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ORIGINAL ARTICLE
ORİJİNAL ARAŞTIRMA

Neonatal Hearing Screening Results with Screening ABR Protocol

Tarama IBC Protokolü ile Yenidoğan İşitme Tarama Sonuçları

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ABSTRACT

Aim: The aim of this study is to present our national hearing screening results with screening ABR protocol and comparing them with the existing literature.

Material and Method: The sample consists of 7134 records of the first, second and third screening of neonates according to the screening Auditory Brain Stem Responses (ABR) protocol in Mardin Education and Research Hospital. The study was conducted retrospectively by reviewing patient records between 1 January 2021 and 31 December 2021. Newborns who remained in the test and were registered due to risk were referred to the reference center to be tested with clinical ABR according to screening ABR protocol.

Results: Of 7134 newborns, 6174 consisted of first test results (86.6%), and were screened for the first test and 955 (13.4%) of them consisted of re-test (second and third test). The rate of passing the first test was 86.6%, and the rate of failure, that is the rate of taking second and third tests was 13.3%. In total 235(3.2%) patients were referred to the reference center due to the risk even though 0.5% failed the test and 2,7% passed the tests. The number of patients with abnormal results in clinical ABR at the reference center was 27 (3.7%). The number of hearing loss requiring rehabilitation was found as 16 (0.5%). Of them; 10 were bilateral advanced hearing loss requiring cochlear implant. Others required rehabilitation with hearing aids; 5 with bilateral moderate hearing loss, 1 with severe unilateral hearing loss.

Conclusion: Congenital hearing loss rate, first and second test failure rates in the newborn hearing screening program are compatible with the existing literature. However, the number of referrals increased compared to the literature, as the number of referrals increased due to the risk due to the screening ABR protocol.

Keywords: Neonatal, hearing screening, auditory brain stem responses (ABR)

ÖZ

Amaç: Bu çalışmanın amacı, Ulusal Yenidoğan İşitme Tarama Programında tarama IBC (İşitsel Uyarılmış Beyinsapı Cevapları) protokolüne göre yenidoğan işitme tarama sonuçların değerlendirilmesi ve literatürle karşılaştırılmasıdır.

Gereç ve Yöntem: Örneklemi 1 Ocak 2021-31 Aralık 2021 yılı Mardin Eğitim ve Araştırma Hastanesi işitme tarama ünitesine başvuran 7134 yenidoğanın test sonuçları retrospektif dosya taraması üzerinden değerlendirilmesiyle oluşturmuştur. Çalışmaya alınan 7134 yenidoğan tarama IBC protokolüne göre değerlendirilmiştir ve tarama İBC protokolüne göre testten kalanlar ve testten geçse dahi riskli yenidoğanlar referans merkeze sevk edilmişlerdir.

Bulgular: 7134 yenidoğanın 6179'u ilk test (%86.6), 955'i (%13.4) test tekrarına gelen ikinci ve üçüncü test sonuçlarından oluşmaktadır. İlk testten geçme oranı %86.6 ve kalma oranı yani ikinci ve üçüncü teste alınan oranı %13.3 olarak bulundu. Toplamda 235(%3.2) hastanın %0.5 testlerden kalma nedeni ile, %2.7'si testlerden geçse bile risk nedeni ile referans merkeze sevk edildiği görüldü. Referans merkez kayıtlarında klinik İBC'de anormal sonuç saptanan hasta sayısı 27 (%3.7) olarak saptandı. Mevcut kayıtlarda rehabilitasyona gereksinim duyulan işitme kayıplı hasta sayısı 16'sı (%0.5) olarak bulundu. Bu yenidoğanların 10'unda koklear implanta gereksinim gösteren bilateral ileri işitme kaybı, diğer hastalar işitme cihazı ile rehabilite edilecek; 5 bilateral orta derecede işitme kaybı, 1 adet tek kulakta ileri işitme kaybından oluşmaktaydı.

Sonuç: Yenidoğan işitme tarama programında konjenital işitme kaybı oranı, birinci ve ikinci testten kalma oranları mevcut literatürle uyumludur. Ancak, tarama İBC protokolü risk nedeni ile sevk sayısını artırdığından referans merkeze sevk sayısı literatüre göre artmış olduğu izlenmektedir.

Anahtar kelimeler: Yenidoğan, işitme taraması, işitsel uyarılmış beyinsapı cevapları (İBC)

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INTRODUCTION

Congenital Hearing Loss (CHL) occurs between 0.1% and 0.3% of newborns. Among newborns treated in Intensive Care Units (ICU), the prevalence increases by as much as 2% to 4% of cases (1). Genetic factors account for 40% of CHL. Other factors leading to CHL include infections (31%), birth-related causes (17%), toxic drugs (4%), and other causes (8%) (2). Early diagnosis and intervention of CHL positively affect children's speech, language, psychosocial development, and school life (3). The first three years of life are significant for neuroplasticity in the auditory system. After this period, brain plasticity decreases, and adaptive capacity decreases leading to limitations in hearing rehabilitation (2).

Joint Committee on Infant Hearing (JCIH) in 1993, approved the universal neonatal hearing screening (NHS) and declared that the diagnosis of HL should be made before the age of 3 months and that the intervention at 6 months was advisable (4).The updates of JCIH were made in 2000,2007 and 2019. In 2019 updates of JCIH screening, diagnosis and intervention was recommended to be completed in one,two,three months, respectively (5). The language development of children treated at 6 months old did not differ from that of their peers with normal hearing. The delayed intervention led to problems with vocabulary, grammar, and education (6). Therefore, the use of NHS is very important for early diagnosis (7,8).

The first NHS was initiated in Turkey in 1994 and 1998 in the university hospital of Marmara and university hospital of Hacettepe. In 2003, Universal NHS started in some pilot hospitals; Gazi, Hacettepe, Marmara, and Dokuz Eylül University Hospital in Turkey, and moved to 81 provinces in Turkey. Since 2014, it has been amended as an NHS program by the Ministry of Health. The goal of this program is to ensure that all babies have access to hearing screening within a month (9). Before 2019, hearing screening was performed by either transient otoacoustic emission (TEOAE) or ABR, or both. Currently, the hearing screening is carried out by ABR in Turkey since 2019. The aim of this study was to present the NHS at a training research hospital that Mardin in 2021 by comparing it with the literature.

MATERIAL AND METHOD

All procedures performed in this study involving human participants were under the ethical principles stated in the 1964 Helsinki declaration and were approved by the Ethical Committee of Noninvasive Clinical Research of the Mardin Artuklu University (Date: 11 October 2021 and numbered: 2021/2). This study was performed between 1 January 2021 and 31 December 2021, at the Mardin Training and Research Hospital which is a secondary care hospital in the Project Turkish NHS program in 2021. A total of 7134 newborns who were born either in or referred to our hospital were included. Newborns with 2. and 3. screening and patients who stayed in the ICU were also included.

The results of newborns evaluated according to the screening ABR protocol in the NHS program of the Ministry of Health were collected retrospectively. The newborns included in this study, either before being discharged from the hospital or being referred from other hospitals, were given the screening ABR test by two trained audiometry technicians in the audiometry unit of our hospital on the same day. (Madsen Accuscreen-D Pro, GN Otometrics, Denmark) portable device was used for the test. All tests were carried out in a soundproof room with a noise value not exceeding 35 dbA.

According to the screening ABR protocol in the NHS program of the Ministry of Health, all newborns with/without risk factors should be screened by ABR. The newborns first screening ABR test should be done within 72 hours of birth. The neonate should not be discharged without ABR testing. If the neonate fails the first test, the second screening ABR test is done within 7-15 days after birth. If the newborn fails a re-test, the third screening ABR test should be performed within 15-30 days (not exceeding 30 days) after birth. The newborns who fails the 3rd screening ABR test should be referred to the reference center. Even if newborns with risk factors pass the test, they were verbally directed to the reference center for follow-up. The newborns screening protocol should be completed within 30 days. If the protocol is not completed within 30 days, it should be referred to the reference center without waiting for the completion of the screening protocol after the first test. **Figure 1** and **Figure 2** (10).

Screening with ABR is a noninvasive test. During the testing, the neonate should be in sleep or be quiet and not crying and moving. ABR waveforms were recorded with three electrodes placed on the skin. Electrodes were attached to the forehead, mastoid, and cheek. Attention should be paid to the cleanliness of the area where electrodes would be attached, in terms of full adhesion and permeability of the electrodes. The shape, latency, and density of the waveforms were compared to the normal, resulting in a "pass" and "fail". In case of delay or absence of waves, the neurological or cochlear defect was suspected. The average time of testing takes 4-15 minutes in screening ABR with 35dB screening stimulus level of device.

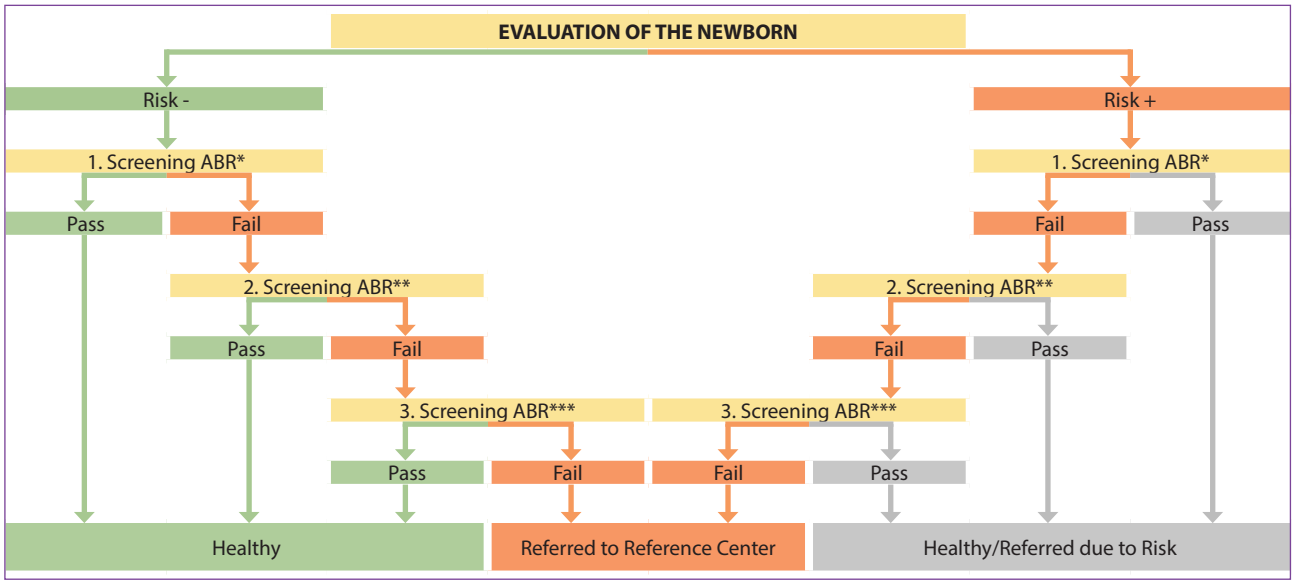

Figure 1. Screening ABR Protocol Flowchart in the newborn hearing screening program

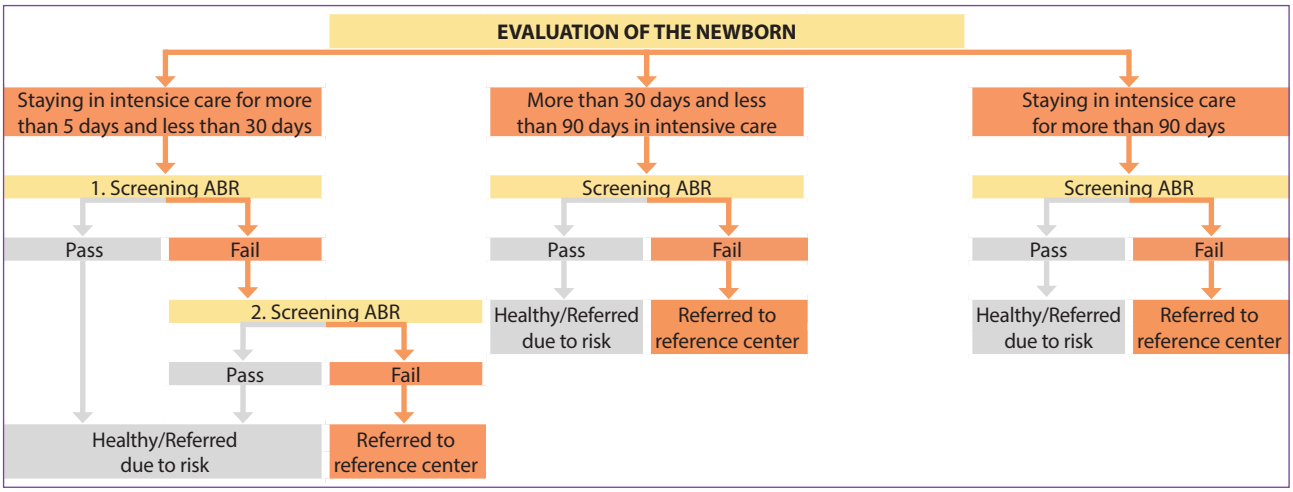

Figure 2. Screening ABR Protocol Flowchart for newborns staying in the ICU (Intensive Care Unit) for more than 5 days

RESULTS

Of 7134 newborns included in the study, 6179 were screened for the first test and 955 of them were for the second and third tests in the audiology clinic of our hospital by portable screening ABR (**Table 1**). In the examination records, 235 newborns were referred to the nearest reference center. Of the 235 newborns, 40 (0.5%) failed ABR screening. The remaining newborns were refereed due to risk (**Table 2**). Recorded findings were found in 27 of them in which ABR abnormalities took place. The findings of 27 newborn whose records were found in the records of the nearest reference center were provided in Table 3. There may be other newborns with hearing loss that applied to other reference centers, were not registered, or did not apply to any reference center. In the examination of the **Table 3**; 10 newborn had bilateral profound hearing loss (bilateral 120Db) and were given hearing device and informed about cochlear implantation. 11 of them were called for follow-up for serous otitis media after treatment at otolaryngology clinics. 1 of them had severe sensorineural hearing loss in one ear, and 5 of them were given a hearing device for moderate sensorineural hearing loss. 16 newborn were diagnosed with hearing loss and had the chance of hearing rehabilitation. The rate of children with hearing loss who were referred to both medical treatment and rehabilitation was found to be 3.78/1000 (0.38%). The number of newborn with hearing loss who could only recover with rehabilitation was found to be 2.58/1000 (0.25%).

Table 1. Data of newborn hearing screening program between 1 of January and 31 of December 2021.

	"Newborns attending first test(n)	Newborns attending second and third test(n)	Total number of screening(n)	Total number of referred
January	492	67	559	30 (5.3%)
February	427	77	504	8 (1.5%)
March	530	78	608	15 (2.4%)
April	466	83	549	17 (3.0%)
May	401	56	457	21 (4.5%)
June	515	80	595	28 (4.7%)
July	515	86	601	23 (3.8%)
August	515	96	611	25 (4%)
September	552	80	632	21 (3.3%)
October	470	61	531	18 (3.3%)
November	635	101	736	15 (2.0%)
December	661	90	751	14 (1.8%)
Total	6179 (86.6%)	955 (13.3%)	7134	235 (3.2%)

"Newborns attending first test: total number of newborns attending to screening including healthy, unhealthy and neonates with risks.

Table2. Newborns referred to reference hospital either by risk or test failure

	Number of newborns referred due to risk	Number of newborns referred due to test failure
January	30	-
February	8	-
March	15	-
April	17	-
May	21	-
June	21	7
July	21	2
August	18	7
September	16	5
October	9	9
November	8	7
December	11	3
Total	195 (2.7%)	40 (0.5%)

Table 3. Findings detected by the nearest reference center by clinical ABR results

January	Bilateral 120dB (4 babies) Bilateral 40dB follow-up
February	R40dB, L25dl follow-up Bilateral 120dB
March	Bilateral 120dB R25dB, L35dB follow-up
April	Bilateral 120dB (2 babies)
May	Bilateral 120dB (2 babies) Bilateral 65dB (hearing aid)
June	Bilateral 40dB follow-up Bilateral 25dB follow-up R50, L20dB
July	Bilateral 70dB hearind-aid R 20dB, L 40dB follow-up Bilateral 25dB follow-up
August	R90, L60dB
September	Bilateral 25dB follow-up R25 dB, L40dB follow-up
October	R45dB, L50dB Bilateral 25dB (2 babies) follow-up
November	-
December	R25dB,L100dB

DISCUSSION

The aim of NHS is to detect CHL as early as possible and rehabilitate the child to catch up with normal hearing peers. Since its establishment, JCIH (11) has been directing NHS with its declarations. CHL is more commonly seen in newborns with risk factors identified by JCIH in 1983. These are TORCH (Toxoplasma, Rubella, Cytomegalovirus, Herpes Simplex) group infections, consanguineous marriage, low birth weight, and APGAR (Activity-Pulse-Grimace-Appearance-Respiration) score, hyperbilirubinemia in the neonatal period, bacterial meningitis, ototoxic drug use, history of neonatal ICU. (11,12,7,8). In 1994, JCIH identified risk factors in babies with CHL, and declared that not only risk-bearing but all newborns should be screened for CHL (13). In 1999 article by the American Academy of Pediatrics recommended that national NHS should be performed before 1 month, diagnosis before 3 months, and the intervention before six months (13). Also, it stated that an effective NHS program included; a minimum 95% screening, false positivity 3%, reference rate <4%, false negativity 0%, and screening TEOAE or ABR before discharge from the hospital (14). Herein, for more than 30 years of knowledge of NHS, we discuss our experience of national NHS in our hospital which is secondary care in South East of Turkey.

Different screening protocols exist for detecting CHL up to now. These protocols vary in the number and timing of screening and the screening methods (15). Protocols are being updated and the aim is to provide better screening and to screen all children with CHL with high sensitivity. In addition, many problems or disadvantages still exist with some protocols, such as high referral rates, great numbers of false positives, or increased rates of lost-to-follow-up of infants in the latter tests (16). Moreover, different NHS programs have been used in different countries (17). Otoacoustic emissions (OAE), ABR or combined protocols were used intensively in our country and in the world. In the literature, triple screening NHS (application of 2 times Transient otoacoustic emissions (TEOAE) and once screening ABR) was most commonly seen. (17,18). 2 stages of NHS with ABR was seen in studies by Rouev and Gaborjan (19). ABR was preferred to avoid the false-negative diagnosis of Auditory Neuropathy Spectrum Disorder (ANSD) and central origin hearing losses. The other aspect of choosing screening ABR has the lower false positive rate than the OAE. Gaborjan et all in their study, reported referral rate was 16% by OAE screening, and the referral rate was 1–2% by ABR in the same clinic (15). In our country, NHS in healthy newborns started with the TEOAE-based protocol. However, with the experience gained from the rapidly growing NHS program, to reduce total cost and reduce the number of newborns in control and follow-up to zero, with the proposal of Science Commission at 24.11.2017 screening ABR was recommended for healthy newborns by official instructions (20).

Easily missed diagnosis of Auditory Neuropathy Spectrum Disorder (ANSD) and consanguinity-related hearing losses are two major indications to use ABR-based screening than OAE-based screening protocols. ANSD was first described in 1996. In ANSD, positive OAE results are present, but ABR testing shows abnormal or absent responses (21) ANSD explains up to 10–14% of children diagnosed with Sensorineural Hearing Loss (SNHL). A mistake can be encountered at hospitals during NHS using OAE. This group of children will pass this test, and are only diagnosed later when it becomes visible to parents or caregivers that they are missing language and developmental stages. The auditory manifestations of ANSD can arise early in life during the perinatal period. Alternatively, ANSD can be acquired or expressed later in life. The most important perinatal risk factor for acquired ANSD is a prolonged neonatal intensive care unit (NICU) stay, where hypoxia, prematurity, and hyperbilirubinemia are potential causes of ANSD (22). About 10%–15% of newborns discharged from a NICU have a higher prevalence of SNHL, especially ANSD. The prevalence of SNHL in the NICU discharged population is around 1/50 in comparison to 1/1000 in normal-term newborn children. Similarly, their ANSD prevalence is also higher compared to normal-term newborns, as ANSD explains up to 30% of all SNHL in NICU discharged children (23). Also, consanguinity of parents was found in 80% of children with hearing loss and 66% of patients with ANSD (24).

The frequency of CHL in the NHS is between 0.1-0.6% in the studies of Thompson, Hahn, and Ghirri. In a large-scale study conducted in Turkey in which 142,128 newborns were screened with OAE between 2005 and 2011, the frequency of CHL was found to be 0.27% (25). In studies conducted in Turkey, the frequency of CHL was found at 0.15% by Kucur et al, and 0.93% by Köseoğlu et al in NHS (26,27). In this study, the frequency of CHL requiring rehabilitation was found to be 0.25%. Although the tests were performed with ABR, our results in terms of the rate of CHL are similar to the existing literature.

Babies with suspected hearing loss are defined as "pass" or "failed" by portable devices. Babies with failed test results are referred to reference centers for clinical ABR for detailed examination of hearing (19). In our study, the rate of newborns who failed the first screening ABR was 13.3%, whereas, the second test and third test screening failure rate were found as 3.2% (**Tablo 1**). In a study in which 2284 newborns evaluated in Istanbul, the frequency of failure in the first test was 15.8% (28). In the first screening measurements made with OAE in NHS, the rate of failure was found to be 5-20%. The reason for this is thought to be debris and amniotic fluid in the neonatal external ear canal (14). In the study in which 3412 newborns were screened in Sanlıurfa, the rate of failure in the first test was %19,2 and was %3 in the second test (29). In the study in which 1664 babies were screened with OAE in Elazıg, failure rate in the first test was %14,9 (30). Our results are consistent with these studies.

One of the most important parameters that need to be evaluated is the reference rate of neonates for further examination after screening. We see the lowest referral rate as 0.23% in the study of Susaman et al in Elazıg (30). While Güvey et al found a reference rate of 0.86% in their study conducted in Sakarya in 2018 (31). Erdoğdu et al found the highest referral rate in Istanbul with 1.5% in the same year (32). In a similar study examining the screening of 52338 babies in Van, they reported the referral rate as 0.54% (33). The referral rate in this study was found to be 3.2%. In the literature, neonatal referral rates in Turkey are similar to less than 1%. The highest results in this study are due to the reference of babies for risk. The rate of neonates referred due to failing the test is 0.5%. The failure rate in the test is lower than in the literature. This can be attributed to the success of ABR. As a result, the screening ABR test protocol in Turkey increases the referral rates due to the babies referred due to the risks.

NHS programs have important contributions to the early diagnosis and treatment of CHL. ANSD and CHL due to consanguineous marriages that can be easily missed by OAE are detected by ABR screening. With the new screening ABR protochol we see that referral rates have increased due to the newborns referred due to the risks. One of the limitations of this study is being retrospective and some records of babies referred to reference centers could not be found. Only data of patients with abnormal ABR at the reference center were detected. Although valuable information has been obtained, we think that the number of newborns with hearing impairment may be higher than the result found in this study due to reference to other centers or loss of follow-up. With prospective studies, more specific results can be achieved with close follow-up of patients.

CONCLUSION

NHS leads to early diagnosis and treatment of CHL. NHS protocols are updated in time. In the last NHS protocol; screening ABR protocol, Auditory Neuropathy Spectrum Disorder (ANSD) and CHL due to consanguinity can be detected with more accuracy as we know they can be missed on screening by OAE. In the screening ABR protocol, reference rates to the reference center increase due to the reference of newborns due to the possible risks.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Mardin Artuklu University non-interventional research ethics Committee (Date 08/03/2022, Decision No: 2022/6).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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