

# High-Risk Neonatal Hearing Screening Program Using Automated Screening Device Performed by Trained Nursing Personnel at Siriraj Hospital: Yield and Feasibility

Pimol Srisuparp MD\*,  
Ruemporn Gleebbur RN\*\*, Sopapan Ngerncham MD\*,  
Jintana Chonpracha RN\*\*, Jeeranan Singkampong RN\*\*

\* Division of Neonatology, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University.

\*\* Pediatric Nursing Division, Department of Nursing, Siriraj Hospital

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**Objectives:** To determine the prevalence and significant risk factors for pathologic hearing screening test results in high-risk neonates and the feasibility of implementing hearing screening program using automated otoacoustic emission (OAE)/ auditory brain stem response (ABR) device performed by trained nursing staffs.

**Study design:** Single-center prospective, descriptive study.

**Material and Method:** All neonates admitted to the Division of Neonatology, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University, who met the high-risk criteria according to Joint Committee of Infant Hearing 1994, American Academy of Pediatrics, were screened with one-step protocol using an automated OAE/ABR device (AccuScreen, GN Otometrics, Denmark). Infants who failed 2 consecutive OAE tests were reconfirmed by ABR prior to discharge. Descriptive analysis was used for the prevalence of pathologic hearing test results, age at screening, duration of procedure, number of risk factors per infant. Univariate analysis using Chi-square test and multiple logistic regression analysis were used for identification of significant risk factors.

**Results:** Five hundred and seven infants were identified to be at-risk in an 18-month study period. The prevalence of pathologic hearing screening test was 6.7% with unilateral and bilateral pathologic results in 13 and 21 infants (2.6% and 4.1%). Only craniofacial anomalies and mechanical ventilation > 5 days were shown to be independent significant risk factors (42-fold and 4-fold increased risk). Median age at screening test performed was 19 days (range 1-149 days) and almost all infants (97.3%) were screened within 3-month postnatal age. The mean time for hearing screening procedure was  $10.7 \pm 8.0$  minutes (range 2-60 minutes), 98.1% of procedure was accomplished within 30 minutes.

**Conclusion:** Hearing screening using automated OAE/ABR devices in high-risk neonates revealed approximately 7% of pathologic results with almost two-thirds having bilateral affected. The significant independent risk factors in this study population were craniofacial anomalies and mechanical ventilation > 5 days. The protocol of having trained nursing staffs to perform the screening yielded good results, i.e., the coverage of screened infants within 3 months of age (97%), feasible duration of procedure.

**Keywords:** Hearing screening, High-risk neonates, Automated OAE/ABR device

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The first 3 years of life are the most important period for speech and language acquisition. Reduced hearing acuity of any severity in infancy or early child-

hood may prevent the child from receiving adequate auditory, linguistic and social stimulation required for speech and language development. Significant hear-

ing loss is one of the most common major abnormalities present at birth. The prevalence of significant bilateral hearing loss is reported to be 1.5 to 6 per 1,000 newborn infant in the well baby nursery population<sup>(1-5)</sup>. Several risk factors associated with hearing loss during early infancy have been described<sup>(6, 7, 8)</sup>. In addition to hereditary cause, a number of in utero and neonatal complications (e.g., infection, immaturity, asphyxia, ototoxic medications and hyperbilirubinemia) have been described as risk factors of neonatal hearing disorders. Such complications are known as common morbidities hampering on infants in neonatal intensive care unit (NICU) in their clinical course. Data have shown that 2-4% of infants survived from NICU experience significant hearing loss<sup>(1, 9, 10)</sup>.

Ideally, identification of all children with hearing impairment as early in life as possible is optimal for initiating appropriate early intervention. Over the past two decades, attempts had been made in developed countries, to early identify all children with hearing impairment. The Joint Committee on Infant Hearing 1990 Position Statement recommended the use of a high risk criteria within neonatal period register for selecting the neonates at risk for congenital or early onset hearing loss<sup>(11)</sup>. However, research shows that the screening using high risk criteria alone misses 50 percent of infants who eventually develop severe to profound hearing impairment<sup>(12-14)</sup>. Recently, the National Institute of Health's 1993 Consensus on Early Identification of Hearing Impairment in Infants and Children<sup>(15)</sup>, and American Academy of Pediatrics' Joint Committee on Infant Hearing (1994)<sup>(16)</sup>, have endorsed universal newborn hearing screening program (UNHSP) for all infants before 3 months of life, with appropriate intervention initiated by 6 months of age.

In Thailand, there are few centers develop neonatal hearing screening to be a part of routine care. The actual countrywide incidence of neonatal hearing loss are not yet available. In our hospital, as a tertiary care center, we have implemented the hearing screening to screen all infant with risk factors since 2004. One-step service with two-stage screening using an automated otoacoustic emissions (OAE) and auditory brainstem response (ABR) device were performed in all high risk infants prior to discharge. This study, considered as a first step toward the implementation of universal neonatal hearing screening, was purposed to

report an prevalence and significant risk factors of neonatal hearing disorders in selective group of infants which might reflect the quality of care, per se. In addition, the study evaluated the ease and the yield of our screening protocol represented by time spent for performing the test and coverage of the screened infants.

## **Material and Method**

### **Study design**

This was a prospective, descriptive study design to determine the prevalence of hearing impairment in high-risk neonates cared for in the Department of Pediatrics, Siriraj hospital from February 2004 through July 2005.

### **Study population**

All infants with age less than 28 days admitted in the Division of Neonatology who met the entry criteria stated below were eligible for the study.

### **Inclusion criteria**

Infants were enrolled in the study if at least one of risk factors, according to the following modified high-risk criteria stated by American Academy of Pediatrics Joint Committee on Infant Hearing 1994,<sup>(5)</sup> were met. These risk factors are family history of hereditary childhood sensorineural hearing loss, in utero infection, such as cytomegalovirus, rubella, syphilis, herpes, and toxoplasma, craniofacial anomalies, including those with morphological abnormalities of the pinna and ear canal excluding isolated ear pits and tags, birth weight less than 1,500 grams (3.3 lbs.), hyperbilirubinemia at a serum level requiring exchange transfusion (18 mg/dl in term, and 15 mg/dl in preterm), ototoxic medications, including but not limited to the aminoglycosides, used longer than 7-day duration or in combination with loop diuretics, bacterial meningitis, apgar scores of 0 to 4 at 1 minute or 0 to 6 at 5 minutes, mechanical ventilation lasting 5 days or longer, stigmata or other findings associated with a syndrome known to include craniofacial, branchial arch, cleft palate, and cervical spine dysmorphism.

### **Exclusion criteria**

Infants were excluded from the study if they had; severe multiple anomalies, incompatible with life, futile condition determined by attending physician, atresia/stenosis of external ear canal both ears, untreated otitis externa.

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*Correspondence to: Pimol Srisuparp MD, Division of Neonatology, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University. e-mail: sipri@mahidol.ac.th*

### Study procedure

One-step screening with a handheld automated OAE/ABR AccuScreen (GN Otometrics, Denmark) was used. We had a group of nursing staffs trained for performing the test until they were comfortably competent. The device provided pass-refer report for both OAE and ABR. After obtaining parental consent, all high risk infants were evaluated by transient evoked otoacoustic emission (TEOAE) technique prior to discharge. Each screening procedure was done by any one of trained nursing staffs who was on duty on that scheduled day. Infants who initially failed TEOAE were reexamined with TEOAE again and if they still had abnormal OAE results, they were confirmed with automated ABR (A-ABR). All infants were scheduled to have this two-stage screening consecutively in the same day.

Data were collected for risk factors, screening results, age at screening, duration of the screening procedure.

**Table 1.** Prenatal and neonatal risk factors (n=468)

Risk factors	n	%
Prenatal risk factors	1	0.2
Family history of hearing loss		
In utero infections (TORCH)	22	4.3
Neonatal risk factors		
Craniofacial anomalies	12	2.4
Very low birth weight infants <1500g	94	18.5
Hyperbilirubinemia	26	5.1
Ototoxic medications > 1 wk	408	80.5
Bacterial meningitis	11	2.2
Low apgar scores	76	15
Mechanical ventilation ≥ 5 days	74	14.6
Stigmata and / or syndrome	5	1

### Data Analysis

The numerical data were reported as median for age at screening and mean ± SD for duration of the procedure. All risk factors were analyzed with Chisquare test and represented the correlation to abnormal hearing test as crude Odds Ratio with 95% confidence interval. Multivariate logistic regression analysis was used to further evaluate the validity of single risk factors.

### Results

During the 18-month study period, a total of 507 infants were enrolled with 493 infants screened. Forty-eight infants failed OAE results and only 34 infants (6.7%) were confirmed by A-ABR to have pathologic hearing screening results. There were unilateral and bilateral pathologic results in 13 and 21 infants (2.6% and 4.1%), respectively.

Table 1 lists the prenatal and neonatal risk factors found in our high risk population. The four top most common risk factors, ranked in order of frequency, included ototoxic medications, very low birth weight infant, low Apgar scores and mechanical ventilation. Almost 90% of infants had only 1-2 risk factors (Table 2). Only 2 infants had the highest of 5 risk factors.

**Table 2.** Number of risk factors per infant (n=468)

no. of risk factors/ infant	n	%
1 factor	307	64.5
2 factors	107	22.9
3 factors	30	6.4
4 factors	27	5.8
5 factors	2	0.4

**Table 3.** Risk factors in infants with pathologic hearing screening results

	Pass (n = 435)		refer (n = 33)		p	Odds Ratio (95% CI)
	n	%	n	%		
Family history of hearing loss	1	0.2	0			-
In utero infections (TORCH)	20	4.6	2	6.1	.70	1.34 (0.30-5.99)
Craniofacial anomalies	4	0.9	8	24.2	.000	34.48 (9.72-122.31)
Very low birth weight infants<1500g	85	19.5	8	24.2	.51	1.32 (0.57-3.02)
Hyperbilirubinemia	24	5.5	2	6.1	.89	1.11(0.25-4.89)
Ototoxic medications > 1 wk	379	87.1	25	75.8	.07	0.46(0.20-1.07)
Bacterial meningitis	10	2.3	1	3.0	.79	1.33(0.17-10.70)
Low apgar scores	65	14.9	11	33.3	.008	2.85(1.32-6.15)
Mechanical ventilation ≥ 5 days	62	14.3	12	36.4	.001	3.44(1.61-7.34)
Stigmata and / or syndrome	4	0.9	1	3.0	.28	3.37(0.37-31.02)

Four hundred and sixty-eight infants had completed records for evaluating the correlation of risk factors and pathologic hearing screening results. Craniofacial anomalies, low Apgar scores and mechanical ventilation >5 days were identified as significant risk factors when using univariate analysis (Table 3). There was trend towards the increased risk of pathologic results in infants receiving ototoxic medication for >1 week (p=0.07). On multivariate logistic regression analysis (Table 4), only craniofacial anomalies and mechanical ventilation >5 days were shown to be significant risks with 42-fold increase in the craniofacial anomalies group.

Study infants were screened at a median age of 19 days (range 1-149 days). Table 5 shows the postnatal age at the time of screening represented as a percentage of total infants screened. Almost all infants (97.3%) were screened within 3-month postnatal age, only 12 infants were screened beyond this period with one infant was screened at age of 149 days. The mean time for hearing screening procedure was  $10.7 \pm 8.0$  ( $\pm$  SD) (range 2-60 minutes). The majority of procedures were accomplished within 30 minutes with 75.4 % and 98.1 % completed within 10 and 30 minutes, respectively.

## Discussion

This study represents an initial attempt for implementing newborn hearing screening program in our hospital. As a largest tertiary care center in the country, our annual birth rates are approximately 9,000-10,000 infants. By extrapolating the incidence of congenital or perinatally acquired hearing disorders from several literature to our population, there will be 15-60 hearing-impaired newborn infants each year who might have potential delay in speech, language and cognitive development. Not until recently, our attempt to improve quality of care was made to collaborate with neuro-otologist at Department of Otolaryngology to perform hearing test with conventional OAE and ABR machine in, at least, high-risk infants prior to discharge as the beginnings of the hearing screening program. Unfortunately, this attempt was not able to test all targeted infants within scheduled date due to technical

obstacles and limited screener. Forty percent of infants were discharged without test performed and failed to return for follow up appointments as an outpatient. To improve our program, we have developed a system to screen infants within our special care unit using an automated device which has ABR combined with OAE test. We have a group of nursing staffs trained for performing the procedure. The advantage of recruiting nursing staff to be a screener is that their work-hour is much more flexible compared to timely-mannered day-time technician. Infants who were not quiet enough to be tested, were rearranged again as soon as the next shift. From our study, the mean duration of procedure of 10 minutes is feasible for trained nurses to perform within their shift. With our program management, we successfully screened almost all of the high-risk infants within their golden period recommended by Joint Committee of Infant Hearing<sup>(16-17)</sup>.

Our observed incidence of pathologic hearing screening results in at-risk population is slightly higher than in other published reports<sup>(1,9,10)</sup>. Recent study from other tertiary center in different area of Bangkok reported the incidence of confirmed pathologic ABR in infant at-risk of 1.5%<sup>(18)</sup>. This difference may result from some factors including the difference in infant s severity of illness, management practice and the distribution of risk factors within each group. In our hospital, the percentage of ototoxic drug usage, which has been shown to be significant risk in several reports<sup>(19-23)</sup>, was somewhat high. Surprisingly, we did not find that this factor had significant insult on hearing function in our study group. However, more strictly

**Table 5.** Distribution of postnatal age at the time of screening (n=448)

Postnatal age	Percentage of infants screened (%)
Neonatal period (28 postnatal days)	67.6
60 days	92
90 days	97.3
120 days	99.8
> 120 days	0.2

**Table 4.** Multivariate logistic regression analysis of significant risk factors for pathologic screening results

Risk factors	Coefficient	p	Odds Ratio	95% CI
Craniofacial anomalies	3.73	.000	41.76	11.23-155.37
Mechanical ventilation > 5 days	1.43	.001	4.16	1.82-9.50

indication and caution of ototoxic medication use are warranted.

Craniofacial anomalies were identified to be independent risk factors with a highest correlation. This finding is similar to those from previous reports<sup>(1, 8, 20)</sup>. From our study, we found a significant risk for pathologic screening results in infants who received mechanical ventilation > 5 days. This finding was not noted from any published studies. The implication of this finding might indicate the need for reviewing the ventilation strategy in our current practice, i.e., the encouragement of gentle ventilation strategy or permissive hypercarbia.

This study did not support familial hearing loss, sepsis and/or meningitis, very low birth weight to be independent risk factors for pathologic hearing screening results as reported by others<sup>(1,10,19-23, 28)</sup>. This finding, except for familial hearing loss, may reflect an improvement of neonatal care in our hospital.

The protocol of our hearing screening program was not planned to test the sensitivity and specificity between automated OAE and ABR used. There were reports showing a good sensitivity and specificity of A-ABR method,  $\leq 98\%$  and  $\leq 96\%$ , accordingly<sup>(24-27)</sup>. Meyer et al reported OAE to have 71 % sensitivity and 73% specificity<sup>(8)</sup>. Some infants from their study showed to have normal OAE with an abnormal A-ABR. In our protocol, infants who passed OAE test did not receive A-ABR. Whether changing protocol to have all infants tested both with OAE and ABR to not missing any case are under our consideration.

## Conclusion

Our study reported the incidence of pathologic hearing screening results in the high-risk infants cared for at Siriraj hospital. The only significant risk factors found in this study were craniofacial anomalies and mechanical ventilation > 5 days. Improvement of ventilatory care is warranted to reduce the unexpected risk for this potential hearing impairment. The protocol using automated screening device for both OAE and ABR performed by nursing staffs were feasible, consumed acceptable time per procedure, flexible and increased coverage of screening at-risk population. The investigator realized that our high-risk program will not identify another 50 percent of infants in well-baby nursery who subsequently developed hearing impairment. However, the result of this study will at least, draw the attention of general practitioners and pediatricians on the importance of early identification of hearing impair-

ment in neonates within the crucial period of speech and language acquisition. The extension of the program to universal hearing screening of all live births should be considered.

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**การตรวจคัดกรองความผิดปกติของการได้ยินในทารกแรกเกิดกลุ่มเสี่ยงสูงด้วยเครื่องมือ  
automated screening โดยพยาบาลประจำการที่ฝึกขึ้นพิเศษในโรงพยาบาลศิริราช**

**พิมล ศรีสุภาพ, รวมพร กลีบบัว, ไสภาพรรณ เงินจำ, จินตนา ชนประชา, จิรนนท์ สิงห์คำป้อง**

ได้ทำการศึกษาอุบัติการณ์และปัจจัยเสี่ยงที่สำคัญต่อการเกิดความผิดปกติของการได้ยินจากการตรวจคัดกรองในทารกแรกเกิดความเสี่ยงสูง ที่ได้รับการดูแลในโรงพยาบาลศิริราชและเป็นการศึกษาความเหมาะสมของโครงการการตรวจการคัดกรองด้วยอุปกรณ์ automated otoacoustic emission (OAE) / auditory brain stem response (ABR) ที่ใช้พยาบาลประจำการที่ได้รับการฝึกการตรวจโดยเฉพาะเป็นผู้ตรวจในหอผู้ป่วยก่อนจำหน่ายกลับบ้าน โดยคัดเลือกทารกกลุ่มเสี่ยงตามเกณฑ์ของ Joint Committee of Infant Hearing 1994, American Academy of Pediatrics ทารกจะได้รับการตรวจด้วยวิธี OAE หนึ่งหรือสองครั้ง หากตรวจไม่ผ่านจะได้รับการตรวจยืนยันด้วย ABR จากการศึกษาพบอุบัติการณ์ความผิดปกติของการได้ยินในทารกกลุ่มเสี่ยงร้อยละ 6.7 มีจำนวนทารกที่มีความผิดปกติของหูสองข้างประมาณสองในสามของทารกที่ตรวจพบความผิดปกติทั้งหมด ปัจจัยเสี่ยงที่สำคัญต่อการตรวจพบความผิดปกติได้แก่ การมีความผิดปกติแต่กำเนิดของใบหน้าและกะโหลกศีรษะ ซึ่งมีความเสี่ยงเพิ่มขึ้น 42 เท่า และการได้รับการช่วยหายใจนานเกิน 5 วัน โดยมีความเสี่ยงเพิ่มขึ้น 4 เท่า ทารกทั้งหมดได้รับการตรวจคัดกรองที่อายุมัธยฐาน 19 วัน (พิสัย 1-149 วัน) โดยร้อยละ 97.3 ของทารกทั้งหมด ได้รับการตรวจก่อนอายุ 3 เดือนหลังเกิด ค่าเฉลี่ยของเวลาที่ใช้ในการตรวจคัดกรองเท่ากับ  $10.7 \pm 8.0$  นาที (พิสัย 2-60 นาที) และการตรวจคัดกรองเกือบทุกรายใช้เวลาไม่เกิน 30 นาที การตรวจคัดกรองความผิดปกติของการได้ยินในทารกแรกเกิดด้วยวิธี automated OAE/ABR โดยพยาบาลประจำการที่ฝึกโดยเฉพาะเป็นวิธีการที่ให้ผลลัพธ์ เป็นที่น่าพอใจสามารถครอบคลุมการตรวจทารกกลุ่มเสี่ยงก่อนอายุ 3 เดือน ได้ถึงร้อยละ 97 และใช้ระยะเวลาในการตรวจไม่นานจนเกินไป

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