Análise crítica de três protocolos de triagem auditiva neonatal******

Critical analysis of three newborn hearing screening protocols

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Abstract
Background: having knowledge about the validity of procedures for newborn hearing screening (NHS) is fundamental, once the purpose of these programs is to identify all newborns with hearing loss at an acceptable cost. Aim: to estimate the specificity and the false-positive rate of NHS protocols using transient evoked otoacoustic emissions (TEOAE) and automated auditory brainstem response (AABR). Method: participants were 200 newborns who were submitted to a hearing screening test between March and July 2006. Three protocols were analyzed: protocol 1, NHS was carried out in two steps using TEOAE; protocol 2, NHS was carried out in two steps using AABR; and protocol 3, NHS was carried out in one step, using the two procedures - testing with TEOAE followed by a retest with AABR for all the newborns who did not pass the TEOAE testing. Results: although there was no statistically significant difference when comparing the referral rates to audiological diagnosis obtained in protocols using TEOAE and AABR, the protocol using TEOAE referred four times more newborns. Protocol 3 presented the highest referral rate, with a statistically significant difference when compared to protocols 1 and 2. Conclusions: the false-positive rate and consequently specificity were better for the protocol using AABR, followed respectively by the protocol using TEOAE and using both TEOAE and AABR.
Key Words: Neonatal Screening; Hearing Tests; Otoacoustic Emissions; Evoked Potentials; Auditory.

Resumo
Tema: conhecer a validade dos procedimentos para triagem auditiva neonatal (TAN) é fundamental, visto que a meta desses programas é identificar todos os recém-nascidos com deficiência auditiva, com um custo aceitável. Objetivo: estimar a especificidade e taxa de falso-positivo de protocolos de TAN, realizados com emissões otoacústicas evocadas transientes (EOET) e potenciais evocados auditivos de tronco encefálico automático (PEATEa). Métodos: 200 recém-nascidos foram submetidos à TAN entre março e julho de 2006. Foram analisados três protocolos: protocolo 1, TAN realizada em duas etapas com EOET; protocolo 2, TAN realizada em duas etapas com PEATEa; e protocolo 3, TAN realizada em uma etapa com dois procedimentos - teste com EOET seguido de reteste com PEATEa para os recém-nascidos que não passaram nas EOET. Resultados: apesar de não ter havido diferença estatisticamente significante quando comparadas as taxas de encaminhamento para diagnóstico audiológico obtidos nos protocolos com EOAET e PEATEa, o protocolo com EOET encaminhou quatro vezes mais recém-nascidos. O protocolo 3 apresentou a maior taxa de encaminhamento, com diferença estatisticamente significante ao ser comparado com os protocolos 1 e 2. Conclusões: a taxa de falso-positivo e conseqüentemente a especificidade foram melhores no protocolo com PEATEa, seguido dos protocolos com EOET e com EOET e PEATEa.
Palavras-Chave: Triagem Neonatal; Testes Auditivos; Emissões Otoacústicas; Potenciais Evocados Auditivos.

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Introduction

The newborn hearing screening (NHS), when part of Neonatal Hearing Health Program, allows identifying hearing loss during the first months of life and, consequently (JCIH, 1994)1, allows diagnostic and intervention at a critical period for language development.

Among the procedures available for NHS, the two most used ones are the transient evoked otoacoustic emissions (TEOAE) and the automatic brainstem auditory evoked potentials (BAEP), which can be applied alone or in combination (JCIH, 2007)2. The knowledge on the validity of these procedures (sensitivity, specificity, false-negative and false-positive rates) is crucial once the goal of NHS is to identify all newborns with hearing loss with acceptable cost (JCIH, 2007)2.

In Brazil, the Legislations GM/MS - number 20733 from September 2004 - and SAS/MS - number 5874 and 5895 from October 2004 - allowed a great progress of early intervention as they facilitated access to centers of reference in diagnosis and intervention with donation of hearing aids associated to individual speech-language therapy. However, there are still no guidelines for implementation of neonatal hearing health programs, especially regarding the newborn hearing screening.

Thus, the purpose of this study was to estimate the specificity and false-positive rate of NHS protocols carried out with transient evoked otoacoustic emissions (TEOAE) and automated auditory brainstem response (AABR).

Method

The present study is part of the project "Newborn Hearing Health Model", which includes the program of universal newborn hearing screening conducted at Santa Isabel Maternity - Bauru / SP.

The study was approved by the Research Ethics Committee of the Dentistry School of Bauru / University of São Paulo (USP), process number 113/2005.

Subjects

The study included 200 newborns, randomly selected from regular nurseries, who were subjected to NHS on the period between March/2006 and July/2006, whose parents agreed with the participation in the research.

The sample was composed by 96 boys and 104 girls. Only 13 of them had risk factors for hearing loss (JCIH,2007)1: four boys and nine girls. It is important to emphasize that, from these newborns, 10 had family history of hearing loss (76.92%), two had congenital infection by HIV (Human Immunodeficiency Virus) (15.38%), and one had a preterm delivery (7.70%).

Methodology

The TEOAE search was conducted with the equipment Capela (Madsen), on the screening mode and non-linear click stimulus with a peak of 80 dBNPS and window of 12.5 ms. The result "pass" was considered when presence of TEOAE with 70% reproducibility and signal noise ratio 6 dB on frequencies of 2, 3 and 4 kHz were observed after 2080 stimuli. When no satisfactory response was obtained on the first collection, the probe was replaced and up to three more collections were conducted in order to determine the final outcome - conduct usually followed on the hearing screening program of the Hospital, once the probe placement is a variable that can significantly interfere on the outcome.

For the AABR, the one channel equipment ABaer (Bio-logic) with non inverted electrode at Fz, inverted electrode at Oz and earth electrode on the forearm (IS 10-20), with maximum electrodes impedance of 8 and with 4 difference among them, were used after cleaning the skin with exfoliating gel scrub (Nuprep) on the regions indicated. The Kendall Meditrace electrode and electrolytic paste (Ten20 EEG Conductive Paste) were used. The stimulation parameters were: click stimulus, alternated polarity, presentation rate of 37.1 clicks/second, intensity of 35 dBHL, band pass filter of 100-1501 Hz, gain of 30,000 and window of 21:33 ms

In the automatic analysis of responses carried out by the equipment the "pass" result is defined when the value of Point Optimized Variance Ratio (POVR) is 3.5 after a minimum of 1536 stimuli, or "not pass" when the POVR value of 3.1 is not maintained after the mean of two series of 6144 stimuli.

The hearing screening was conducted at the maternity, in a room with noise level of 44 dBNPS measured by a decibel-meter type 2236 from Brüel & Kjaer (dBHL scale).

The newborns were always in company of parent or guardian and were asleep or in somnolence state.

Hearing Screening-test: the procedures were performed in newborns with more than 24 hours of life to minimize the influence of vernix that may be present on their external auditory canal 6. The order of procedures application was alternated, that is, sometimes the TEOAE was applied first and sometimes the AABR was the first one to be applied in order to control the variable sequence of procedures.As a result, the newborn who did not pass the screening test, even if just in one ear, was referred for hearing screening retest, which occurred at the maternity, between seven and 30 days of life, coinciding to the schedule of the Guthrie Test. Newborns who passed the screening test were discharged and parents were instructed to follow the development of their hearing and oral language.

Hearing Screening retest: on the hearing screening retest, the procedure which the newborn has not previously passed was repeated. When the "pass" result was obtained, the same conduct as described above was followed. In case of "no pass", the newborn was referred for audiological evaluation at the Clinic of the Speech-Language Pathology and Audiology Course of the Dentistry School of Bauru - USP, accredited by the SUS as High Complexity Center in hearing impaired care.

Audiological Evaluation: the process of diagnosis - which occurred before two months of age - involved otorhinolaryngological evaluation; anamnesis on the overall development of the child; and behavioral, electrophysiological and electroacoustic procedures. The newborns and their families were assisted by a team of professionals, involving Audiologist and Speech-Language Pathologist, Otorhinolaryngologist, Psychologist and Social Worker.

Time required for completion of the procedures

The time for completion of TEOAE and AABR was measured, using a digital stopwatch, in a sample of 50 randomly chosen newborns. The duration from the time spent preparing the newborn to the end of the procedure was calculated. The time spent on orientation was not included because it depended on the outcome.

Analyzed Protocols

To determine sensitivity and specificity of any hearing screening it would be required that all newborns made complete diagnostic evaluation after the hearing screening - which would be unworkable in practice, once the prevalence of hearing impairment is 1/1000 alive newborns 7,8. However, the combined use of evoked otoacoustic emissions and automated auditory brainstem response, allows one test to evaluate the other and, thus, to establish sensitivity and specificity values close to real8.

Based on earlier studies6,8, the true negative was considered when the two procedures showed the presence of response on hearing screening in both ears, determining the false-negative rate equal to zero and consequently 100% sensitivity.

The estimated rate of false-positive and specificity was performed for three protocols:

. protocol 1: NHS in two stages - Test and retest with TEOAE;
. protocol 2: NHS in two stages - with AABR test and retest;
Protocol 3: NHS in one stage with two procedures
. test with TEOAE followed by retest with AABR for newborns who did not pass on the first procedure.

The result was characterized false-positive when:

. newborns obtained "no pass" result on the screening test, but "pass" result on the screening-retest, and
. newborns with "no-pass" results on hearing screening retest, but diagnosed with normal hearing after audiological evaluation.

Data Analysis Method

A descriptive statistical analysis was performed to estimate the specificity and the percentage of protocols false-positive and the confidence interval of 95% was calculated for specificity. The chi-square test was performed to compare the referral rates on the protocols. The paired t test was used to compare the duration and procedures TEOAE and AABR and t Student test was used to analyze the relationship between the age at the test and the result. The significance level was of 5% or p ? 0.05.

Results

Table 1 shows the results of hearing screening and the referral rate of protocols 1, 2 and 3.

All infants referred to perform audiological evaluation presented normal hearing after the retest hearing screening. Thus, all newborns who did not pass the hearing screening were considered false-positives.

The rate of false-positive and the specificity with a confidence interval for the three studied protocols are described in Table 2.

In the comparison of referral rates for audiological diagnostic among protocols 1 (TEOAE), 2 (AABR) and 3 (TEOAE+AABR), it was found that there was no statistically significant difference when protocols 1 and 2 were compared (p = 0177). However, there were statistically significant differences between protocols 1 and 3 (p = 0041) and protocols 2 and 3 (p = 0002).

The analysis of time spent to perform the TEOAE and the AABR is presented in Table 3.

TABLE 1. Test and retest hearing screening results on the different protocols.

Procedures	Hearing Screening									
	Test				Retest				Referral	
	Passed		Did not Pass		Passed		Did not Pass			
	n	%	N	%	n	%	n	%	n	%
Protocol 1	128	64	72	36	68	34	4	2	4	2
Protocol 2	184	92	16	8	15	7,5	1	0,5	1	0,5
Protocol 3	188	94	12	6	---	---	---	---	12	6

Note: Protocol 1: transient evoked otoacoustic emissions (TEOAE); Protocol 2: automated auditory brainstem response (AABR); Protocol 3: the two procedures associated.

TABLE 2. False-positive rate and specificity of studied protocols.

	False-Positive Rate		Specificity	CI* 95%
	n	%	%	%
Protocol 1	4	2	98,0	95,0 a 99,2
Protocol 2	1	0,5	99,5	97,2 a 99,9
Protocol 3	12	6	94,0	89,9 a 96,5

Note: Protocol 1: transient evoked otoacoustic emissions (TEOAE); Protocol 2: automated auditory brainstem response (AABR); Protocol 3: the two procedures associated; CI - Confidence Interval

TABLE 3. Duration (in minutes) for the implementation of hearing screening with the two studied procedures.

	Mean	SD	Minimum	Maximum
TEOAE	6,75	2,00	3,66	12,16
AABR	9,22	4,26	4,70	23,43
p			<0,001*	

Discussion

The comparative analysis of the protocols used in programs of newborn hearing screening is not easily conducted due to the wide range of variability of results obtained when analyzing the validity of the procedure utilized (false-positive, false negative, specificity and sensitivity). This fact can be justified by several reasons that occur in isolation or in combination, determining the results of the program: (1) the criteria used to pass on the hearing screening; (2) the age of newborns at the time of the test differs among studies; (3) the population of the study, including healthy newborns or ones with risk factors; (4) time between test and retest of the hearing screening, and (5) how the data are analyzed and presented - which interferes on the calculation of the validity of the procedure.

In literature, when the newborn hearing screening was performed through Protocol 1 (TEOAE), the rate of referral ranged from 0.6 to 12.03% 9,10,11, the false-positive rate from 0, 64% to 5.8% 10,11 and the specificity from 91.8 to 99.7% 12,14,15. With Protocol 2 (AABR) the rate of referral ranged from 0.2 to 5.3% 6,13,14,15,16, the false-positive rate from 0.34 to 3.9% 14,15,16,17 and the specificity from 93 to 99.7%8,15,18.

Otherwise, with Protocol 3 (TEOAE + AABR), the rate of referral ranged from 1.8% to 8.6% 6,11,13, the false-positive rate reported was 9%19, and no study that described the specificity of the protocol was found.

It can be observed in Tables 1 and 2, that the obtained results were consistent with literature when considering the rate of referral, the false-positive and the specificity of the protocol.

In the analysis of the referral rate for audiological diagnosis, there was a statistically significant difference among protocols when comparing Protocol 3 (TEOAE + AABR) to Protocols 1 (TEOAE) and 2 (AABR). The Protocol 3 (TEOAE +AABR) showed higher rate of referral (6%) when compared to the others (2%).

Although no statistically significant difference was found when comparing referral rates of Protocols 1 (TEOAE) and 2 (AABR), it was noticed that the protocol with TEOAE sent newborns four times more for audiological diagnosis than the one with AABR did. The sample of this study was small to demonstrate a significant difference. However, in practice, when analyzing the proportion of 4/1, this data becomes relevant in the decision of which procedure should be implemented on a program of newborn hearing screening.

With respect to protocol 3 (TEOAE+ AABR), one could consider a lower rate of referral, once the hearing screening was performed involving two procedures 11,13. However, the results showed the opposite probably because, in this protocol, the procedures were performed in sequence - i.e. in the same unfavorable conditions not inherited to cochlea and auditory nerve. It is emphasized that the realization of the retest in Protocols 1 (TEOAE) and 2 (AABR), was done from seven to 30 days after the test, probably decreasing the influence of these variables. Thus, in Protocol 3 (TEOAE + AABR), the procedures must be performed before hospital discharge, but at different times. The proposed is difficult to be deployed in most maternity hospitals in Brazil, once on the vaginal birth, the discharge is defined 24 hours after birth. Additionally, the rate of false-positive and, therefore, the specificity was better in Protocol 2 (AABR), followed by Protocols 1 (TEOAE) and 3 (TEOAE + AABR), (Table 2). It is important to consider that the implications caused by the rate of false-positive cover from the increase in the cost of the program, once the number of newborns unnecessarily referred for audiological evaluation requires professionals availability and use of complex procedures with expensive and sophisticated equipments, parents emotional stress, among others.

In the literature only three studies that compared different NHS protocols using the TEOAE, the AABR and the two procedures combined were found 6,11,13,20. As observed in the present study, the AABR showed to be the procedure with more validity for the implementation of newborn hearing screening when compared to the TEOAE 13,21-22. However, the possibility of mild hearing loss not being identified is highlighted23.

Another aspect analyzed was the duration for TEOAE and AABR completion in a program of NHS (Table 3) with statistically significant difference ($p < 0001$). The TEOAE was a faster procedure, which is in agreement with described in literature6,19,24.

However, the analysis should be performed considering the duration of completion of protocols in the NHS program and not the procedure itself. When considering that the duration of protocol completion is directly related to the amount of "no pass" results on the first phase - thereby determining the number of newborns to be submitted to NHS retest - it is possible to suppose that, at the end, there will be a balance on the total hours that the professional should devote to perform the studied protocols, once that the protocol performed with TEOAE determines the greatest number of retest of the hearing screening.

Conclusions

The lowest rate of false-positive and, consequently, the better specificity, was observed in the protocol with AABR, followed by protocols with TEOAE and TEOAE + AABR.

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