

## Original Article

# Screening of Hearing in Newborn Infants: Follow-Up and Outcome After 40 930 Births in Babol, Northern Iran

Yadollah Zahed Pasha, MD<sup>1</sup>; Mohammad Zamani, MD<sup>2,3\*</sup>; Ali Hashemi Fard, BSc<sup>4</sup>; Ermia Zahed Pasha, MD<sup>5</sup><sup>1</sup>Non-Communicable Pediatric Diseases Research Center, Amirkola Children's Hospital, Babol University of Medical Sciences, Babol, Iran<sup>2</sup>Student Research Committee, School of Medicine, Babol University of Medical Sciences, Babol, Iran<sup>3</sup>Cancer Research Center, Health Research Institute, Babol University of Medical Sciences, Babol, Iran<sup>4</sup>Babol Clinic Hospital, Babol University of Medical Sciences, Babol, Iran<sup>5</sup>Department of Pathology, Rohani Hospital, Babol University of Medical Sciences, Babol, Iran**Abstract****Background:** The purpose of this study was to investigate the results of hearing screening in all newborn infants, and their follow-up in Babol, northern Iran.**Methods:** Between 2006 and 2014, all healthy neonates delivered in 3 hospitals were included in this cross-sectional study. Newborns were screened using the transient evoked otoacoustic emissions test before discharge. Those who failed to pass the examination were tested for auditory brainstem response (ABR) by the age of one month. The infants referred from the previous level underwent tests of auditory steady state response, ABR and impedance audiometry before the age of 3 months. For infants with the diagnosis of bilateral hearing impairment, it was recommended to use a hearing aid in 3 months. Then, their parents were recommended to take infants again to the hearing testing centers within next 6 months. If the infant's hearing was not improved, he/she was advised to undergo cochlear implantation.**Results:** In total, 40930 newborns were screened. Out of them, 62 (1.5 per 1000 live births) were finally diagnosed to have hearing impairment, of whom 14 had unilateral and 48 had bilateral disorders (candidate for supportive measures). Overall, 986 (2.4%) were lost to follow-up and 11 (0.03%) died over the first 3 months of age. At the end of the 6-month follow-up for supportive stage, 15 out of 48 infants received a hearing aid and 18 (0.4 per 1000 children) underwent cochlear implant surgery. Fourteen out of 48 cases were lost to follow-up over supportive stage.**Conclusion:** It is recommended that all newborns undergo hearing screening test before hospital discharge, and those with impairment receive supportive measures from 3 months of age, and be re-examined at 12 months of age.**Keywords:** Cochlear implantation, Hearing aid, Hearing loss, Hearing screening, Infant, Newborn**Cite this article as:** Zahed Pasha Y, Zamani M, Hashemi Fard A, Zahed Pasha E. Screening of hearing in newborn infants: follow-up and outcome after 40 930 births in Babol, Northern Iran. Arch Iran Med. 2018;21(9):382-386.

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**Introduction**

Hearing disorder is the most common sensory disorder in the world, and deafness is the most frequent curable disability in children.<sup>1,2</sup> Hearing loss is an important factor affecting negatively on health, language acquisition and speech, leading to delay in emotional, social, learning and mental development.<sup>3,4</sup> The World Health Organization (WHO) reported that the overall rate of persons with hearing loss (defined as >40 decibel hearing level [dB HL]) was more than 120 million in 1995, increasing to reach 278 million in 2005.<sup>6</sup> Currently, hearing impairment (moderate to profound) is reported in 360 million people around the world.<sup>7</sup> In addition, about 6 per 1000 live births every year have permanent deafness across the world at birth or in childhood, of whom 90% are from developing countries.<sup>6</sup> About half of the hearing loss in children is associated with no known risk factors.<sup>8</sup>

According to the report by WHO in 2001, the incidence of this disorder is ten times more common in high risk neonates than healthy newborns.<sup>9</sup>

Early detection of hearing loss and opportune medical intervention could result in improvement of social, communication and educational development.<sup>5</sup> Universal newborn hearing screening (UNHS) program is an essential practice and the gold standard for early diagnosis of hearing impairment in newborns and children.<sup>8,10</sup> This program was started in the 1990s in most American and European countries.<sup>11</sup> All neonates in Germany and France have undergone a mandatory hearing screening since 2009 and 2013, respectively.<sup>12,13</sup> In 2009, most of the countries started the UNHS program under the guidance of the WHO.<sup>14</sup>

Hearing impairment can be prevented in half of the cases via primary interventions. Also, by using methods

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such as hearing aids, cochlear implants, speech-language therapy, and educational and social support, the difficulties of the disease could be diminished.<sup>15</sup> According to the Early Hearing Detection and Intervention (EHDI) program, which addresses the early intervention in addition to screening program based on the “1-3-6” plan, all neonates should be screened no later than 1 month of age. Then, any hearing loss diagnosis should be confirmed no later than 3 months of age, and finally, early intervention services should be implemented for children with an identified hearing impairment no later than 6 months of age.<sup>16</sup> Furthermore, in 2000, the Food and Drug Administration (FDA) approved cochlear implantation for treatment of hearing loss in children aged 12 months.<sup>17</sup>

UNHS program is a part of national screening program in Iran.<sup>18,19</sup> A national study (2005–2012) showed a prevalence rate of 3 per 1000 infants for hearing impairment.<sup>18</sup> Babol is one of the first cities in Iran in which the newborn hearing screening program was introduced.<sup>20,21</sup> A survey by Haghshenas et al.<sup>20</sup> performed during 2009–2011, indicated a rate of 1.8 per 1000 neonates for hearing loss. The present study aimed to evaluate the prevalence of hearing impairment in newborns in Babol, based on UNHS program during 2006–2014. We also performed, for the first time in Iran, a follow-up on the patients with hearing disorders to assess the effectiveness of supportive measures.

## Materials and Methods

### Locations and Participants

This prospective cross-sectional study included all neonates delivered at Shahid Yahyanejad hospital and Rohani Hospital (2 governmental hospitals) and Babol Clinic hospital (a private hospital) in Babol, a city in Mazandaran province in north of Iran. These hospitals are 3 centers with maternity wards in Babol where all deliveries occur. The survey took place from May 2006 to March 2014, but the data from Rohani hospital were collected from 2007 to 2014. This study was conducted on healthy neonates, and those admitted to neonatal intensive care unit (NICU) were excluded from the study. The included neonates underwent hearing screening tests before discharge. The parents of the newborns were informed about the importance of the program. Our study was a national screening project, and there was no need to obtain informed consent from the subjects. However, the families were free to participate in the study or reject the participation. All who understood the importance of the study, accepted to enroll in the project.

### Screening Procedure

The screening program was implemented in 2 steps:

1. **Confirmation step:** First, all healthy newborns were screened prior to hospital discharge with transient evoked otoacoustic emissions (TEOAE) test. Anyone who failed to pass the examination was referred to the next stage within one month of age. In this step, the subjects were screened by auditory brainstem response (ABR) test for confirmation of hearing disorder. Cases with a hearing loss were referred to the second level of screening for diagnostic testing.
2. **Diagnostic step:** Cases who were referred from the previous stage were scheduled for the next examinations 3 months after birth. In this phase, tests of auditory steady state response (ASSR), ABR and impedance audiometry were performed on the infants. Ranges of hearing loss severity were categorized using ABR as follows<sup>22</sup>: moderate, 41–70 dB HL, severe, 71–90 dB HL; and profound, > 90 dB HL. Two expert audiologists conducted the screening tests.

### Supportive Strategies

In this step, we recommended that infants with bilateral hearing disorder use a hearing aid within 3 months after diagnosis of the impairment. In other words, the opportunity for hearing aid was between 3 and 6 months of age.

In the following 6 months (i.e., until 12 months of age), we recommended that the parents take their infants to the hearing testing centers for re-assessment of the hearing. If the infant's hearing improved, he/she could continue to use hearing aid. If the child's hearing loss was severe or profound, he/she should be assessed for a cochlear implantation.

During the supportive period, we contacted the parents and asked them for the last status of their child. In addition, we followed-up those children who were referred to us with ABR every 6 months.

### Instrumentation

In the following, the names of equipments used in our screening program are presented: TEOAE screening, ERO•SCAN device (Maico®, Germany); ABR test, Eclipse EP25 (Interacoustics®, Denmark); impedance audiometry, TITAN A226 (Interacoustics®, Denmark); ASSR test, Eclipse (Interacoustics®, Denmark).

TEOAE is an instrument to assess mechanical cochlear function and to detect the hearing loss of this origin, but it does not quantify the impairment. ABR evaluates the function of auditory brainstem in response to click stimuli. It was conducted by applying filter settings of 100–3000 Hz with 40 dB SPL and 16–24 pulses per second.

### Statistical Analysis

Data were analyzed using STATA software. The 95% confidence intervals (CIs) were computed for the estimates.

## Results

### Screening Stage

Overall, 40930 neonates were included in the study. In the first step, based on TEOAE test, 88.3% (36122/40930) of the newborns showed normal results, while 11.7% (4808/40930) failed to pass the examination and were tested again one month later. At this step, 19.4% (931/4808) were lost to follow-up and 6 neonates died. Out of the 3,871 retests, 241 (6.2%) screened positive and were referred to the next stage up to 3 months of age, and 1.4% (55/3871) were lost to follow-up.

In the second step, 0.15% (62/40930; 95% CI: 0.11-0.19) of the infants were diagnosed to have hearing loss, of whom 14 (22.6%) had unilateral disorder (8 with canal atresia or conductive hearing loss; 6 with sensorineural hearing loss) and 48 (77.4%) were affected bilaterally. Out of 62 subjects with hearing impairment, 39 were boys (62.9%) and 23 were girls (37.1%). The frequency of diagnosed hearing impairments is shown in Table 1.

In total, 2.4% (986/40930; 95% CI: 2.2–2.6) were lost to follow-up and 0.03% (11/40930; 95% CI: 0.01–0.05)

died during the program. Figure 1 shows the flow-diagram of hearing screening program applied in our survey.

### Supportive Stage

Out of 48 cases who were candidate for the supportive measures, 25 cases were referred to our centers and 14 did not follow-up. At the end of this stage, it was found that 15 children received a hearing aid and 18 children had an implanted cochlea. The mean age of cochlear implantation was  $26.33 \pm 9.89$  months, ranged from 18 to 48 months.

During the first 12-month follow-up, 4 more children (1 boy and 3 girls) who had passed the first level of screening stage, were referred to our centers with complaint of hearing impairment. They had no risk factors for hearing loss (e.g., family history, history of trauma, persistent pathology in their ear, etc.)

## Discussion

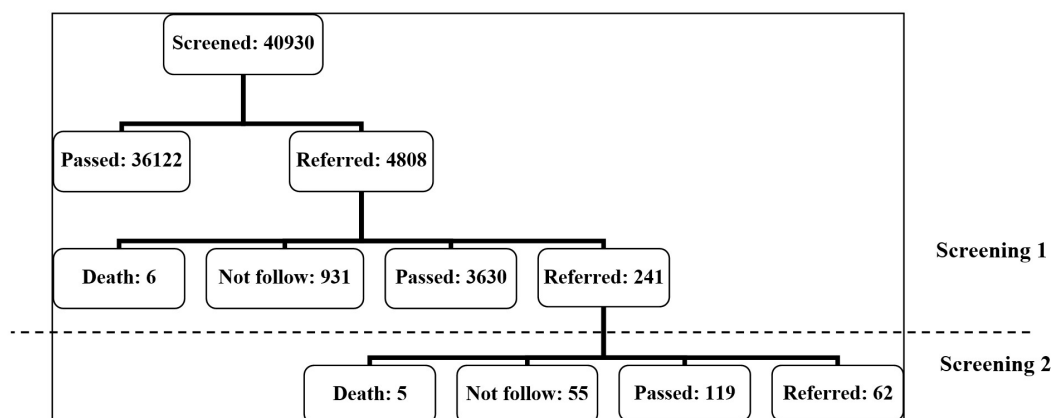
In our study, which was done over a nine-year period, the prevalence of hearing impairment was calculated at 1.5 per 1000 live births, similar to the previous report from Babol (1.8 per 1000 live births).<sup>20</sup> In comparison with the mentioned study, our survey had a higher coverage (40930 neonates in our study vs. 15165 neonates in Haghshenas et al's study) and was superior from this standpoint. In Khuzestan, southeastern Iran, based on TEOAE, AABR, ABR and OAE assessments, Saki et al<sup>19</sup> reported a rate of 2.41 per 1000 live births, which was higher than our results. Also, in a study in Yazd, a rate of 6.5 per 1000 newborns was reported which was higher than our results.<sup>23</sup>

There are a number of studies on the cases with specific conditions. In our study in Babol, which was conducted on infants admitted to NICU, 2.1% of 330 newborns

**Table 1.** Frequency of Diagnosed Hearing Impairments

Hearing Loss Types	N = 62
Bilateral	48
Moderate	18
Severe	5
Profound	25
Unilateral	14
Sensorineural (R/L) <sup>a</sup>	6 (3/3)
Conductive (R/L)	8 (3/5)

<sup>a</sup> R, right; L, left.



**Figure 1.** Flow Diagram of Hearing Screening Program. Screening 1: By one month of age; Screening 2: By 3 months of age.

were diagnosed to have permanent hearing loss.<sup>21</sup> A recent report from Mashhad, northeast Iran, exhibited that the impairment occurred 6.5 times more in NICU newborns (1.94%) compared with infants in the rooming-in unit (0.3%), suggesting that hearing impairment screening is more necessary for high-risk newborns.<sup>9</sup>

Reports from other countries also show variations in the prevalence of hearing loss. In a study in India, 2.9% of screened NICU newborns were diagnosed with a hearing loss.<sup>24</sup> Sensorineural hearing loss, conductive and auditory neuropathy were observed in 0.91%, 1.83% and 0.19% of the subjects, respectively.<sup>24</sup> In the United States, it has been declared that 4000 to 8000 neonates are diagnosed annually with permanent hearing impairments at birth.<sup>25</sup> According to the Hearing Screening and Follow-up Survey (HSFS) conducted during 2006–2012, it was identified that the rate of hearing loss in the United States was 1.1 per 1000 live births in the first year, and with an ascending trend, reached 1.6 per 1000 live births in 2012.<sup>26</sup> In Europe, reports show low rates of hearing impairment, for example 0.08% in France,<sup>27</sup> 0.18% in Italy<sup>28</sup> and 0.14% in Belgium.<sup>29</sup> The reason of these variations can be related to methods of diagnosis, study population and study date.

Hearing loss is believed to be multifactorial in etiology. Genetic factors, infectious diseases, chronic ear infections, use of special drugs, aging and noise, can be involved in hearing loss.<sup>15</sup> Recent data in Taiwan, alluded to the mutations of connexin genes and *SLC26A4* gene in newborns with congenital hearing loss.<sup>30</sup>

The reason why health professionals emphasize earlier supportive interventions is related to language learning. As mentioned above, the FDA used to encourage cochlear implantation at the age of 1 year, but current views are tending to modify this approach. Recent data show that cochlear implantation under 12 months of age is associated with better outcomes for speech and language development, and more safety in surgery.<sup>31</sup> A study by Dettman et al.<sup>32</sup> indicated that children implanted below 12 months had significantly higher speech production and language standard scores than children implanted after that age. Moreover, O'Connell et al.<sup>33</sup> concluded that cochlear implantation before 1 year of age had a non-significant higher rate of postoperative complications vs. implantation after 12 months of age.

Notably, four children who passed the first step of screening, were diagnosed with hearing impairment when re-assessed before the age of 12 months. As shown in previous articles, permanent hearing loss not only could occur at birth (congenital form), but also could be delayed-onset, or progressive hearing loss.<sup>34,35</sup> The Joint Committee on Infant Hearing recommended

that children at risk of hearing loss who passed neonatal hearing screening, should undergo an audiological evaluation at least once at 24 to 30 months of age, to detect delayed-onset hearing impairment.<sup>16</sup>

One of the limitations of our program like other screening programs was that parents failed to bring their children for follow-up. Costs, lack of easy access to hearing testing centers, and low level of knowledge towards importance of hearing screening, were some causes leading to follow-up failure. Follow-up rate in our study was high (97.6%) compared with the other surveys with a failure rate of more than 40% in follow-up.<sup>36</sup>

In conclusion, according to the findings, the UNHS program implemented in Babol, has had good outcomes in terms of coverage of newborns and follow-up rate. We recommend this program for evaluation of all neonates before hospital discharge. Also, they should receive supportive care from 3 months of age and then be re-evaluated until 12 months of age. One of the considerable points found in this study was that a number of cases were referred to our centers with delayed-onset hearing loss. Therefore, it is recommended that the clinicians should attend to the parents' compliant of their child's hearing impairment in the first months of life, despite passing the early hearing screening test with no diagnosis of hearing impairment.

#### Authors' Contribution

Study design, YZP; Data collection, AHF, MZ, EZP; Data analysis, MZ; Drafting the manuscript, MZ, AHF, EZP; Intellectual input and manuscript revision, YZP. All authors have read the manuscript and approved its final version.

#### Conflict of Interest Disclosures

The authors have no conflicts of interest.

#### Ethical Statement

Considering that our study was a national screening project, there was no need to obtain the ethical approval. However, the families were free to participate in the study or reject the participation.

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