EMISSIONS (TEOE): NEWBORN HEARING SCREENING PROGRAM PROTOCOLS

Emissões otoacústicas evocadas por estímulo transiente: protocolos de triagem auditiva neonatal

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ABSTRACT

Purpose: to describe the results of three TEOE protocols obtained from automatic equipment used in a Newborn Hearing Screening Program. **Method**: during two months, TEOEs of 287 neonates in São Paulo were studied. To register them, we used a three-protocol, set up with different pass/fail criteria. The following protocols were registered: Protocol A: to pass in four frequency bands, not necessarily consecutive-; Protocol B: to pass in three frequency bands, not necessarily consecutive – and Protocol C: to pass in two frequency bands, not necessarily consecutive, as well. The parameters that we used to consider these answers were: reproducibility above 50%, as well as signal/noise ratio > 3dB at 1.0 and 1.5 kHz and > 6dB at 2.0, 3.0 and 4.0 kHz. **Results**: TEOEs of 574 ears were analyzed and the 2.0, 3.0 and 4.0 frequencies showed the highest pass percentages (94.1, 95.8 and 92.7% for protocols A, B and C respectively). Protocol C showed the highest pass percentage, achieving 96,9%. Nevertheless, the results obtained in Protocol B, which had the presence of three bands, showed a similar percentage to Protocol C (96,2%). Therefore, there was a not statistically significant difference between Protocols B and C. 1.0 kHz frequency achieved a percentage of only 9.9 in the tested ears. **Conclusions**: one has to research Protocols A, B and C with gold standard in order to verify which one suits best in terms of sensibility and specificity, even though the three protocols studied showed similar results in pass criteria for two or three frequency bands.

KEYWORDS: Hearing; Hearing Loss; Neonatal Screening; Infant, Newborn

INTRODUCTION

The diagnosis of hearing loss in the first six months of life is a key factor to minimize the irreversible effects that sensory deprivation can result in the global development[1-3]. In this critical period of neurological maturation, there is the beginning of auditory development which occurs when a readiness for the basic perceptual abilities and language can be acquired[4-6].

The prevalence of severe or profound sensor neural hearing loss ranges from four to six per 1000 life births[7], or one to three in 1000, according to the Brazilian Committee on Hearing losses[8,9]. These findings show that in certain populations, this percentage increases dramatically, as is the case of children who remain in Neonatal Intensive Care Units (ICU-N), whose prevalence is 10.2%[10,11].

Currently, the implementation of Universal Neonatal Hearing Screening Programs (*"Programas de Triagem Auditiva Neonatal Universal"* – PTANU) is increasingly common in all countries[3]. In Brazil, on August 2, 2010, it was decreed and signed into Law No. 12.1303, which mandates the realization of evoked otoacoustic emissions in neonates, in all hospitals.

Because of this demand, programs and multidisciplinary committees have been developed in order to discuss and recommend actions regarding

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hearing health of newborns and infants, like the Joint Committee of Infant Hearing (JCIH) in the USA, and the COMUSA in Brazil[12-14].

The implementation of TANU aims to identify hearing disorders that can compromise the proper development of communicative skills of every child at birth or, at most, up to three months old. In case of confirmation of hearing impairment, it must be held early intervention until the baby's six months of age, as recommended by the JCIH[13]. Thus, the implementation of the TANU program makes sense only when the diagnosis is performed to characterize the hearing *status*, followed by appropriate intervention to enhance the development of auditory and communication skills along development[12].

Authors suggest that the realization of the Newborn Hearing Screening using electroacoustic and electrophysiological measures, such as otoacoustic emissions evoked by transient stimulus (*Emissões Otoacústicas Evocadas por Estímulo Transiente* – EOAET) and Auditory Evoked Potential of the Automatic Auditory Brain Stem (*Potencial Evocado Auditivo de Tronco Encefálico Auditivo Automático* – PEATE-A), as this population is unable to respond appropriately to behavioral tests due to age[15-20]. These two techniques have been widely applied as effective tools in the Universal Newborn Hearing Screening (*Triagem Auditiva Neonatal Universal* – TANU), both in developed and in developing countries

EOAET screenings became major instruments for detecting hearing loss of cochlear origin, as they allow the study of the mechanical aspects of cochlear function in a non-invasive, objective, and independent of the potential of the nerve action[21], enable the obtaining of objective information, clinically, on the pre-neural elements of the cochlea.

This method does not quantify the hearing, but detects its presence[21] due to EOAET be present in all individuals whose thresholds are better than 20 and 30dBnNA. Thus, the presence of this phenomenon can confirm cochlear integrity, and may establish the functionality of otoacoustic activity of outer hair cells (OHC) in the cochlea. Because of these features, in addition to greater speed and reliability, this test has the ideal profile for the PTAN[22.23].

The National Institutes of Health (NIH) conducted a survey in order to determine the characteristics and performance of the three exams that assess peripheral auditory system: EOAET, EOAE-PD and PEATE. In this study, 7,179 newborns were tested for the presence of five frequency bands (1.0, 1.5, 2.0, 3.0 and 4.0kHz). Based on these results, we recommended analysis parameters that ensure more reliability to the test. It turned out that EOAET are affected depending on the frequency, because noise levels are higher when tested frequencies are lower, making it more difficult to individuate the presence of otoacoustic emissions with spectrum below 1.5 kHz[24].

Different parameters and criteria for passing/failing are used in automatic equipment, which can modify the sensitivity and specificity of the test applied to a population of neonates and infants. However it is necessary to choose safe criteria for false-positive and false-negative results which do not occur in excessive numbers or allowed ones, thus, maintaining the reliability of this test. In this perspective, the objective of this study was to describe the results of three EOAET protocols, analyzing five EOAET frequency bands from automatic equipment used in the Neonatal Hearing Screening Program.

METHOD

We studied the EOAET results of 287 neonates from a public hospital in the city of São Paulo, from April to June 2010.

The trials were conducted by students of the Program of Postgraduate Studies in Phonoaudiology from PUC-SP (master and doctorate), and phonoaudiologists working as voluntaries. The team was divided into scales during the week to ensure the daily duty call, except Sundays, the day that the TAN is not performed.

Preferably, the trials were held near the hospital, within 48 hours of life, in a quiet room or on the bed with the baby in natural sleep. TAN was not performed in newborns with less than 24 hours of life[25].

The Newborn Hearing Screening Programme (*Programa de Triagem Auditiva Neonatal* – PTAN) used as research protocol on as otoacoustic emissions evoked by transient stimulus (TEOAE) in neonates without Risk Indicators of Hearing Loss (*Indicadores de Risco para Deficiência Auditiva* – IRDA), and Auditory Evoked Potential of the Automatic Auditory Brain Stem (Potencial Evocado Auditivo de Tronco Encefálico Automático – PEATE-A) to identify hearing impairment in neonates with IRDA.

To achieve the objective of the present study it was only analyzed the passing and failing results of the TEOAE. For the record of the TEOAE it was used the Otoport Lite equipment from the Otodynamics company, using nonlinear click stimulus, which occurs predominantly in the frequency range from 1.000 to 4.000 Hz, with an intensity of 64 dB pe SPL. The criterion of analysis of emissions was signal/noise ratio of 6dB SNR in 4 out of 5 tested frequency bands. We used 260 sweeps of 16 stimuli, the maximum test time was 300 seconds, and the frequency bands of device registers were: 1.0 1.5, 2.0, 3.0 and 4.0 kHz. The parameters used to consider the presence of answers were: reproducibility above 50%, as well as signal to noise ratio> 1.0 and that 3dB at 1.5 kHz and> 6 dB in 2.0, 3.0 and 4.0kHz.

It was researched three different protocols to enable analysis of criteria for distinct passing/failing. In addition to this possibility, it was possible to visualize the end result of passing/failing for each of the five tested frequency bands.

Protocol A: Passing-Failing in four frequency bands;

Protocol B: Passing-Failing in three frequency bands;

Protocol C: Passing-Failing in two frequency bands.

The study was approved by the Ethics Committee from the Pontifical Catholic University of São Paulo – PUC / SP, Research Protocol No. 063/2010.

The results were organized in an Excel document, to perform the quantitative statistical analysis through the Equal Proportions test to compare results, besides the P-value.

RESULTS

The results for each frequency and for the frequency bands in each ear were analyzed by the test of equality of two proportions (Table 1 and Table 2). Only on analysis of four bands it was found a small significant difference in the distribution of both ears. However, in all other results, ears behaved in the same way.

Table 1 – Distribution of ears for each frequency

Frequency		Right Ear		Left Ear		p-value
		N	%	N	%	
1kHz	Passing	24	8,4%	33	11,5%	0,209
	Failing	263	91,6%	254	88,5%	
1,5kHz	Passing	223	77,7%	229	79,8%	0,540
	Failing	64	22,3%	58	20,2%	
2kHz	Passing	265	92,3%	275	95,8%	**0,077**
	Failing	22	7,7%	12	4,2%	
3kHz	Passing	272	**94,8%**	**278**	**96,9%**	0,211
	Failing	15	5,2%	9	3,1%	
4kHz	Passing	262	91,3%	270	94,1%	0,200
	Failing	25	8,7%	17	5,9%	

Table 2 – Distribution of ears for each frequency band

Band		Right Ear		Left Ear		p-value
		N	%	N	%	
4 Bands	Passing	218	76,0%	240	83,6%	**0,022**
	Failing	69	24,0%	47	16,4%	
3 Bands	Passing	272	94,8%	280	97,6%	**0,082**
	Failing	15	5,2%	7	2,4%	
2 Bands	Passing	275	**95,8%**	**281**	**97,9%**	0,151
	Failing	12	4,2%	6	2,1%	

Having in mind that the results of the right and left ears did not obtain statistically significant differences, the sample size was doubled and so 574 ears were analyzed in order to make the study even more reliable.

When comparing the 5 frequencies for passing and failing responses, the equality test of two proportions was also used (Table 3 and Table 4). In Table 3, it is possible to observe the proportional distribution among all levels of response. In Table 4, however, are the p-values. Thus, it was found that the frequency with higher percentage of passing was 3 kHz with 95.8% and so the lowest failure rate was of only 4.2%. However, in the p-value analysis (Table 4) it can be noted that this frequency cannot be considered statistically different from the 2 kHz frequency, with 94.1% of passing and 5.9% of failing.

Table 3 – Distribution of frequencies

Frequency	Passing		Failing	
	N	%	N	%
1kHz	57	9,9%	517	90,1%
1,5kHz	452	78,7%	122	21,3%
2kHz	540	94,1%	34	5,9%
3kHz	550	95,8%	24	4,2%
4kHz	532	92,7%	42	7,3%

Table 4 – P-values from table 3

	1 kHz	1,5 kHz	2 kHz	3 kHz
1,5 kHz	**<0,001**			
2kHz	**<0,001**	**<0,001**		
3kHz	**<0,001**	**<0,001**	0,178	
4kHz	**<0,001**	**<0,001**	0,342	**0,022**

When comparing the three protocols by which we analyzed the frequency bands for the passing/failing responses (Table 5), we found that the band with the highest percentage of passing was the one that considered two frequency bands, Protocol C, with 96.9%. However, statistically, this percentage is not considered different from the analysis of 96.2% of 3 bands Protocol B (p = 0.520) (Table 6). Therefore, both frequency bands are considered equal in the distribution of passing/failing. However Protocol A (4 bands) obtained 79.8% of the percentage of passing, with a high failure rate (22.2%) when compared to protocols B (3.8%) and C (3.1%.)

Table 5 – Distribution of bands

Frequency Bands	Passing		Failing	
	N	%	N	%
4 Bands	458	79,8%	116	20,2%
3 Bands	552	96,2%	22	3,8%
2 Bands	556	96,9%	18	3,1%

Table 6 – P-values from table 5

	4 Bands	3 Bands
3 Bands	**<0,001**	
2 Bands	**<0,001**	0,520

DISCUSSION

Because there was no significant difference in the statistical analysis of TEOAE to the right and left ear (Table 1 and Table 2), this study's discussion emphasizes, only the results in which both ears were simultaneously analyzed.

Thus, more robust response measures of TEOAE (defined by the signal to noise ratio – SNR) were observed for the frequencies of 3, 2 and 4 kHz, as shown in Tables 3 and 4. These results corroborate the study which found higher levels of emissions for the same found frequencies[26].

Furthermore, it was found that the frequency with lower passing percentage was 1 kHz with 9.9%, which consequently had the highest percentage of failings with 90.1%. The high failure rate in otoacoustic emissions (OAE) is attributed to many factors such as noisy environments and physiological noise that can interfere with the recording of TEOAE, especially in the lower frequency bands[26]. False-positive TAN also has been linked mainly to the effects of internal and external noise[26]. The internal noise is created by the own subject (coughing, swallowing, snoring, breathing), as to the external sources it may include environmental noise and other electromagnetic interference[27].

Taking into account that the maximum test time from the automatic device to record TEOE, in NASP of this study, is 300 seconds, to get results in lower frequencies it would be needed to dedicate a larger test time. Given the poor SNR and the increased time spent in the measure, the efforts to get useful information for 1.0 kHz and 1.5 kHz, as part of a TANU program is not necessary. However, the environmental noise may still contaminate the recording of TEOAE responses and cause false results, especially when continuous or reverberating sounds are present. Thus, the noise problem at low frequencies is not completely solved with the use of control filters[27].

As the OAE signal has reduced amplitude, which usually is found between –20 and 20dBNPS the environmental noise is usually the most important cause of problems in the evaluation of EOA[28]. Because of environmental noise, it is difficult to determine whether the EOA is absent for the non-functioning of the active processes of the cochlea or the noise level is just high[23]. Researchers do not recommend including as a routine the measurements at the frequencies of 1.0 kHz and 1.5 kHz, suggesting that TANU programs use as criteria for passing the higher frequencies[29].

Furthermore, it was found that the distribution of passing and failing by comparing the three different protocols programmed into the automatic equipment of TEOE and taking into account the distribution of frequency bands in the Protocol C analysis (2 bands), have itself rates of higher response presence of 96.9%. However this percentage is not considered statistically different from Protocol B, which considered the presence of three bands (96.2%), because it showed a value of p = 0.520. Thus, both bands can be considered similar in the distribution of passing/failing, and they both can be used as the protocols of NHS Programs.

Protocol A, which considered the presence of 4 bands, showed 79.8% of percentage of passing, with a high failure rate, with 22.2%, the highest rate of false-positive when compared to the Protocols B (3, 8%) and C (3.1%). These indices make us think back to cases of false positives, i.e., that have altered results due to other factors that are not related to organic onsets of the auditory system. We must avoid cases of false positives because they can lead to problems in the quality of the program, creating unnecessary anxiety in parents[16], and increasing referrals to failure to retest the TEOAE and overloading responsible clinics for auditory diagnoses[14].

The literature describes some national and international studies using different criteria for passing and failing, indicating that there is still no current consensus on what would be the best criterion for passing/failing, the phonoaudiologist should adopt using otoacoustic emissions evoked by transient stimulus in neonatal hearing screening. In 2000, a study, in order to ensure the quality of neonatal screening, used a more strict protocol of passing/failing criteria, signal to noise ratio (SNR) present in four out of the five tested bands (1.0, 1.5, 2.0, 3.0 and 4.0Hz)[26]. Other studies did not describe the reason for the choice, but they have a satisfactory result of TEOAE answers present in three out of five tested frequency bands[29.30]. The criteria for passing/failing used for research, whose aim was to analyze the absolute amplitude and response level of otoacoustic emissions evoked by transient stimulus in preterm and full-term, was the reproducibility of the cochlear response of at least 70% correlation and signal to noise ratio of 6 dB SPL at 3 frequencies, including 4kHz[31].

CONCLUSION

More robust measures of TEOAE responses (defined by the signal to noise ratio – SNR) were observed for the frequencies of 3, 2 and 4 kHz. It was found that the Protocol A (4 bands) showed a high failure rate, with 20.2%. This percentage makes us think back to cases of false-positives, since they can lead to problems in the quality of the program, creating unnecessary anxiety in parents, in addition to increasing referrals of failures to retest the TEOAE and overloading responsible clinics for hearing diagnoses. However, both protocols B (three bands; 96.2%) and C (2 bands; 96.9%) are not considered statistically different (p = 0.520) in the passing/failing distribution, and they can be both used as protocols for the NHS Programs.

Even though the protocols B and C have shown similar results between the passing criteria for 2 and 3 frequency bands, they should be included in future studies, a research done along with an examination considered gold standard (Auditory Evoked Potential of the Automatic Auditory Brain Stem with click stimulus) in order to confirm the clinical applicability of TEOAE protocols.

These findings may contribute to the choice of protocols which bring greater sensitivity, specificity and safety in neonatal hearing screening and can be used in public policies implemented in Brazil recently.

It is important that the phonoaudiologists are aware of these issues and, wherever be necessary, to seek grants which denote evidence to assist in the decision on the use of tools and instruments in their clinical practice. But for this to occur, the study centers and universities should contribute even more strongly in the validation and extension of knowledge pertaining to the applications of the technologies currently available in speech therapy.

RESUMO

Objetivo: descrever os resultados de três protocolos de EOAET de um equipamento automático utilizado em um Programa de TAN. **Método:** o equipamento utilizado foi programado com três critérios diferenciados de passa/falha. Protocolo A: Passar em 4 bandas de frequência, não precisando ser consecutivas; Protocolo B: Passar em 3 bandas de frequência, não precisando ser consecutivas e Protocolo C: Passar em 2 bandas de frequência, não precisando ser consecutivas. Os parâmetros para considerar presença de respostas foram: reprodutibilidade acima de 50%, relação sinal ruído > que 3dB em 1.0 e 1.5kHz e > 6dB em 2.0, 3.0 e 4.0kHz. **Resultados:** 574 orelhas foram analisadas, sendo que as bandas de frequência de 2.0, 3.0 e 4.0kHz foram as que apresentaram percentuais de "passa" mais elevados (94,1; 95,8 e 92,7%, respectivamente). A banda de frequência de 1.0kHz obteve resposta presente em apenas 9,9% das orelhas testadas. Verificou-se que a análise do Protocolo C (2 bandas) foi a que apresentou o maior percentual de passa (96,9%). Porém este percentual não é considerado estatisticamente diferente do Protocolo B, 3 bandas, (96,2%) com valor de p=0,520. Assim, ambas as bandas são consideradas iguais, podendo-se utilizar qualquer uma das duas. Entretanto o Protocolo A (4 bandas) obteve 79,8% de percentual de passa, apresentando uma taxa de falha elevada (22,2%). **Conclusões:** deve-se pesquisar, com o padrão-ouro, todos os protocolos para verificação daquele com melhor sensibilidade e especificidade, apesar de terem apresentado resultados similares entre critérios de passa para 2 ou 3 bandas de frequência.

DESCRITORES: Audição; Perda Auditiva; Triagem Neonatal; Recém-Nascido

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