation

Hearing screening failure was the outcome used to calculate the sample size. Owing to limited information on the subject, it was assumed that 50% of the participants would have a hearing screening failure. This was a precautionary approach to ensure a sufficient sample size to account for any possible proportion, with the variation of proportion largest at 50%. This approach was to ensure a more reliable result within the desired confidence interval and margin of error. Using WINPEPI, a sample size of 624 was required to estimate the hearing screening failure rate with a precision of 4% for a 95% confidence interval (CI).

Statistical analysis and ethics approval

Statistical analysis was performed using Stata 18 (IBM Corp., USA). Continuous variables were summarised using means (standard deviations (SD)) and categorical variables were summarised using count (percent). We performed logistic regression to determine variables associated with hearing screening failure in the univariate analysis. Variables with a p-value <0.1 in the univariate analysis were entered into the multivariate logistic regression model. For multivariate logistic regression, statistical significance was set at a p-value <0.05. We reported estimates with the corresponding 95% CI.

Ethics

Ethical approval was granted by the Undergraduate Research Ethics Committee of Stellenbosch University (ref. no. U23/10/292) and the National Health Research Database (ref. no. WC_202310_025). Patient data were de-identified and statistical analysis was completed on the anonymised data. A waiver of individual informed consent was granted as the data were collected retrospectively with no direct contact between the researcher and the participants, minimal risk was posed to participants, and the rights and welfare of the patients were not adversely affected.

Results

Description of the study population

Over a 1-year period, 508 VLBW infants underwent hearing screening and were included in this study. Of these, 136 (26.8%) were extremely low birthweight (ELBW; <1 000 g) infants. The mean (SD) birthweight and gestational age at birth were 1 158 g (210 g) and 29.88 (2.13) weeks, respectively. Sex distribution was similar (245 (48.2%) males and 263 (51.77%) females). Most of the infants were delivered via caesarean section 354 (69.7%), and 154 (30.31%) infants were born via normal vaginal delivery (NVD). Of the infants born via NVD, none required assisted delivery. The median (interquartile range) APGAR scores were 7 (5 - 7), 8 (7 - 9), 9 (9 - 10) at 1, 5 and 10 minutes, respectively.

The three most common comorbidities in the study population were respiratory distress syndrome in 472 (92.9%), jaundice requiring phototherapy in 431 (85.4%), and being born to women living with HIV in 105 (20.7%) (Table 1).

The most common interventions received by the study population were: non-invasive ventilation with continuous positive-airway pressure (CPAP) in 466 (91.7%); receiving intravenous gentamicin in 284 (55.9%); and surfactant administration to 133 (22.2%) infants (Table 1).

Hearing screening failures

The rate of hearing screen failure was 7% (95% CI (5 - 9)), with a total of 35 hearing screening failures. Of the 35 hearing screening failures, 17 (48.6%) occurred in ELBW infants. ELBW, exposure to ototoxic drugs (gentamicin), non-invasive ventilation (nasal prong oxygen (NPO_2), high-flow nasal cannula (HFNC) and retinopathy of prematurity (ROP) increased the odds of hearing screening failure (Table 2).

None of the infants who had jaundice required an exchange blood transfusion. However, of the 409 who received phototherapy, 16 (3.8%) had total bilirubin levels approaching the recommended therapeutic level for exchange transfusion. Only one of these infants failed the hearing screen. No significant association was found between failing the hearing screen and total bilirubin levels approaching the recommended therapeutic level for exchange transfusion (p=0.87).

Table 1. Comorbidities and medical care received by the study population (*N*=508)

	n (%)
Comorbidities	
Respiratory distress syndrome	472 (92.9)
Jaundice requiring phototherapy	431 (85.4)
Baby born to a mother living with HIV	105 (20.7)
Intraventricular haemorrhage (Grade)	95 (19.3)
1	63 (12.8)
2	21 (4.2)
3	8 (1.6)
4	3 (0.6)
Retinopathy of prematurity (Stage)	76 (15.0)
1	33 (6.5)
2	41 (8.1)
3	2 (0.4)
4	0 (0)
5	0 (0)
Positive blood culture*	50 (9.8)
Necrotising enterocolitis†	48 (9.5)
Congenital infections	
Cytomegalovirus	20 (3.9)
Syphilis	16 (3.2)
Meningitis	1 (0.2)
Medical care received	
Non-invasive ventilation	
CPAP	466 (91.7)
NPO_2	415 (81.7)
HFNC	340 (66.9)
Ototoxic drug exposure: Gentamicin	284 (55.9)
Surfactant administration	133 (22.2)
Admission to NICU >5 days	35 (6.9)
Invasive ventilation	
Conventional mandatory ventilation	12 (2.4)
High-frequency oscillatory ventilation	8 (1.6)

CPAP = continuous positive-airway pressure; NPO2 = nasal-prong oxygen at ≤2 L/min; HFNC = high-flow nasal cannula at >2 L/min; NICU = neonatal intensive care unit.
*Positive blood culture refers to growth of a pathogenic organism on a blood culture medium and does not include contaminants.
†Necrotising enterocolitis is a life-threatening gastrointestinal emergency in neonates and is caused by acute inflammation and damage to the intestinal tract. It was classified according to the modified Bell's staging.

Only a small number of infants from the study sample were diagnosed with intraventricular haemorrhage (IVH) grades 3 and 4. Consequently, the affected sample was too small to reasonably estimate the association of IVH grades 3 and 4 with failing the hearing screen. Therefore, only IVH grade 2 is included in Table 2. Similarly, culture-positive meningitis was excluded from Table 2 as there was only 1 infant with culture-positive bacterial meningitis, resulting in a sample that was too small to reasonably estimate the effect of meningitis on failing the hearing screen.

Due to missing data on ROP, the multivariate analysis was performed twice, including and excluding ROP, and the results differed (Table 3). ELBW was found to be significant in both (p=0.04 and p=0.02), and ototoxic drug exposure (gentamicin) was found to be significant in the multivariate analyses excluding ROP (p=0.04).

The results of the multivariate analysis excluding ROP are considered more precise than the results including ROP as these have a bigger data sample and are not influenced by missing data.

Discussion

In the present study, we found that 7% of VLBW infants failed the hearing screen. This is higher than the 5% referral rate recommended by the HPCSA guidelines for Early Hearing Detection and Intervention for universal hearing screening.[4] In the literature, there is a wide variation in the reported prevalence of hearing screening referrals. However, there seems to be a consensus that preterm and lower birthweight infants have a higher hearing screening referral rate when compared with term infants with larger birthweights. Wroblewska-Seniuk *et al.*[15] found an inverse relationship between hearing screening failures and younger gestational age. Likewise, Von Dommelen *et al.*[16] found increased hearing screening referral rates in younger gestational ages and lower birthweight. In a similar study, Borkoski-Barreiro *et al.*[17] found that VLBW infants were 2.2% more likely to have hearing loss than the general population. However, there are technical challenges that must be considered when looking at the hearing screening results of infants. False positive results may occur if an infant is crying during the hearing screen or if there are high ambient noise levels.[13,14] Although an argument could be made that the higher hearing screening failure rates found in VLBW infants are due to false positives associated with technical challenges of hearing screening, this is unlikely. Hearing screening programs are specifically designed to have multiple screenings done in a quiet room to avoid false positives. Additionally, these technical aspects apply to all infants undergoing hearing screening and are not unique to lower birthweight infants or infants of younger gestational age. Based on the findings from literature, it is likely that the higher proportion of failures in this study is due to the cohort consisting exclusively of VLBW and ELBW infants, who are at higher risk of hearing loss.[15-17]

ELBW infants had a significant association with failing the hearing screen in this study (p=0.02). There is a paucity of data related to hearing screening failures specifically among ELBW infants in the literature. However, like VLBW, ELBW is closely associated with preterm birth and can be seen as an indicator of biological maturation.[17] As auditory maturation starts during pregnancy and peaks at 6 months postnatally,[18] immature ELBW infants are more vulnerable to insults to their auditory system. This was demonstrated in a study by Xoinis *et al.*,[19] which showed that ELBW infants are at higher risk for sensorineural hearing loss and auditory neuropathy. Consequently, ELBW infants have more risk factors for hearing loss and experience more complications of prematurity. Bielecki *et al.*[20] reported that the greater the number of risk factors the infant is exposed to, the higher the probability of hearing impairment. Therefore, our finding of a significant association between ELBW and failing the hearing screening in this cohort is consistent with published literature, as these infants have a more vulnerable developing auditory system and experience a greater number of complications of prematurity.

The results of this study also demonstrated a significant association between ototoxic drug exposure (gentamicin) and failing the hearing screen (p=0.04). Gentamicin is an aminoglycoside antibiotic commonly used to empirically treat suspected or confirmed bacterial infections in neonates owing to its cost-effectiveness and high bactericidal efficacy.[21] However, gentamicin is known to be ototoxic in prolonged use, damaging inner ear cells and resulting in irreversible sensorineural hearing loss.[14] The results of the

Table 2. Univariate logistic regression of association between complications of prematurity and failing the hearing screen

Variable	cOR	95% CI	*p*-value
Birthweight			
VLBW	1	-	-
ELBW	2.81	1.40 - 5.63	0.004*
Apgar at 5 min			
>7	1	-	-
<7	0.92	0.77 - 1.10	0.37
CPAP			
No	1	-	-
Yes	3.31	0.44 - 24.82	0.24
HFNC			
No	1	-	-
Yes	2.40	1.98 -5.90	0.06*
NPO_2			
No	1	-	-
Yes	2.75	0.83 - 9.18	0.099*
Respiratory distress syndrome			
No	1	-	-
Yes	2.72	0.36 - 20.44	0.33
Jaundice			
Yes (phototherapy)	1	-	-
No	1.22	0.49 - 3.06	0.67
Ototoxic drug exposure			
No	1	-	-
Yes (gentamicin)	2.41	1.10 - 5.25	0.03*
Surfactant			
No	1	-	-
Yes	1.67	0.79 - 3.52	0.18
Baby born to a woman living with HIV			
Yes (on ART)	1	-	-
Yes (not on ART)	4.45	0.72 - 27.43	0.11
No	1.73	0.59 - 5.05	0.32
Intraventricular haemorrhage			
No	1	-	-
Grade 1	1.79	0.74 - 4.31	0.20
Grade 2	1.50	0.33 - 6.82	0.60
ROP			
No	1	-	-
Stage 1	0.93	0.20 - 4.27	0.92
Stage 2	2.96	1.11 - 7.86	0.03*
Stage 3	14.36	0.85 - 241.89	0.06*
Positive blood culture			
No	1	-	-
Yes (early)	1.66	0.61 - 4.00	0.32
Necrotising enterocolitis			
No	1	-	-
Yes (medical)	0.99	0.29 - 3.34	0.97
TORCH infections			
No	1	-	-
Syphilis	2.10	0.46 - 9.70	0.34
Cytomegalovirus	2.60	0.72 - 9.37	0.14
NICU >5 days			
No	1	-	-
Yes	1.84	0.61 - 5.54	0.28

(continued)

Table 2. (continued) Univariate logistic regression of association between complications of prematurity and failing the hearing screen

Variable	cOR	95% CI	*p*-value
Invasive ventilation			
No	1	-	-
Yes (conventional mandatory ventilation)	1.25	0.16 - 10.01	0.83
Yes (high-frequency oscillatory ventilation)	1.97	0.24 - 16.49	0.53

cOR = crude odds ratio; CI = 95% confidence interval; VLBW = very low birthweight; ELBW = extremely low birthweight; CPAP = continuous positive-airway pressure; HFNC = high-flow nasal cannula at >2 L/min; NPO = nasal-prong oxygen at <2 L/min; ART = antiretroviral therapy; ROP = retinopathy of prematurity; TORCH = toxoplasmosis, rubella, cytomegalovirus, herpes simplex; NICU = neonatal intensive care unit; HFO = high-frequency oscillatory ventilation.
*Included in multivariate analysis.

Table 3. Multivariate logistic regression demonstrating associations between complications of prematurity and failing the hearing screen

	Including ROP			Excluding ROP		
Variable	aOR	95% CI	*p*-value	aOR	95% CI	*p*-value
Birthweight						
VLBW	1	-	-	1	-	-
ELBW	2.66	1.06 - 6.63	0.04	2.45	1.19 - 5.04	0.02
Ototoxic drug exposure: Gentamicin						
No	1	-	-	1	-	-
Yes	1.95	0.73 - 5.21	0.18	2.31	1.05 - 5.07	0.04
HFNC*						
No	1	-	-	1	-	-
Yes	4.64	0.60 - 35.98	0.14	1.77	0.69 - 4.50	0.23
ROP						
No	1	-	-			
Stage 1	0.85	0.18 - 4.02	0.84			
Stage 2	2.46	0.89 - 6.80	0.08			
Stage 3	9.75	0.52 - 181.24	0.13			

aOR = adjusted odds ratio; CI = confidence interval; VLBW = very low birthweight; ELBW = extremely low birthweight; HFNC = high-flow nasal cannula at >2 L/min; ROP = retinopathy of prematurity.
*NPO_2 excluded owing to collinearity with HFNC.

current study are in keeping with the findings of Garinis *et al.*,[21] who also reported a significant association between gentamicin and failing the hearing screen. Additionally, their study found a greater association with cumulative doses of gentamicin. Infants who received 4 or more cumulative doses had the highest hearing screening failure rate, and infants who received only 2 cumulative doses still had a higher hearing screening failure rate than those who did not receive gentamicin. Additionally, Garinis *et al.*[21] found that exposure to vancomycin, another aminoglycoside antibiotic, was also associated with greater hearing screening failures. Similarly, a retrospective study done by Frezza *et al.*,[23] found a correlation with cumulative doses of aminoglycosides and sensorineural hearing loss. In their study, an association was even found with a 3-day empiric course of aminoglycosides, which led them to conclude that the immature cochlea is more susceptible to repeated doses of aminoglycoside antibiotics. Additionally, there have been recent discoveries of mutations in mitochondrial DNA found in families with sensorineural hearing loss after receiving low doses of aminoglycosides. This has emphasised the role that genetic susceptibility may play in the effect of aminoglycoside use on hearing. These findings highlight that the ototoxicity of aminoglycoside antibiotics, such as gentamicin, is related to various factors such as cumulative doses, duration of treatment and genetic susceptibility.[14] However, more research is needed to investigate the mechanism of ototoxic drugs on the immature cochlear system as well as the ototoxic effects of other drugs such as vancomycin and amikacin, which are not used as commonly in the neonatal setting nor investigated as frequently.

There was no proven association between ROP diagnosis (stage 2 or stage 3) and failing the hearing screen; however, the results were greatly affected by missing data. There are many overlapping risk factors for ROP and hearing loss such as low birthweight, prematurity, hypoxia, sepsis, long NICU stay and mechanical ventilation. Additionally, there seem to be possible overlapping pathogenetic mechanisms, as oxidative stress has been associated with ROP and sensorineural hearing loss.[22] There are varying reports in the literature regarding the association between ROP and hearing loss. A study by Yücel *et al.*[22] found an association between the severity of ROP and failing the hearing screen. However, a study done by Song *et al.*[24] demonstrated a higher incidence of hearing screening failure in the ROP group compared with the non-ROP group, but did not show a statistically significant association. More research is needed to investigate the possibility of an association, and to better understand the possible interplay and pathogenesis of these conditions.

In this cohort of VLBW and ELBW infants at TBH, the most frequently occurring comorbidities and treatments were respiratory distress syndrome, non-invasive ventilation, jaundice requiring phototherapy, exposure to ototoxic drugs, surfactant administration and HIV exposure. These findings are similar to a study done by

Kanji *et al.*[12] (in a tertiary hospital in Gauteng), who reported the most frequent complications of prematurity in their cohort of 86 VLBW infants as jaundice, respiratory distress syndrome, NICU stay longer than 48 hours, mechanical or assisted ventilation, exposure to ototoxic drugs and IVH grade 2. Although there is a similarity in complications of prematurity, more epidemiological research needs to be done to look at the frequency of the different complications of prematurity in at-risk neonates in SA.

Study strengths and limitations

The major strength of this study was the large number of variables that were analysed. This study also had a larger sample size than similar studies done in SA and is one of the few studies reporting exclusively on the prevalence rate of hearing screening failures among VLBW infants in SA. The retrospective nature of this study was a major limitation, as evidenced by the large number of missing data values, especially related to ROP screening, resulting in the statistical analysis needing to be adjusted. This was also a single-centre study at a major tertiary hospital, and therefore, findings may not be generalisable to other facilities in high- and LMIC. Additionally, only the effect of gentamicin was investigated in the present study. Other aminoglycosides used in neonatal care, such as amikacin, were not investigated as they are not used as commonly in our setting.

Conclusion

In the present study, conducted at a tertiary hospital in SA, the proportion of hearing screening failures was 7%, and a significant association was found between failing the hearing screen in ELBW infants and receiving gentamicin. Future research should focus on identifying novel risk factors for hearing screening failures in the SA context. Special attention should be given to ROP.

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