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Role Of Post Test Surveillance In Newborn Hearing Screening Program

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Abstract: To study the impact of the Post-test surveillance program designed by us on the outcome of the New Born Hearing Screening Program. Babies born in a tertiary care hospital and babies referred from nearby hospitals were included in the 'universal newborn hearing screening' program. The study was conducted from June 2023 to October

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2024. Hearing screening was done by Transient Evoked Oto Acoustic Emissions test using MAICO ERO SCAN system and results stored. After the test the babies were enrolled in the posttest surveillance program which monitored the speech milestones of the babies in their home till 6 months of age. The results are presented. A methodology flow chart was designed and implemented. 100 babies were screened. There were 31 male and 69 female babies and the male female ratio was 1:2. The incidence of newborn hearing loss identified in our study was 10 per 1000. Profound hearing loss was detected in a high-risk baby and referred for Cochlear implants. The post-test surveillance program designed by us helped to monitor the speech development of the babies in their home for six months after testing and covered the problem of false positive cases and provided a satisfactory outcome of the newborn hearing screening program. New Born Hearing Screening using Transient Evoked Oto Acoustic Emissions test is a simple method with good sensitivity and specificity. We recommend a 'Universal screening' method to be followed in the screening protocol. The six months post-test surveillance program is a very useful adjuvant which helps to address the problem of false positive results and achieve the goal.

Keywords: *Universal newborn hearing screening, Oto acoustic emissions, TEOAE, Post-Test surveillance program.*

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I. INTRODUCTION

Speech is important for communication and speech development in children requires a good hearing from birth to infancy. The importance of early detection of hearing defects and their impact on the speech and language development of children has been emphasized by many researchers [1, 2, 3]. Early detection and rehabilitation by 6 months of age is advantageous over a late detection. When the deficiencies are identified and rehabilitated before 6 months of age those children will develop speech and language without any delay like normal children [1, 2, 4, 3]. Prior to the New Born Hearing Screening [NBHS] program, hearing defects in children were diagnosed as late as 26 months and rehabilitated at the age of 32 months [3].

Mother of Pediatric Audiology Marion Downs started the hearing screening in 1963 and led to the formation of Joint Committee on Infant Hearing [JCIH] in 1969 [5]. Transient Evoked Oto Acoustic Emissions [TEOAE] was first used for hearing screening by Maxon et al. in 1993 [6]. JCIH endorsed Universal Newborn Hearing Screening in 1994.

The New Born Hearing Screening [NBHS] program is a well-known program implemented in many countries and various standardized protocols are available. NBHS program aims to ensure the presence of adequate hearing at birth and early identification and rehabilitation of hearing impairment. In the NBHS program there are reports of false positive cases and minimal hearing loss and congenital hearing loss appearing late may be missed by the NBHS [7]. One of the problems of NBHS in developing countries is the monitoring of speech milestones of the babies after testing. As the babies are monitored at home by the family members any delay in speech milestones may be missed or ignored due to social stigmas.

Hence, monitoring speech milestones after the NBHS by trained personnel is imperative to ensure timely development of speech and early intervention if required. However, the requirement of repeated home visits to remote locations by an audiologist or health worker poses practical challenges. In a US national survey, Pynnonen et al. (2016) [8] observed that parental awareness of the NBHS improves with better communication regarding test results and by emphasizing the need for follow-up and retesting. To address these problems, we designed a program to keep the child under surveillance at home following the NBHS. With input and cooperation from the audiologist-cum-speech pathologist, a six-month Post-Test Surveillance (PTS) program was planned, and a methodology flow chart was created and implemented [Fig. 1].

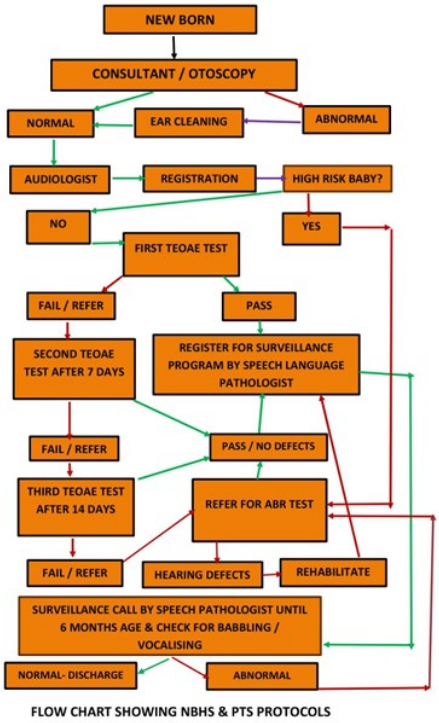


Fig. 1. Flow chart showing the Methodology

The incidence of congenital hearing loss in rural and urban areas in India has been reported as 10 and 20 per thousand as per an ICMR based survey [2]. NBHS is a simple and effective approach to identify hearing deficiencies in newborns. Nagapoornima et al. (2007) in their study have called for private institutions to take up the challenge of organizing newborn hearing screening to help the underprivileged [2]. Our hospital is located in a suburban area and caters to a large rural population. As a social initiative to help the underprivileged, Our NBHS program was started in June 2023 with an objective to provide free hearing screening using TEOAE to all babies born in our area and to detect hearing deficiencies early. The JCIH currently recommends a benchmark for NBHS as 1m-2m-3m [screening by 1 month, confirmed diagnosis by 2 months and enrollment for intervention by 3 months] [9]. The Indian Academy of Pediatrics [IAP] recommends a NBHS benchmark of 1m-3m-6m [10]. We followed a 'Universal screening' protocol in NBHS. For the first-tier screening TEOAE is used which is a sensitive and cost-effective method [2]. According to the consensus statement of the IAP, all high-risk infants and infants nursed in NICU and infants who fail repeated OAE screening tests should be referred for the Auditory Brainstem Response [ABR] test [11]. Currently we are scheduling ABR as a second-tier screening test for the High-risk babies and first test failure babies and referring them.

II. MATERIAL AND METHOD

The period of study was from June 2023 to October 2024. The NBHS program is conducted at the Audiology and Speech pathology wing of the Department of Otorhinolaryngology of a tertiary care teaching hospital located in Chennai, Tamil Nadu, South India. Our NBHS program follows the "Universal Screening protocol" and all babies born in our hospital and babies referred from nearby hospitals undergo NBHS. After an Ear examination and clearing of the external canal debris by the Consultant the baby is sent to the Audiologist for registration. After explaining the procedure and informed consent, the baby is registered and Demographic data with contact phone numbers, mother age, Prenatal illness, Consanguinity, Family history of deafness, Obstetric history, Baby's age, weight, Apgar Scores at 1 minute and 5 minutes, Neonatal Intensive Care Unit [NICU] stay were collected and documented. TEOAE screening was done using MAICO ERO SCAN system in a sound proof room by the female audiologist [Fig. 2] and the results were conveyed to the parents. The high-risk babies are referred for ABR test irrespective of the TEOAE test result.

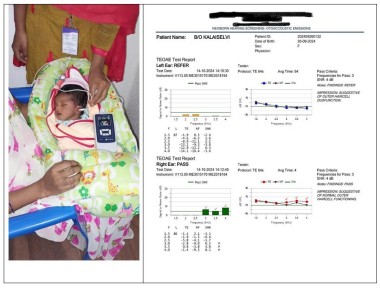


Fig. 2. Showing the TEOAE test and the report

The babies who did not pass the first TEOAE test were reassured and the reasons for test failure explained to the family and the benefits of retesting and participation in the surveillance program emphasized. Second screening test is scheduled after 7 days from the first test and the Third test is done after 14 days from the second test. The mothers were contacted via mobile phone by the female audiologist to remind them about the retest schedule. Those who didn't pass all the three screening tests were referred for ABR test.

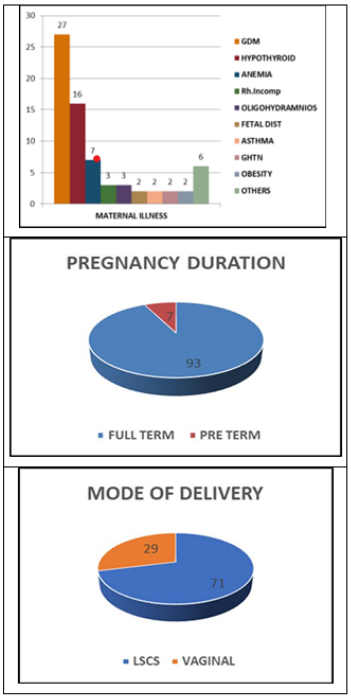
During the post-test surveillance program, the mothers are called every 2 months and their infant's basic motor & speech milestones development such as head holding, vocalizing or babbling are inquired and documented. The babies who are not showing normal speech development by 6 months are referred for ABR testing. The methodology is shown in the flow chart [Fig. 1].

III. RESULTS

100 babies were screened in the study and 93 babies were born in our hospital and 7 were referred from other hospitals. There were 31 male and 69 female babies and the male female ratio was 1:2. The maternal age ranged from 22 to 39 years. Abnormal Obstetric history was given by 8 mothers. One mother has conceived through IVF. In Prenatal illness history, 53 mothers reported various illnesses and some of them had multiple illnesses. Gestational Diabetes Mellitus was the most commonly reported illness. Two cases of fetal distress and cases of consanguinity, Varicella infection in 1st trimester, and one case of hearing impairment in both parents were reported.

There were 93 full term and 7 preterm pregnancies. Normal vaginal delivery was conducted in 29 mothers and Caesarean section was performed in 71 mothers. The various maternal data are shown in Table 1.

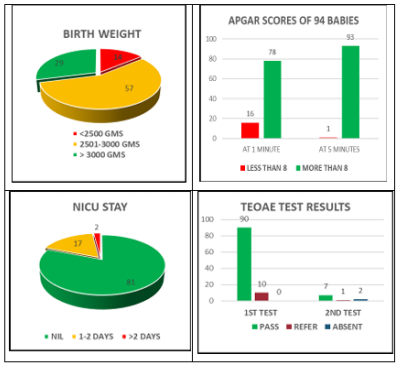
TABLE 1
SHOWING MATERNAL DATA



The babies' age ranged from 01 to 60 days. Low birth weight [<2500 grams] was seen in 14 babies. Apgar scores of 94 babies were only available and 6 babies referred from nearby hospitals didn't have Apgar score details in their discharge summary. Analysis of the available data showed that at 1 minute 16 babies had scored less than 8 and after 5 minutes 15 of them recovered to an Apgar score of 8 and 1 baby with initial score of 6 improved to a score of 7. NICU records showed that 19 babies were nursed there. 17 babies were nursed for one to two days and many were under observation for few hours only. 2 babies were nursed for more than two days in the NICU.

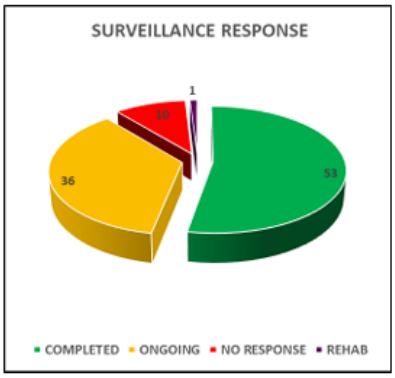
The first hearing screening of the babies was done between 1 to 60 days after birth. There were 10 failures in the first screening. During the second screening test 7 babies passed the retest and 2 babies were absent. The mothers of the absentees responded to the PTS calls by the audiologist and confirmed the development of vocalization and babbling in their babies. 1 high risk baby born to hearing impaired parents was referred for ABR testing and diagnosed as profound hearing loss and attending cochlear implant counseling. The various data of the babies are shown in Table 2.

TABLE 2
SHOWING INFANT DATA



In the PTS program 90 mothers responded. 53 babies have developed speech milestones such as vocalizing or babbling within 6 months. 36 babies are still under surveillance. 1 baby was referred for cochlear implant. There were 10 mothers who could not be contacted due to incorrect phone numbers. The surveillance data is shown in Table 3.

TABLE 3
SHOWING SURVEILLANCE DATA



IV. DISCUSSION

The inner ear is fully formed around 25 weeks of Intra Uterine Life. From birth till 6 months of age, the infant's inner ear and the auditory pathways are in a receptive state to receive and get tuned to sound signals of different frequencies coming from outside. Various environmental sounds, speech, and music are some of the important stimuli for auditory tuning. Providing a low noise environment and good sleep practices after birth at home or in the NICU are important factors for the auditory development of the infant [12]. Family history of deafness, Craniofacial abnormalities, Intrauterine In-

fections, Hyperbilirubinemia, Preterm birth, Low birth weight, Low Apgar score, NICU stay or Mechanical ventilation, or Aminoglycoside administration for more than five days are some of the risk factors associated with neonatal hearing loss as per JCIH and IAP [9, 11].

There are four categories of NBHS programs [6], namely:

1. ABR only
2. OAE only
3. OAE followed by ABR
4. Both OAE and ABR

TEOAE alone is the commonly used screening test in most centers as it is a cost-effective and quick method for first screening. The sensitivity of TEOAE was found to be 95–98% and the specificity 80–85% [13]. Combining both OAE and ABR in NBHS protocols provides good diagnostic sensitivity and specificity. Such protocols help in diagnosing both cochlear and retrocochlear hearing losses and reduce referral rates. But it is the most expensive protocol [14, 6]. The ABR equipment is expensive and the procedure requires more time, skills, training, and a sleeping infant with placement of electrodes. Hence, it is mostly used as a second-tier screening test. The IAP recommends creating a centralized NBHS facility with ABR setup to cover the cost [11]. The JCIH recommends that each country should develop its own NBHS protocols based on budget and government decisions. Typically, the NBHS is a two-stage approach with a first stage of screening normal babies with TEOAE and screening high-risk babies with ABR before discharge from the hospital, and a second stage of referring those who fail multiple OAE screenings for ABR [6]. The high-risk baby in our study was screened with OAE and referred for an ABR test. As per the PTS protocol, any baby showing delayed speech development by 6 months of age is to be referred for ABR [Fig. 1].

The disadvantage of screening only high-risk babies during NBHS programs has been well emphasized. In the study group of hearing-impaired children, 50% of children did not have any high-risk factor [15]. The earlier detection of impairment in those children was missed due to the "High Risk only" screening protocol followed for the children's NBHS program [15]. It has been stated that 70% of babies with hearing loss will be missed by screening only high-risk babies in NBHS [2]. Both authors have recommended that irrespective of risk factors, all newborns should be screened at birth [2, 15]. The IAP also recommends a "universal screening" protocol in NBHS [11]. Our NBHS program follows a "universal screening" protocol.

The ideal timing for the first screening test differs across various NBHS programs. The rate of first test pass increases with the infant's age, and the best results are seen when the first screening test is done on the 5th day after delivery according to Kumar et al. (2024) [16]. It is better to do the first screening test after 48 hours to avoid the problem of fluid and debris in the external or middle ear [7]. Nagapoornima et al. (2007)[2] recommended the first test at 6 weeks after birth [2]. In our study, the first screening test was done between 1–60 days after birth. We also accepted a few babies born before launching the NBHS program for screening; those babies underwent the first screening test at the age of 60 days. Some babies were referred late due to NICU stay or their mother not being fit to move. For safety reasons, babies are referred only when the mother or a close relative accompanies the baby for testing. All babies born in our hospital were screened before discharge.

Smolkin et al. (2012) suggested that the preferable timing of the first screening test for Cesarean babies is 48–132 hours [13]. In our study, the first screening test for Cesarean babies was done between 1–30 days after birth. Kaveh et al. (2021) speculated that Cesarean babies fail more often in the first screening test than vaginally delivered babies due to the presence of amniotic fluid in the middle ear which affects hearing [17]. In our study also, first test failure was more common among Cesarean babies than in vaginal delivery babies [7 vs 3]. Durante et al. stated that higher levels of TEOAE are seen in female babies due to the presence of more OHCs in the cochlea, prevalence of spontaneous OAEs, and stronger hearing sensitivity [18]. In our study, first test failures were seen more in female babies than in male babies [9 vs 1]. Low birth weight is another high-risk factor for newborn hearing loss. In our study, 14 babies had low birth weight, where 12 babies passed the first test and 2 babies failed. They were enrolled in the PTS and recalled for retesting. One baby attended the retest and passed. The second baby could not attend the retest as the parents had moved away, but PTS calls revealed that the child had developed babbling and vocalization in time. Low Apgar score is another high-risk factor. In our study, 16 babies (17%) had an Apgar score of less than 8 at 1 minute, and their Apgar scores improved at 5 minutes; all 16 babies successfully passed the first screening test. NICU stay and mechanical ventilation beyond five days is another high-risk factor. In our study, 19 babies were nursed in the NICU. Seventeen were nursed for less than two days (some under observation for a few hours only), while 2

babies were nursed for more than two days. All 19 babies passed the first screening test.

Family history of deafness is another high-risk factor. One high-risk baby, with both parents hearing-impaired, was referred from a nearby hospital for NBHS. The limitations of the TEOAE screening test and the need for an ABR test were explained to the parents. The baby failed the first screening test and was referred for an ABR test. The baby was diagnosed with bilateral profound hearing loss and referred for a Cochlear implant. Birth asphyxia is also a high-risk factor. In our study, two mothers who had fetal distress were delivered by Cesarean section, and the babies had normal Apgar scores at 1 minute and 5 minutes and passed the first screening tests successfully.

The incidence of newborn hearing loss detected during screening tests varies from 1 to 8 per 1000 live births [13]. In our study, the incidence was 10 per 1000, probably due to a small sample size. Late-onset congenital hearing impairment due to Cytomegalovirus infection and some congenital hearing impairments presenting in minuscule forms are not detectable by NBHS. The problem of emergent hearing impairment is reported to be 10% of all childhood impairments [7]. In an NBHS program, multiple tests are required at different time intervals before confirming a test failure and referral for ABR. The problem of making multiple trips to the hospital with the infant creates social, emotional, and psychological stress for the family, in addition to the financial burden and increases absenteeism [17, 19]. This was observed by Pynnonen et al. (2016) [8] in their US National survey, highlighting that parental awareness, better communication, and follow-ups are important for a successful NBHS [8]. The PTS played an excellent role by ensuring surveillance after NBHS, addressing the problem of absenteeism due to social factors and false positive results, and helping us achieve the goal of NBHS.

PTS PROGRAM

This program was indigenously designed and developed in collaboration with the Audiology and Speech Language Pathologists. At the time of registration, the female audiologist establishes good rapport with the mother in the local language. Mothers are explained in detail about speech milestones and the objective and benefits of the PTS program. The importance of keeping their child under surveillance for 6 months after testing to monitor the development of speech is emphasized and well accepted by the mothers. The mothers are instructed to observe the child's speech development and are encouraged to answer PTS phone calls and share information about the speech milestones of their child. Every 2 months, the female audiologist called the mothers and inquired about the general well-being of the mother and baby, as well as the speech milestones. This created a positive feeling with the mothers, and the familiar female voice of the audiologist created a comfort zone for the mothers, leading to better responses.

The PTS was continued until the baby reached 6 months of age, as most babies with normal hearing start babbling by 6 months of age [20]. Those babies who do not show normal speech development by 6 months are recalled for ABR testing to rule out auditory pathway pathologies [21]. Unfortunately, surveillance calls are mistaken as marketing calls by some mothers, which could be a reason for missed follow-ups.

The PTS program greatly helped us establish a good rapport with mothers and minimize absenteeism to 2%. It alleviated mothers' fears about their child's speech development and helped the investigators collect better results. The response rate in our PTS program was 90%, and only 10% could not be contacted due to wrong phone numbers. Monitoring the screened baby until they achieve babbling or vocalizing helped us achieve the goal of NBHS. We observed that the PTS program complements the NBHS program. PTS is a simple program that can be easily implemented in developing countries and remote areas where accessibility to healthcare is limited. The flow chart showing the PTS methodology is provided for reference [Fig. 1]. Although our study period was short and the number of subjects was small, the diligent implementation of the PTS program helped us achieve the goal of NBHS.

V. CONCLUSION

NBHS using the TEOAE test is an easy method with good sensitivity and specificity. A "Universal screening" protocol for the NBHS is recommended. We conclude that the PTS program is a simple, cost-effective, easy-to-implement program complementary to NBHS. It will have a positive impact on the outcome of NBHS and greatly help in effectively implementing the NBHS program in areas where access to healthcare is limited. PTS will help address the problem of false-positive results, absenteeism, and late-onset congenital hearing loss. It will help investigators achieve the goal of NBHS.

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C. *Compliance with Ethical Standards*

- There are no potential conflicts of interest involved.
- There is no research involving human participants and/or animals.

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