

## Original Research

# Universal newborn hearing screening using A-TEOAE and A-ABR: The experience of a large public hospital

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### Abstract.

**BACKGROUND:** Universal newborn hearing screening (UNHS) aims to identify hearing loss in the early postnatal period; prompt detection of bilateral or unilateral hearing loss is mandatory for timely intervention.

**METHODS:** This retrospective study reports the results of the first two years of a UNHS program on 4,719 newborns in a large public Italian hospital. Screening was divided into two levels: automated transient otoacoustic emissions were used for first level; automated auditory brainstem response for second level. Second level included children with a “refer” response at first level and babies with a family history for hearing loss or other risk factors. Hearing loss diagnosis was made using clinical auditory brainstem response.

**RESULTS:** During first level, 254 (5.4%) newborns were “refer”. At retest, 130 (51.1%) babies were PASS and 48 (18.8%) were “refer”. 76 babies dropped out (29.9%). 146 babies (3.1%) were referred to the second level: 48 for a “refer” response at first level and 98 for a PASS response but potential hearing loss due to risk factors. 24 babies dropped out (16.4%). Out of 122 newborns tested in the second level, 105 (86.1%) had a PASS response and 17 (13.9%) were “refer”. Our screening protocol identified 7 (0.14%) babies with profound hearing loss; 5 had unilateral and 2 had bilateral hearing loss. 2 babies dropped out at diagnostic level (11.8%).

**CONCLUSIONS:** A correct and early diagnosis of hearing loss is mandatory to prevent permanent consequences; the spread of hearing screening programs is the optimal solution to reach this goal.

Keywords: Universal newborn hearing screening, hearing loss, A-TEOAE, ABR

### Abbreviations

|         |   |      |                                      |
|---------|---|------|--------------------------------------|
| UNHS    | universal newborn hearing screening       | ABR  | clinical auditory brainstem response |
| A-TEOAE | automated transient otoacoustic emissions | SNHL | sensorineural hearing loss           |
| A-ABR   | automated auditory brainstem response     | NICU | neonatal intensive care unit         |
|         |   | NDP  | neonatal department of pathology     |

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### 1. Introduction

The estimated incidence of sensorineural hearing loss (SNHL) at birth ranges from 1 to 3 per

1000 newborns in the United States and is very high compared to other congenital disorders [1, 2]. The largest study on prevalence of prelingual deafness in Italy was published by Bubbico et al. in 2007 and showed 40,887 cases of prelingual sensorineural hearing impairment  $\geq 60$  dB, with a prevalence in the Italian population of 0.72 per 1,000 inhabitants [3].

Many studies demonstrated that children with congenital hearing loss who received early diagnosis and intervention (at  $< 6$  months of age) had significantly better outcomes for speech and language development compared to non-treated children [4–6]. Currently, rehabilitation of hearing loss is mainly based on the use of hearing aids and cochlear implants; new perspectives include regeneration of the neural epithelium and ganglion neurons through gene therapy and implantation of stem cells [7].

It has been demonstrated that a universal newborn hearing screening (UNHS) program, based on automated hearing evaluation with the combined use of automated transient otoacoustic emissions (A-TEOAE) and automated auditory brainstem response (A-ABR) testing reduces the negative impact of undiagnosed SNHL [8–10], with significantly better speech and language development in children with SNHL who were born in hospitals with UNHS programs compared to that of children who were born in hospitals without a screening program [4]. Both procedures are non-invasive, quick and easy to perform.

Nevertheless, there are several open discussion topics, such as the technologies used in the screening protocol, the personnel that should be involved, and the cost-effectiveness ratio of the screening [11]; the most recent guidelines of the Joint Committee on Infant Hearing, outlined in 2007, recommend the implementation of hearing screening programs in all hospitals and birth centres [12].

San Camillo – Forlanini Hospital (SCFH) is the second biggest public hospital in Rome, Italy; it manages more than 3,000 births per year and serves as a hub for secondary birth centres in the same area. Following Italian national laws, UNHS has been introduced since 2013 in all major hospitals and birth centres [13, 14]. The aim of this retrospective study is to report and discuss the results of the first two years of the UNHS program in SCFH and to highlight the major problems encountered during the initial phase of the program, as well as the effectiveness of our screening protocol in the identification of children with SNHL.

## 2. Materials and methods

This clinical retrospective study was performed on 6200 newborns in SCFH and satellite birth centres between January 2014 and January 2016; 4,719 (76.1%) children were included in the program and screened for SNHL. Most of the children included in the study were born in the SCFH ( $n=4,596$  - 97.4%), while a smaller percentage ( $n=123$  - 2.6%) in satellite birth centres. Children born in the SCFH were referred to the UNHS program by the internal nursery ( $n=4,345$  - 94.6%), Neonatal Intensive Care Unit (NICU) ( $n=185$  - 4%) and Neonatal Department of Pathology (NDP) ( $n=66$  - 1.4%). UNHS procedures were divided into two levels: A-TEOAE were used for the first level, A-ABR for the second level. Hearing loss diagnosis was performed using clinical ABR.

### 2.1. First level

A-TEOAE test (Accuscreen GN Resound) was used for first level screening. Evaluation was based on noise-weighted averaging counting of significant signal peaks; stimuli were non-linear click sequences at a 70 dB SPL level (45 dB HL) with a frequency range of 1.5–4.5 kHz.

A-TEOAE test was performed in all newborns 2–3 days after birth. Exams were executed placing the ear plugs in both ears, one ear at a time, in the nursery, NICU or NDP by a well-trained nurse during sleep or at the end of feeding. For each patient, personal identification code, birth conditions and history for SNHL were tracked in an internal database. After testing, newborns were divided into three categories: a) Babies without hearing risk factors and with a bilateral PASS response were considered to have normal hearing and were excluded from subsequent analyses; information on progressive genetic hearing loss and auditory neuropathy were given to the family; b) Babies without risk factor for SNHL and with a unilateral or bilateral “refer” response were instructed to perform a new A-TEOAE test (retest) in the pediatric department one week after discharge; in case of a PASS response, children were considered to have normal hearing, while in case of a new “refer” response, children were referred to second level screening; and c) Babies with a bilateral PASS response but with a family history for SNHL, pregnancy or auditory neuropathy risk factors were referred to second level screening.

## 2.2. Second level

A-ABR test (Accuscreen GN Resound) was used for second level screening. Evaluation was based on noise-weighted averaging and sample masking using a click stimulus of 40 dB nHL. Second level screening included children with a repeated “refer” response at first level and, according to the Joint Committee on Infant Hearing 2007 [12], babies with a family history of SNHL, pregnancy or auditory neuropathy risk factors. Pregnancy risk factors included maternal infections during pregnancy or delivery, such as Toxoplasmosis, Syphilis, HIV, Hepatitis B, Rubella, CMV, Herpes simplex. Other risk factors included admission to a neonatal intensive care unit greater than 5 days; prematurity (<37 weeks); exposure to ototoxic medications such as gentamycin and tobramycin or loop diuretics such as furosemide; hyperbilirubinemia that required transfusion; syndromes associated with hearing loss such as Pendred, Usher, Waardenburg, Neurofibromatosis; and craniofacial anomalies, including those involving the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies [12]. All babies were tested during the third month of life.

Based on the results of A-ABR, subjects were divided into: a) Babies with normal A-ABR at 40 dB nHL with the presence of a normal wave morphology and latency and no risk factors were considered to have normal hearing and were excluded from subsequent analyses; b) Babies with normal A-ABR at 40 dB nHL with a family history of SNHL, pregnancy or auditory neuropathy risk factors were suggested to monitor hearing function through TEOAE, ABR, tympanometry and acoustic reflex at regular intervals every six months for the first three years, then every twelve months for the following three years; this protocol allowed to reduce false positive cases and identify children with late or progressive hearing loss; and c) Babies with abnormal unilateral or bilateral A-ABR were referred to the diagnostic level to perform a clinical ABR. Test was performed after at least one month and in any case before six months of age to exclude incomplete neuronal development that could be responsible for the abnormal A-ABR waves.

## 2.3. Hearing loss diagnosis

Children with a “refer” response in A-ABR were further investigated using clinical ABR (Epic Plus, Labat) to confirm the presence or the absence of

hearing loss before six months of age. After cleaning skin with abrasive paste, silver plated surface electrodes were applied in conventional positions using adhesive tape (black – left or right earlobe, red – Fz, green – breastbone). A non-invasive stimulus (click) was delivered using soft ear drops; impedance less than 3 kohms was required. In accordance to actual ABR criteria, we analysed the absolute latency of waves I, III, and V, interpeak latencies (I-III, III-V, I-V), interneural difference of interpeak I-V. Electrophysiological threshold was found by decreasing the intensity of the stimulus to the lowest intensity able to generate wave V. Results were confirmed by repeating wave tracking at least twice during the same session. ABR was considered within normal range if a wave V could be found with at least two repetitions at 60 dB SPL (35 dB nHL) with normal latency and interpeak values for patient’s age. We also investigated the presence of conductive hearing loss in all patients; conductive hearing loss was diagnosed with a positive otoscopy for middle ear disorders, a type B or C tympanogram with absent acoustic reflexes, and increased values of waves I, III and V absolute latency with normal I-III, III-V and I-V interpeaks.

## 3. Results

4719/6200 (76.1%) neonates were screened during a 24-month period in SCFH and its satellite birth centres. In the first level of the screening program with A-TEOAE, 4,465 (94.6%) newborns had a PASS response, while 254 (5.4%) had a “refer” response. “Refer” cases were bilateral in 108 cases (2.3%) and unilateral in 146 (3.1%) (56 right ear and 90 left ear). When performing A-TEOAE retest after one month in children with a “refer” response, 130 (51.1%) had a PASS response and 48 (18.8%) had a “refer” response, bilateral in 27 (10.6%) cases and unilateral in 21 (8.2%) cases (7 right ear and 14 left ear). 76 babies (29.9%) dropped out from the screening protocol for unreported reasons. Surprisingly, only 30 children had a family history of risk factors for SNHL.

146 babies (3.1%) were referred to second level: 48 (32.9%) for a “refer” response at first level and 98 (67.1%) for a PASS response but potential SNHL due to risk factors. Among these, 24 (16.4%) dropped out. Out of 122 newborns tested in second level, 105 (86.1%) had a PASS A-ABR response and 17 (13.9%) were “refer” (10 in both ears and 7 in one ear, 3

right ear and 4 left ear). It should be noted that all children with risk factors ( $n=98$ , 100%) had a PASS response at A-ABR. 17 babies that failed second level screening were instructed to perform clinical ABR to identify hearing threshold. Among these, 8 children (47%) had normal hearing threshold, while in 5 cases (29.4%) threshold could not be found in one ear (3 right ear and 2 left ear) and in 2 (11.8%) in both ears. In babies with bilateral hearing loss, anamnestic investigations showed no risk factors for SNHL. 2 babies (11.8%) dropped out and parents could not be contacted after repeated attempts.

#### 4. Discussion

It is universally recognised that the most important indicator for success in a UNHS program is the number of cases of SNHL diagnosed and treated before 6 months of age [1, 2, 4, 9, 12, 15, 16]. Literature reports an estimated incidence of moderate to profound SNHL at birth between 1 to 3 per 1000 newborns [1, 2]. Congenital bilateral SNHL is associated with delayed language and learning and speech development [17, 18]; in the recent years, also unilateral SNHL has been demonstrated to have effects on learning and intellectual abilities especially thanks to functional magnetic resonance imaging studies [19–21]. Without a screening program, hearing impairment in children is not easily detectable at an early stage and could therefore result in a delayed diagnosis. Instead, the early use of available therapies, such as speech and language therapy in association with an adequate amplification, could reduce the gap in language skills between deaf and normal-hearing children [22, 23].

The main well-known problem of UNHS is the heterogeneity of criteria for referring to further investigation during the screening phases and in identifying high-risk neonates, and optimal protocols and tests [24]. To date, several protocols have been proposed: A-TEOAE + retest A-TEOAE followed by ABR [25], A-TEOAE + retest A-TEOAE + second retest A-TEOAE followed by ABR [26], A-TEOAE + retest A-TEOAE + second retest A-TEOAE followed by A-ABR [27], A-TEOAE followed by ABR [28] or A-TEOAE + retest A-TEOAE followed by A-ABR [29–31]. A-TEOAE is the most appropriate technique for first level screening thanks to its accuracy, costs and execution modalities [32] as demonstrated in over 100,000 screening tests [13]. Moreover, using A-ABR in the first level may

be impractical in nurseries due to the high number of false positive cases [33], and should be used as a second level technique in infants who fail A-TEOAE or in those with recognized risk factors [34].

The importance of A-TEOAE retest in first level screening has been already demonstrated in several studies [30, 32] and confirmed in the present one: among our screened children, 254 had a “refer” response at first level A-TEOAE, then reduced to 48 with retest. A-ABR investigation in the second level is certainly necessary to better investigate hearing loss in patients with a “refer” response to A-TEOAE, but is also useful to identify an auditory neuropathy in children with audiological risk factors [16, 17, 34]. Also, it is important to remark that, in our protocol, A-TEOAE test was performed in the pediatric department, and to all “refer” babies before addressing them to second level screening. This allowed to drastically reduce the number of false positives and, therefore, the workload for personnel in the audiology and otolaryngology departments.

The coverage rate of UNHS is near 100% in occidental countries, with percentages of 98–99% in the United States, France and UK [30, 35–37]. In our study, the coverage rate was 76.1%. The 23.9% unscreened children could be attributed to the logistics and coordination issues typical of the initial phase of a screening program involving multiple birth centres. In fact, only 2.6% of the newborns included in the study were referred by satellite birth centres; furthermore, the coverage rate decreased consistently during the second year of the screening program: children not included in our screening protocol were 1,162 (78.5%) during the first year and only 319 (21.5%) in the second year. In Italy, UNHS coverage has undergone a steep increase during years from 29.3% in 2003 (156,048 newborns screened) to 48.4% in 2006 (262,103 screened) [38]. Recent data for UNHS in Italy showed a high coverage in the north-west (79.5%, 108,200 of 136,109 births) and north-east area (57.2%, 52,727 of 92,133 births), while some areas such as the main islands (Sicily, Sardinia) still have a limited diffusion of hearing screening programs (11.3%, 7,158 of 63,460 births) [38]. Fortunately, UNHS in Italy will soon reach a coverage near 95–98% thanks to the recent introduction of the program in the National Health System as of late 2016.

The two main problems that we encountered during the first two years of the UNHS program in our hospital were missed identification of children with

auditory neuropathy at first level and, especially, the issue of drop-out babies.

In children with auditory neuropathy, the integrity of outer hair cells results in a PASS response at A-TEOAE and therefore SNHL may remain undiagnosed during first level screening procedures. To reduce the risk of undiagnosed auditory neuropathy, we always recommend families of children who pass the first level of screening to perform a new audiological examination if they notice abnormalities about the hearing of the child.

The alarming percentage of newborns who fail the initial testing and are lost at follow-up is a common contemporary issue [39], especially in countries where UNHS is not mandatory [40]. In our study, we reported a total of 102 (40.2%) drop-out babies out of 254 that initially failed first level screening: 76 (29.9%) during first level retest, 24 (16.4%) during second level and 2 (11.8%) at diagnostic level. To decrease percentage of drop-outs, we introduced a targeted training to the personnel involved in screening procedures and provided appropriate education about UNHS and the risk factors of undiagnosed hearing loss to pediatricians, neonatologists and gynaecologists. The elevated number of drop-out patients highlights the importance of a serious cooperation between audiological centres, maternity units and families. A correct training of family pediatricians is also crucial for a correct follow-up for children with potential progressive SNHL.

The incidence of SNHL at birth in this study was 1.48/1,000 newborns; however, the relevant number of drop-out patients at different stages of the screening program ( $n=102$ ) and the low incidence of bilateral (0.08%) and unilateral (0.1%) SNHL compared to other studies in the literature could be suggestive of a higher percentage.

## 5. Conclusion

Bilateral hearing is essential for correct development of speech and social skills. In the presence of hearing loss, even if unilateral, children can show impaired language development, social problems and academic difficulties.

We report and discuss the preliminary results of the UNHS program in our hospital. During the first two years of the program, we screened 4719/6200 (76.1%) neonates and identified 7 babies (0.14%) with profound SNHL, with an incidence of SNHL at birth of 1.48/1,000 newborns. The two main issues

we encountered were in common with other UNHS programs and included difficulties in identifying children with auditory neuropathy and, especially, the worrying phenomenon of drop-out babies. In our study, 102 (40.2%) out of 254 patients that failed first or second level screening dropped out; more importantly, 2/17 babies (11.7%) that failed second level screening and were instructed to perform clinical ABR for probable hearing loss dropped out and parents could not be contacted after repeated attempts.

The implementation of a UNHS program in our hospital has required consistent organizational efforts and the education and employment of dedicated personnel, in addition to the involvement of family pediatricians to identify children with progressive or late-onset SNHL. A correct and early diagnosis of hearing loss is mandatory to prevent permanent consequences, and the spread of UNHS programs is the optimal solution to reach this goal.

## Conflicts of interest

None.

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