# NEONATAL HEARING SCREENING WITH TRANSIENT EVOKED OTOACOUSTIC EMISSIONS USING NARROW BAND STIMULUS

## *Triagem auditiva neonatal com emissão otoacústica transiente utilizando estímulo de banda estreita*

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**ABSTRACT**

**Purpose:** to assess the sensitivity and specificity of an automated Transient Evoked Otoacoustic Emissions equipment using narrow band stimulus. **Methods:** the hearing screening results of 300 newborns were analyzed. A portable automated equipment was used with narrow band stimulus to conduct the Transient Evoked Otoacoustic Emissions. All newborns were also submitted to the Brainstem Auditory Evoked Potentials using 100μs-duration click stimuli, which was considered the gold standard test. **Results:** the proportion of "pass" results in the neonatal hearing screening was 90.7%. Considering the gold standard results, it was observed a false-positive rate of 9%. The Transient Evoked Otoacoustic Emissions with narrow band stimulus presented sensitivity of 100% and specificity of 92%. **Conclusion:** the *narrow* band stimulus was efficient enough to be used in neonatal hearing screening programs.

**KEYWORDS:** Infant, Newborn; Hearing Tests; Otoacoustic Emissions, Spontaneous; Evoked Potentials, Auditory; Hearing Loss

## INTRODUCTION

Efforts are being made in order to establish a National Policy on attention to auditory health, considering that the impact caused by sensory deprivation during child development has turned hearing impairment a public health problem [1]. In consequence to the implementation of programs aiming towards early detection of hearing loss [2-4], optimization of the procedures used to ensure the efficiency of the developed programs and universal access to Neonatal Hearing Screening (NHS) have been sought[5]. In this context, the time of test conduction, its sensitivity (efficacy) and specificity (efficiency) determined by the employed techniques are extremely important [6].

Literature has shown that the Transient Evoked Otoacoustic emissions Test (TEOAE) is the procedure deemed adequate for NHS, as it is a low-cost procedure that uses a weak intensity acoustic stimulus covering a wide frequency range, and also for being a quick and simple procedure [7-9].

However, one of the main difficulties in registering the TEOAE during NHS is typically the effect of noise [8], is it is not always possible to conduct NHS in acoustically treated rooms. Thus, the screening generally requires the newborn to be calm during the test and in adequate conditions examination tends to be quicker, detecting a robust emission sign level [10].

Therefore, different states of activity may affect the TEOAE, such as, for example, sneezes, mandible and muscular movements. Both the physiological processes as well as the state of activity may result

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in weak response level of the TEOAE, where the physiological noises are reported as impacting the range between 500-1500 Hz [11]. Thus, the authors agree that robust responses are common in medium and high frequency bands, though usually with lower general reproducibility, due to the influence of noise in the low frequencies [8,12].

Since then, equipment manufacturers have tried to maintain undesired responses at a low level, by using filters[13]. The high-pass and low-pass filters are electronic and allow the analysis of a single specific signal frequency band, thus increasing the signal-to-noise ratio in TEOAE registration[14]. The high-pass filter allows only signals with frequencies above the established values to be analyzed; reducing the contribution of low frequencies on the TEOAE trace, and the low-pass filter does the same enabling the analysis of frequencies below the established value[15].

In the year of 1994, authors have described and implemented the use of a parameter that uses the narrow-band filter, named *Narrow*. The research studied the sensitivity and the specificity in 162 ears and the results showed that 100% of newborns passed in the TEOAE with the *Narrow* parameter, and that the sensitivity and specificity of screening with the narrow-band criteria were 100% and 98.1%, respectively. The group classified as noisy had a higher mean for the variable test time and the authors concluded that the low frequencies are filtered before affecting the signal-to-noise ratio result [13].

In 1999, researchers in Milan, aiming to reduce the initial artifact associated to the TEOAE test, studied the efficacy of the effect of the "high-pass" and "low-pass" band filters, using the results from test signal and reproducibility, calculated for the general response as well as for each frequency band. The TEOAE were tested bilaterally in 629 newborns, and the cut-off frequency occurred outside the 1.6-4.2 kHz interval. The results using the band filter were compared to the TEOAE test that did not use the filter. Results showed that 46.0% of newborns "passed" the TEOAE before using the "high-pass" and "low-pass" filters, increasing the "pass" results percentage to 47.4% after using the filter. The study also concluded that the reproducibility with the "high-pass" and "low-pass" filter was always greater than when the test was conducted without the filter[16]. Another study has also observed that the reproducibility and the signal-to-noise ratio may be improved when "high-pass" and "low-pass" filters are used when registering TEOAE[17] and that they are both especially useful to reduce the interference cause by noise below 1.0 kHz [18].

Different pass/fail parameters and criteria may be used in automatic equipment that may change the sensitivity and specificity of the test used in a population of newborns. However, safe criteria should be chosen in order to ensure that false-positives and false-negatives do not occur in excessive or allowed numbers, maintaining this test's reliability. Thus, Thus, the purpose of the present study is to assess the sensitivity and specificity of a TEOAE automatic equipment that uses a narrow-band stimulus (*narrow)* with a "high-pass" and "low-pass" filter.

## METHODS

The Newborn Hearing Screening was conducted at the Amparo Maternal Hospital, located in the city of São Paulo. The facility has a partnership with the Pontifical Catholic University of São Paulo (PUCSP) for the conduction of scientific investigations.

The study was approved by the Research Ethics Committee of the Pontifical Catholic University of São Paulo - PUC-SP, protocol number 063/2010, and was funded by the Coordination for Improvement of Higher Level Personnel (CAPES). In compliance with the bioethics determinations of the Research Ethics Committee at PUCSP, only the newborns whose parents signed the Free and Informed Consent Term were included in the study.

The newborns included in the study were required to be over 24 hours old and over 37 weeks gestational age. Those with congenital syndromes or neurological disorders evidenced in the records were not included.

The subjects of this study were 300 newborns (600 ears), evaluated in the period between November 2010 and November 2011, of which 154 (51.3%) were males and 146 (48.7%) were females. Only 42 (14%) newborns had Risk Indicators for Hearing Loss (RIHL).

Literature shows that the "fail" index in the TEOAE may be attributed to several factors, such as: probe adjustment and monitoring, facilitating maneuver and newborn state of consciousness. In order to reduce false-positives, these factores were controlled during data collection. For test administration, all newborns were placed in the cribs provided by the hospital, laying on their sides, or in their mothers' arms.

TEOAE research was conducted using a portable *Otoport Lite* automatic equipment by *Otodynamics.* The stimulus was a non-linear click, lasting 80 microseconds and intensity of 84dB peSPL. 260 stimuli were used for response collection, and the maximum test time was 300 seconds.

The TEOAE automatic device conducts tests with different screening parameters that are already part of the device's standard protocol and may be chosen and adjusted by the evaluator. In this study, the inserted standard was the one named narrow band, or *Narrow* parameter, with the purpose of reducing noise, and conducts an algorithmic and vector analysis in a frequency range between 841 Hz - 4757 Hz, using a filter between the frequencies of 1600 Hz - 3200 Hz. The response is automatically provided by the device through the signals "*Pass*" (pass) or "*Refer*" (fail).

Then, all newborns underwent the Brainstem Evoked Auditory Potential (BEAP) using an *Eclipse Black Box - software* EP25 equipment by *Interacoustics MedPC*. The parameters were: 100μs click stimulus; Repetition Rate in 27.7Hz; Alternate Polarity; Filter 100-3000Hz and a 25ms Window. This test was considered to gold-standard to ensure and verify the sensitivity and specificity of the responses obtained in the TEOAE.

For this study, the Minimum Response Level (MRL) considered normal was 20 dBnHL. The BEAP was initially tested in 40 dBnHL intensity and, then in 20 dBnHL intensity. When the presence of wave V in 20 dBnHL was not observed, the electrophysiological threshold was tested, beginning in 80 dBnHL for assessment of auditory integrity. Then, intensity was decreased in 20dB steps until wave V could no longer be observed, and then increased in 10 dBnHL steps, until this wave could be registered and reproduced once again.

The electrophysiological threshold was considered the lowest intensity in which wave V could be observed and reproduced, and wave V was considered as the greatest negative deflection occurring between 5 and 20 milliseconds after stimulus presentation.

It should be noted that the EP25 software has a detection method that considers residual noise (40 nV) and wave reproducibility (50%) as criteria te determine presence or absence of response. Therefore, when the register reached these levels, the software would automatically stop response registration after a minimum of, at least, 800 presented stimuli. However, in the absence of response, the researcher was able to withdraw this criterion, allowing the answer to be evoked with up to 2000 presented stimuli.

In the cases where absence of wave V in 20 dBnNA, in air conduction, the mothers were referred to a complete audiological investigation in a Child Hearing Center, in an interval of approximately 30 days.

During the research at the hospital, four result combinations could occur (Table 1):

**Table 1 – Result possibilities in the newborn hearing screening with *Transient Evoked Otoacoustic Emissions* and gold-standard using *Brainstem Evoked Auditory Potential***

| NHS TEOAE | Gold-Standard (BEAP) | Result |
|---|---|---|
| *Pass* the TEOAE | Presence of response | True- Negative |
| Pass the TEOAE | Absence of response | False-negative |
| *Fail* the TEOAE | Presence of response | False-positive |
| *Fail* the TEOAE | Aubsence of response | True-Positive |

Key: TEOAE Transient Evoked Otoacousitc Emissions; BEAP Brainstem Evoked Auditory Potential.

Statistical measurements were conducted and these reflect the validity of the "pass-fail" criteria of the TEOAE through narrow-band – *Narrow* considering BEAP as the gold-standard. The following aspects were analyzed: sensitivity, specificity, positive predictive value, negative predictive value, accuracy, likelihood ratio and Youden index, corresponding to the *Narrow* "pass-fail" criteria (Altman, 1999). The statistical analysis was made using the Minitab 16 e SPSS 18 applications.

## RESULTS

Table 2 shows the percentages of TEOAE results for the "pass-fail" criteria for narrow-band (*Narrow),* where it may be seen that the "pass" percentage was 90.7%.

When analyzing the BEAP, gold-standard, it was observed that five (0.8%) ears had absent responses and 595 (99.2%) present responses.

**Table 2 – Distribution of results of the *Transient Evoked Otoacoustic Emission* for the "pass-fail" criterion considering the 600 tested ears**

| Criterion | "Fail" | | "Pass" | |
|---|---|---|---|---|
| | n | % | n | % |
| **Narrow** | 56 | 9.3 | 554 | 90.7 |

Key: N – Sample number

The distributions of joint and marginal frequencies of the BEAP diagnosis and in the TEOAE for the "pass-fail" criteria investigated in this study are found in Table 3.

It may be seen that, in the *Narrow* "pass-fail" criteria, the five ears with absent responses in the BEAP were classified as "fail". Thus, there were no false-negatives. The number of newborns with absent responses in the TEOAE and present responses in BEAP was zero.

Table 4 shows the results regarding time of examination.

**Table 3 – Distribution of the results in the *Brainstem Evoked Auditory Potential* (present and absent) and in the *Transient Evoked Otoacoustic Emission* (pass and fail)**

| TEOAE Narrow | BEAP | | Total |
|---|---|---|---|
| | Absent | Present | |
| **Failed** | **5** | 51 | 56 |
| **Passed** | 0 | 544 | 544 |
| **Total** | **5** | 595 | 600 |

Key: TEOAE Transient Evoked Otoacousitc Emissions; BEAP Brainstem Evoked Auditory Potential.

**Table 4 – Descriptive Statistics Values observed for examination time, in seconds**

| Examination Time | N | Mean | Standard Deviation | Minimum | Median | Maximum |
|---|---|---|---|---|---|---|
| *Narrow* | 600 | 17.5 | 19.4 | 6 | 8 | 107 |

Key: N – Sample number

The false-positive proportion estimate shows that, of the 595 with present responses in the BEAP, 51 were classified as "fail" by the *Narrow* "pass-fail" criteria. Thus, the false-positive proportion was 0.09.

Sensitivity, considering the gold-standard, was 100% and specificity was 92% with a confidence interval (95%) of [0.89; 0.94]. The positive predictive value was calculated and a 0.09 value was obtained with a confidence interval (95%) of [0.03; 0.20] showing that the pass response accurately indicates a present response. Since there was a low prevalence of deaf subjects in the sample, the negative predictive value is not reliable and was therefore excluded from the study.

Even though predictive values are useful in practice, they depend on the prevalence of the interesting result (*fail*). In this case, the prevalence of "fail" was low, and therefore there is a strong indication that the "pass" result in the TEOAE accurately indicates present response, and little indication that a "fail" result will really indicate a patient with an absent response.

The value of "pass-fail" accuracy of the TEOAE for the Narrow criteria is 92% in a confidence interval [0.89; 0.94] and the observed value of the likelihood ration (LR) was 11.7 in the *Narrow* "pass-fail" criteria.

The Youden index was used and showed that the sensitivity of the Narrow "pass-fail" criteria was equal to 1, which coincided with its specificity.

## DISCUSSION

Different parameters may be applied to the software of newborn screening automatic equipment, and among these are those using broad band and narrow band (*Narrow)* stimuli[14,15]. However, differences among the parameters may lead to an increase in the number of false-positives and false-negatives, decreasing the quality of the program [19] .

The present study has analyzed the application of an automatic TEOAE equipment using a narrow band stimulus – *Narrow,* highlighting aspects related to sensitivity, specificity and examination time, extremely important features in a NHS program.

Newborn hearing screening was conducted in 300 newborns (600 ears) using TEOAE. The results show that 90.7% of the ears "passed" hearing screening with narrow band stimulus "*Narrow*". Studies using the broad band stimulus have reported worse results, 66.7%[20], 86.1% [21] and 64% [22], considering the first moment of screening. It is thus observed that when the broad band stimulus is used, the amount of "fail" results is higher and considering that there were no cases of false-negatives for the "Narrow" stimulus in the present study, the results show that using this stimulus may result in better efficiency of the screening program with a reduction of new appointments for retesting.

In this context, considering the results for the gold-standard, the present study had a false-positive rate of 9%. However, a study mentioned above[22] that used the broad band stimulus estimated a 36% rate of false-positives in NHS using TEOAE. Another study, conducted in England, that also used the broad band stimulus, observed a rate of 11.2% of false-positives [23]. A reference from 2005 has also sown a greater percentage (12.2%) than found in the present study using narrow band[24].

The differences found between the studies mentioned above may be related to the fact that the narrow band stimulus – Narrow restricts (with the use of high-pass and low-pass filters) the assessment of lower frequencies, mainly emphasizing frequency regions between 1600Hz-3200Hz [13]. Previous studies reinforce that satisfactory signal-to-noise relationships in frequency bands of 1.0kHz and 1.5kHz, as part of the "pass-fail" criteria in a NHS program with TEOAE would not be necessary [5,10]. However, several factors beyond the type of stimulus may be related to the differences found among the several studies, including hours of life and the newborn's state of consciousness during screening, using or not using a facilitation maneuver and environmental noise. In the present study, these factors were controlled and the newborn was over 24 hours old and was naturally sleeping during screening, similarly to the 2009 study[22] , differing only by the fact that, in the latter, the TEOAE equipment was not portable or automatic. In the 2003 study[20] screening was conducted by a researcher with no formal training in hearing screenings, which may also have influenced test results; moreover, the mean age during screening was 20 hours, while in the present study all newborns were over 24 hours old, and, therefore, the presence of vernix in the ear may have influenced the results.

Furthermore, the present study was concerned with controlling procedures that may influence the "pass-fail" results in NHS testing, such as probe adjustment, using a "facilitation maneuver", probe monitoring and stability [22,25,26]. Hours of life (≥24 hours), the newborn's state of consciousness and noise were also controlled[12,27,28].

It should be noted that the implications caused by the false-positive rate imply in the increase in program cost due to unnecessary referral for audiological diagnosis, as well as in emotional stress of parents and/or caregivers [29].

The quality of NHS programs may be measured based on the efficacy and efficiency of the procedure employed [30]. In both hearing and hearing impaired individuals, screening procedures may provide true or false outcomes, confirmed by a reference test, considered a gold-standard. The main purpose of NHS programs is using a screening test with precise "pass-fail" criteria.

A program is considered effective when it uses a test where the sensitivity is equal or close to 100%[30]. When analyzing this study's results it has been observed that the *Narrow* criterion had 100% sensitivity. This means that no hearing impairment went undetected; that is, the three (100%) individuals (5 ears) with hearing loss were accurately identified. Researcheres, seeking to validate the *Narrow* parameter have also found 100% sensitivity and 92% specificity in NHS using TEOAE[13].

In addition to high sensitivity and specificity, examination time is an important aspect to be considered, since NHS should be universal [9,31]. The present study showed that the mean time for conduction of the TEOAE, using the narrow band parameter – *Narrow* was 17.5 seconds. A 1994 study compared narrow and broad band parameters and concluded that the mean test time for the *Narrow* "pass-fail" criterion was smaller. The time since probe adjustment and result appearance was timed and recorded. The authors state that the time for

broad band is 70% longer than that for the *Narrow* - narrow band parameter. Test time for the broad band parameter criterion was 155 seconds and for the Narrow parameter for narrow band criterion test time was 92 seconds. The authors concluded that test time in the "frequency band criterion" is probably longer due to noise in low frequencies. In the *Narrow* parameter for narrow band stimulus, low frequencies are filtered before they can affect the signal-to-noise ratio results[13].

However, the time found in this study (17.5 seconds) was also shorter when compared to the 60 to 80 seconds reported by a study conducted in 2002, that also assessed time after probe placement, in 52 newborns without risk factors for hearing impairment, aged up to 48 hours[32].

The high-pass and low-pass filters are tools that are commonly used by screening equipment to decrease examination time, since they increase the signal-to-noise ratio and response reproducibility in TEOAE [16]. Test time using a broad band stimulus is probably longer due to the noise of low frequency bands, since, for the narrow band stimulus – *Narrow* these frequencies are filtered before they affect the signal-to-noise ratio result[13].

Techniques such as decreasing the time window should be used in automatic TEOAE equipment in order to favor the response level recording quality of the TEOAE [10,13]. Thus, this study's results that showed a considerably short examination time with high sensitivity (100%) and specificity (92%) indicate this criterion's efficacy, making UNHS easier in noisy environments.

New technologies that seek to maximize results and guarantee effectiveness of the procedures in UNHS are being developed. However, there are still few studies regarding the efficiency and efficacy of the narrow band stimulus in NHS procedures using TEOAE, showing the need for new investigations concerning these aspects.

## CONCLUSION

The "pass-fail" criterion using the narrow band stimulus offered acceptable indexes of sensitivity and specificity, proving efficient for use in UNHS programs.

**RESUMO**

**Objetivo:** avaliar a sensibilidade e a especificidade de um equipamento automático de Emissão Otoacustica Evocada Transiente que utiliza um estímulo de banda estreita, *Narrow*. **Métodos:** foi analisado o resultado da Triagem Auditiva Neonatal de 300 neonatos. A Emissão Otoacústica Evocada Transiente foi realizada com um equipamento portátil automático, com o estímulo de banda estreita - *Narrow*. Todos os neonatos foram submetidos ao Potencial Evocado Auditivo de Tronco Encefálico com o estímulo clique, duração 100μs como padrão-ouro. **Resultados:** o percentual de "passa" na Triagem Auditiva Neonatal foi de 90,7%. Considerando os resultados do padrão-ouro, foi observado uma taxa de falso-positivo de 9%. A sensibilidade e especificidade encontradas foram de 100% e 92%, respectivamente. **Conclusão**: o estímulo de banda estreita - *Narrow* mostrou-se eficaz para ser utilizado nos programa de Triagem Auditiva Neonatal Universal.

**DESCRITORES:** Recém-Nascido; Testes Auditivos; Emissões Otoacústicas Espontâneas; Potenciais Evocados Auditivos; Perda Auditiva

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