The Journal of International Advanced Otology

J Int Adv Otol 2023; 19(5): 402–406 • DOI: 10.5152/iao.2023.22987

Original Article

Newborn Hearing Screening: Early Ear Examination Improves the Pass Rate

Yehuda Schwarz[1,2], Roye Mauthner[1,2], Oded Kraus[1,2], Ofer Gluk[1,2], Omer Globus[2,3], Liron Kariv[4*], Sharon Ovnat Tamir[1,2*]

[1]Department of Otolaryngology Head and Neck Surgery, Assuta Ashdod Samson University Hospital, Ashdod, Israel
[2]Ben Gurion University of the Negev, Faculty of Health Sciences, Beer Sheba, Israel
[3]Department of Neonatology, Assuta Ashdod Samson University Hospital, Ashdod, Israel
[4]Hearing, Language and Speech Institute, Assuta Ashdod Samson University Hospital, Ashdod, Israel

ORCID iDs of the authors: Y.S. 0000-0003-1459-5730, R.M. 0000-0002-4518-8620, O.K. 0000-0003-4494-1470, O.G. 0000-0002-7858-710X, O.G. 0000-0001-5234-564X, L.K. 0000-0003-0635-1867, S.O.T 0000-0002-5093-9310.

Cite this article as: Schwarz Y, Mauthner R, Kraus O, et al. Newborn hearing screening: early ear examination improves the pass rate. *J Int Adv Otol.* 2023;19(5):402-406.

BACKGROUND: Temporary conductive hearing loss due to vernix accumulation in the external ear canal may lead to a false-positive result in newborn hearing screening tests. The aim of this study was to evaluate whether ear examination and intervention may reduce the false-positive rate prior to hospital discharge.

METHODS: A case series of 42 newborns who failed initial otoacoustic emissions screening were studied in our institution between May and December 2020.

RESULTS: During the study period, a total of 735 neonates (1470 ears) were screened by otoacoustic emissions in our hospital. Forty-two newborns who failed otoacoustic emissions were included in our study. They constituted 3.9% (n = 58 ears) of the total number of ears screened. Forty-four ears (75.9%) passed and 14 ears (24.1%) failed otoacoustic emissions rescreening performed shortly following vernix cleaning. Twelve of the remaining 14 ears passed at 10-day rescreening. The remaining 2 ears presented true bilateral hearing loss. During the study period, the general false-positive rate decreased from 56/735 (7.61%) to 12/735(1.63%) ($P < .00001$).

CONCLUSION: Cleaning the vernix of infants who failed otoacoustic emissions prior to hospital discharge lowers the false-positive rate of universal neonatal hearing screening. We may assume that vernix cleaning will reduce significant healthcare workload, costs of unnecessary investigations, as well as parental anxiety.

KEYWORDS: Hearing loss, newborn hearing screening, otoacoustic emission, referral rate, vernix

INTRODUCTION

Infant hearing screening is a universally accepted method for the early detection of hearing loss. While it is undisputed importance in the early detection and intervention for children with permanent hearing loss, there has been some concern regarding high false-positive rates. Vernix in the external ear canal is one of several causes of failing otoacoustic emissions (OAE) testing in newborns. Assessment of hearing-related problems in newborns and young children has become accessible due to OAE and automated auditory brainstem response (A-ABR) testing, which are the most used tests in Universal Newborn Hearing Screening (UNHS) programs. However, one drawback is the high number of false-positive results which means it is not a true sensorineural hearing loss but related to conductive issues. For every 1000 children that undergo UNHS, 1-3 children may have sensorineural hearing loss, while a referral rate of 4% means that approximately 10 newborns will be referred for further investigations for every 1 that has sensory neural hearing loss.[1] The high referral rates mean that parents leave the hospital questioning the hearing ability of their child and need to return for follow-up evaluation. This may create parental anxiety, as newborns with normal hearing might be told that their child needs further audiological testing. It also delays affirmation of "true" hearing status and adds expenses to follow-up screening programs. The false positive may also undermine confidence in early hearing screening programs causing detection and intervention programs.[2]

*Contributed equally as co-senior authors.

Corresponding author: Yehuda Schwarz, e-mail: yehudasc@assuta.co.il

Received: November 16, 2022 • **Accepted:** May 18, 2023 • **Publication Date:** September 29, 2023
Available online at www.advancedotology.org

During fetal development in a fluid environment, the middle ear is filled with amniotic fluid. There is also evidence that immediately following birth, neonates may have residual fluid derived from amniotic fluid in the middle ear cavity.[3,4] Therefore, both vernix occluding the external ear canal and middle ear cavity amniotic fluid may explain the reason for high false-positive hearing screening results.

We hypothesized that by examining and defining the ear status and cleaning the external ear vernix as needed, we may define and maybe improve the pass rate of newborn OAE results.

MATERIAL AND METHODS

This prospective study was undertaken in Samson Assuta Ashdod University Hospital between May and December 2020. This study was approved by the institutional review board ethics committee of Samson Assuta Ashdod University Hospital, with ethics committee approval number 0084-19-AAA. Written informed consent was obtained from all newborn parents who participated in this study.

A 2-step screening protocol is implemented in our hospital, as indicated by the national ministry of health, using OAEs and A-ABR. All newborns undergo initial transient-evoked otoacoustic emission (TEOAE) test during the first postnatal day and those who fail this test (in one or both ears) are rescreened by TEOAE on the following day. Newborns who fail both TEOAE tests are tested by A-ABR prior to discharge. In the present study, parents of newborns who failed the second TEOAE on one or both ears were offered to participate in the study by the hearing screening technician.

Inclusion criteria included newborns that were healthy and had no personal or familial risk factors for hearing loss; all other infants were excluded.

Patient and maternal demographics were extracted from medical records and included mothers' complete medical history, mode of delivery (vaginal/Cesarean section), and newborn clinical indices including gestational age, gender, and Apgar scores post-partum.

The recruited newborns' ears were examined by 2 blinded senior otolaryngologists by otomicroscopy and all findings were documented. If vernix was found by the first physician, then the second physician cleaned the ear/s and the first physician examined the ears again. After vernix removal, the newborns were rescreened using OAE within 3 hours.

We compared the rate of failure on OAE screening on the days of the study group before and after our intervention.

Equipment

Transient-evoked otoacoustic emission screening was conducted with an Otoport Screener (Otodynamics Ltd, Hatfield, Hertfordshire, UK). A nonlinear click stimulus with a click rate of 80 presentations/s and an analysis time window of 3 to 13 ms post stimulus was used. Click levels varied around 80 ± 3 dB (Decibel) peak equivalent SPL (Sound Pressure Level) (dB pe SPL) as measured in the newborn's ear canal, and a microphone filter band of 1.2-4.8kHz was set. The rejection level for testing was set individually at 42-55 dB SPL according to the noise level. For each ear, the pass criteria were set as follows: (a) total OAE response > 0; (b) reproducibility > 80%; (c) presence of emissions with signal amplitude greater than −5 dB in 3 specific frequency bands: 2, 3, and 4 kHz with SNR (Signal to Noise Ratio) levels > 6dB; (d) minimum of 50 samples. Newborns were tested in their cribs while asleep or awake and quiet.

A Karl Kaps microscope was used to examine the ears and a suction probe to clean the vernix when needed.

Statistical Analyses

Data were stored and analyzed using Microsoft Excel and later exported for statistical analysis with Statistical Package for Social Science (SPSS) version 23.0 for Windows (IBM SPSS Corp.; Armonk, NY, USA).

RESULTS

During the study period, 740 newborns were born. Seven hundred thirty-five underwent newborn hearing screening and 5 (0.68%) were discharged without performing the screening. Of the 735 newborns, 60 failed the first OAE screening and the OAE prior to their discharge. The parents of 42 newborns (58 ears) agreed to participate in this study.

Table 1 shows both patient and maternal demographics. There was an equal number of female and male babies, while 9 males and 7 females failed OAE tests bilaterally. Twenty-two (1.5%) newborns failed the screening solely on the left side, while only 4 (0.3%) failed solely on the right side.

Out of 58 ears participating in the study, 44 (75.8% of the study group) passed the OAE following our intervention of cleaning the external ear canal from vernix. Fifty-four ears (92.8%) were examined by the otolaryngologists up to 5 hours from failing the second OAE testing (first stage of hearing screening), and then retested (3rd OAE) up to 3 hours following the examination. Fourteen ears (24%) failed the OAE test after cleaning the external ear canal. Twelve out of 14 ears passed the OAE rescreening approximately 10 days after initial screening. One newborn was a true positive and had true bilateral sensorineural hearing loss (Table 2).

Our high initial failure rate of 58 ears failing their first OAE out of 735 newborns screened (7.89%) has been reduced to 14 out of 735 (1.9%)

Eighteen parents did not give their consent to participate in the study and are not included in the reported analysis (cleaning the ear before repeating the test); the result of the second-stage OAE test (usually 10 days after discharge) was that 13 children passed the rescreening, 2 had true sensorineural hearing loss, and 3 were lost to

Table 1. Patient Demographics

Category	Number
Total number of newborns	42
Gender (M/F)	21/21
Birth weight (g) (average (range))	3147 (2120-4000)
APGAR average score	10
Healthy mothers (yes/no)	31/11
Delivery mode (vaginal/ cesarean)	36/6

APGAR, Appearance, Pulse, Grimace, Activity, and Respiration.

Table 2. Case-Cohort Study Data

Category	Number (During Study Days, *n* =)	Percent (%)
Newborns	740	
Discharged without screening	5	
Newborns screened	735	99.3
Passed first round	675	91.8
Failed	60	8.2
Ears screened	1470	99.3
Participated in study (newborns)	42	
Ears failed in study	58	3.9
Passed after intervention (newborns)	33	78.6
Passed after intervention (ears)	44	75.9
Passed at 10 days rescreen (newborns)	8	19
Failed at 10 days rescreen (newborns)	1	2.4
Male	21	2.9
Isolated left ear failed	12	0.8
Isolated right ear failed	0	0.0
Bilateral failure	9	0.6
Female	21	2.9
Isolated left ear failed	10	0.7
Isolated right ear failed	4	0.3
Bilateral failure	7	0.5

Table 3. Physical Examination Findings of Study Group

Category	First Examination	Second Examination
Physician (S.O.T./Y.S.)	S.O.T. 17	Y.S. 17
	Y.S. 25	S.O.T. 25
External ear canal diameter (ears)	Narrow 22	Narrow 29
	Normal 62	Normal 54
		N/A 1
External ear canal content (ears)	Clear 20	Clear 24
	Vernix 60	Vernix 55
	Fluid 0	Fluid 0
	N/A 4	N/A 5
Tympanic membrane position (ears)	Intact 73	Intact 75
	Bulging 5	Bulging 2
	Retracted 0	Retracted 0
	N/A 6	N/A 7
Tympanic membrane color (ears)	Transparent 70	Transparent 71, opaque 5
	Opaque 8	N/A 8
	N/A 6	
Middle ear content (ears)	Ventilated 68	Ventilated 68
	Fluid 2	Fluid 2
	N/A 14	N/A 14
Vernix cleaning (ears)	Cleaned 5	Cleaned 60
	Not cleaned 79	Not cleaned 23
		N/A 1

N/A, not applicable; S.O.T., senior otolaryngologist; Y.S., senior otolaryngologist.

follow-up. Since 2 of the screened ears are true-positive results, these ears were deduced from the initial analysis giving; 56 false positives before intervention compared with 12 false positives with intervention, a false-positive reduction from 7.61% to 1.63% ($P < .00001$) in chi-square test.

The initial objective of our study was to understand the reason for failing the first OAE screening test. Therefore, 2 blinded investigators (Y.S. and S.O.T.) examined the newborns. The decision of which physician will examine the newborn first was made randomly (S.O.T.: 17/Y.S.: 25). Vernix was removed under the microscope using a Frazier aspiration tube number 3 or 5.

There was an 81% correlation between both examiners. The physical examination findings of the first and the second examiner are found in Table 3. We found that the most dominant finding was vernix both by the first examiner (60 ears) and the second examiner (55 ears).

DISCUSSION

Universal Newborn Hearing Screening is a well-established program to diagnose hearing loss in the newborn period. In our hospital, we perform a TEOAE on the first day after delivery. Newborns who fail, undergo a second TEOAE on the following day (discharge day) and if failed, an A-ABR is performed. Newborns who do not pass the first screening tests undergo another A-ABR and OAE 10 days later. Newborns who do not pass these steps are referred for a diagnostic ABR test. First-stage (OAE) false-positive rate ranges in the literature between as low as 1.9% and up to 8%.[5] Our high referral rate of 7.9% during the study period is higher than the annual rates of 3.5% during the years 2018 until 2020 (our hospital was founded in 2017), and it may be related to the fact that the study was performed during the COVID 19 pandemic. Failure rate in the newborn hearing screening is much higher in the newborns screened within 24 hours from birth compared to between 24 and 36 hours.[6] During the pandemic, mothers and newborns were discharged much faster than usual, which may explain the high referral rate.

Universal Newborn Hearing Screening does not routinely include examining the ears of newborns per se or specifically for occluding vernix in the external ear canal before being discharged. Amniotic fluid and vernix may occlude the middle and external ear respectively and lead to false-positive results.

In our study, 2 senior otolarngologists (Y.S. and S.O.T.) were blinded to each other's findings. The degree of correlation was 81% when relating to the findings in Table 3. We can also review (Table 3) that vernix was diagnosed by the first examiner in 60 ears and by the second examiner in 55 ears, while the first and second examiners diagnosed fluid in the middle in only 2 ears.

In the literature, a 13% prevalence of occluding vernix was found in neonates up to 48 hours after birth.[7] Cleaning the vernix significantly

increased the passing rate of hearing screening.[7,8] Spontaneous vernix clearance usually takes place during the first 24-48 hours after birth, but vernix in the ear canal may persist for over a month in some infants.[7] Incorporating the cleaning of vernix in our study reduced by 78% the false-positive results and brought down the failing rate of the first OAE test by more than 50%. Our results are compatible with a study by K J Doyle et al. displaying that cleaning the vernix increased the pass rates for ABR and OAE screening to 91.5% (88.5% initially) and 84% (79% initially), respectively.[7] The cleaning of the outer ear canal with a swab which was studied by Chang et al[9] improved pass rate from 76% to 91%.[9]

It is important to note that as the study progressed the correlation between our senior physicians became higher. There was actually a 100% agreement when reviewing the last 15 newborns. As we understood the importance of cleaning the vernix, we gave it a high priority in our microscopic examination. Neonatal ear examination can prove to be quite challenging. Neonates have relatively small external auditory canals, as the extreme oblique position of the membrane makes the examination difficult, not to mention the relatively short time the clinician must examine the infant, due to agitation or crying.[10] We used an otomicroscopic examination which is considered to be the "gold" standard for the diagnosis of external and middle ear pathologies. Cleaning the vernix with suction under a microscope is a relatively easy procedure for an otolaryngologist, and we had no complications.

Our data demonstrate that the initial hearing screening was performed between 8 hours and 34 minutes and 14 hours and 51 minutes following birth. Those failing underwent another test (TOAE) prior to discharge. This was performed usually between 1 and 4 days following birth. There were 2 newborns who did not pass the rescreening when coming back at 10 and 17 days later and were included in our study before continuing to perform an ABR.

A second OAE was performed usually on the day of discharge. Within the following 5:46 hours after the OAE, we performed our physical examination (39/42 newborns) which was followed by a third OAE straight after cleaning the vernix. The third OAE was performed on 39 newborns within 3 hours from our examination. Although referral rates were shown to be decreased with the use of repeat OAE tests,[11] we performed the vernix cleaning adjacent to the OAE testing so we can say quite confidently that the positive change in the results is mainly due to the cleaning of the ear canal.

Our ear examination and intervention were performed prior to mother and child being discharged from the hospital. This has a great advantage because in some populations up to 65% of children who failed hearing screening may be missed to follow-up.[12] Parental involvement, concern about stigma, and socioeconomic factors are a few factors related to this high percentage.[13] In order to reduce the referral rate to an appropriate level, it is recommended that UNHS be conducted at 2-20 days following birth in healthy babies.[14] This recommendation is difficult to obey as parents are usually discharged the day following birth. The great advantage of vernix cleaning is that it can be performed before discharge and by that enabling the parents to go home with a definite result. High referral rates due to false-positive results in newborn hearing screening programs can lead to additional workload for healthcare providers and cause parental anxiety. When a newborn is referred for further audiological testing, it adds expenses to the follow-up screening programs and delays the affirmation of their hearing status. To address this possible conflict, it is important to find a balance between both. This can be achieved through ongoing review and improvement of screening protocols, as well as effective communication with parents.

Reducing the false-positive rates may have a positive effect on the costs of newborn screening programs. The high percentage of false positives during newborn hearing screening has an economic burden on our society. Burke et al[15] calculated a cost of £100 per newborn with a false-positive hearing screening test.[15] The need for performing a second TEOAE and A-ABR increases the costs. If we reduce the false-positive rates, we may also reduce the cost of a CMV test which is performed in our institution once failing initial screening and adding to the parent's time "wasted" on coming in for additional hearing tests. Not to mention the burden on the audiology department, which has limited resources.

There is a considerable percentage of parents that experience anxiety following a false-positive test result during hearing screening.[16] This increased anxiety levels might have greater impact on parents' emotional status and performance especially if the newborns are the first children of these parents.[17] Parental anxiety may be found in those whose infants require follow-up testing.[18] This can undermine confidence in early hearing screening programs, causing some families to opt-out of testing or delay screening for their children. Therefore, reducing the false-positive rate through interventions such as vernix cleaning can not only improve the accuracy of screening but also minimize parental anxiety. Vernix cleaning before discharge should be the objective of any screening program.

The limitations of the study may be due to selection bias. Thirty percent (18/60) of the potential responders were not surveyed. We cannot be certain that those responding can represent the entire population. We do not know whether there are ethnical or cultural differences toward the hearing screening program. Further limitations may be due to the size of the studied group as well as the relative homogeneity of the group; we cannot conclude that these results are valid for infants who suffer from genetic or other pathologies.
Performing newborn hearing screening before mothers and newborns are discharged home has a relatively high risk of false positives. Cleaning the vernix of infants who failed OAE prior to hospital discharge lowers the false-positive rate. Due to the significance of our results and the ease of applicability in which this intervention can be applied, we recommend UNHS programs consider adding an otoscopic examination by an otolaryngologist for all newborns who fail the initial hearing screening and intervening as needed. This may improve the newborn hearing screening pass rate as well as reduce the risk of parental anxiety and costly testings.

Ethics Committee Approval: This study was approved by Ethics Committee of Samson Assuta Ashdod University Hospital University, (Approval No: 0098-22-AAA, Date: September 21, 2022).

Informed Consent: Written informed consent was obtained from all newborn parents who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – Y.S.; Design – Y.S., S.O.T.; Supervision – O.G.; Resources – N/A; Materials – N/A; Data Collection and/or Processing – S.O.T., R.M., O.K.; Analysis and/or Interpretation – L.K., R.M., O.K.; Literature Search – L.K.; Writing – Y.S.; Critical Review – S.O.T.

Acknowledgment: The authors would like to thank Tanya Starobinski, the audiology technician, for performing the OAE tests and helping recruit the newborns as well as their parents.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: The authors declared that this study has received no financial support.

REFERENCES

1. Hyde ML. Newborn hearing screening programs: overview. *J Otolaryngol*. 2005;34(suppl 2):S70-S78.
2. Sanford CA, Keefe DH, Liu YW, et al. Sound-conduction effects on distortion-product otoacoustic emission screening outcomes in newborn infants: test performance of wideband acoustic transfer functions and 1-kHz tympanometry. *Ear Hear*. 2009;30(6):635-652. [CrossRef]
3. Roberts DG, Johnson CE, Carlin SA, Turczyk V, Karnuta MA, Yaffee K. Resolution of middle ear effusion in newborns. *Arch Pediatr Adolesc Med*. 1995;149(8):873-877. [CrossRef]
4. Priner R, Perez R, Freeman S, Sohmer H. Mechanisms responsible for postnatal middle ear amniotic fluid clearance. *Hear Res*. 2003;175(1-2):133-139. [CrossRef]
5. Clemens CJ, Davis SA, Bailey AR. The false-positive in universal newborn hearing screening. *Pediatrics*. 2000;106(1):E7. [CrossRef]
6. Lupoli L, Garcia L, Anastasio AR, Fontana ACTime after birth in relation to failure rate in newborn hearing screening. *Int J Pediatr Otorhinolaryngol*. 2013;77(6):932-935. [CrossRef]
7. Doyle KJ, Burggraaff B, Fujikawa S, Kim J, MacArthur CJ. Neonatal hearing screening with otoscopy, auditory brain stem response, and otoacoustic emissions. *Otolaryngol Head Neck Surg*. 1997;116(6 Pt 1):597-603. [CrossRef]
8. Doyle KJ, Rodgers P, Fujikawa S, Newman E. External and middle ear effects on infant hearing screening test results. *Otolaryngol Head Neck Surg*. 2000;122(4):477-481. [CrossRef]
9. Chang KW, Vohr BR, Norton SJ, Lekas MD. External and middle ear status related to evoked otoacoustic emission in neonates. *Arch Otolaryngol Head Neck Surg*. 1993;119(3):276-282. [CrossRef]
10. Bluestone CD, Klein JO. *Otitis Media in Infants and Children*. 2nd ed. Philadelphia: Saunders 1995:90-101.
11. Akinpelu OV,Peleva E, Funnell WR, Daniel SJ. Otoacoustic emissions in newborn hearing screening: a systematic review of the effects of different protocols on test outcomes. *Int J Pediatr Otorhinolaryngol*. 2014;78(5):711-717. [CrossRef]
12. Papacharalampous GX, Nikolopoulos TP, Davilis DI, Xenellis IE, Korres SG. Universal newborn hearing screening, a revolutionary diagnosis of deafness: real benefits and limitations. *Eur Arch Otorhinolaryngol*. 2011;268(10):1399-1406. [CrossRef]
13. Wroblewska-Seniuk KE, Dabrowski P, Szyfter W, Mazela J. Universal newborn hearing screening: methods and results, obstacles, and benefits. *Pediatr Res*. 2017;81(3):415-422. [CrossRef]
14. Chung YS, Oh SH, Park SK. Referral rates for newborn hearing screening based on the test time. *Int J Pediatr Otorhinolaryngol*. 2019;127:109664. [CrossRef]
15. Burke MJ, Shenton RC, Taylor MJ. The economics of screening infants at risk of hearing impairment: an international analysis. *Int J Pediatr Otorhinolaryngol*. 2012;76(2):212-218. [CrossRef]
16. Mohd Khairi MD, Rafidah KN, Affizal A, Normastura AR, Suzana M, Normani ZM. Anxiety of the mothers with referred baby during Universal newborn HEARing Screening. *Int J Pediatr Otorhinolaryngol*. 2011;75(4):513-517. [CrossRef]
17. Beaula Vincy VK, Seethapathy J, Boominathan P. Parental anxiety towards 'refer' results in newborn hearing screening (NHS) in south India: A hospital based study. *Int J Pediatr Otorhinolaryngol*. 2019;116:25-29. [CrossRef]
18. Patel H, Feldman M. Universal newborn hearing screening. *Paediatr Child Health*. 2011;16(5):301-310. [CrossRef]