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Are auditory steady-state responses a good tool prior to pediatric cochlear implantation?

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ABSTRACT

Introduction: ASSR allow frequency-specific evaluation in intensities up to 120 dB HL and detection of residual hearing in patients with severe-to-profound hearing loss.
Aim: to compare ASSR thresholds and behavioral test results in children with suspected severe-to-profound hearing loss.
Methods: Cross sectional study to compare ASSR and behavioral responses (VRA or audiometry) in 63 pediatric cochlear implant candidates (126 ears) aged between 6 and 72 months. We included children with normal otomicroscopy, absent responses to click-ABR and otoaccoustic emissions. We excluded children with inner ear malformations, auditory neuropathy spectrum disorder or who did not complete VRA or achieve EEG noise $<$ 30 nV during the ASSR test. Air-conduction ASSR stimuli were continuous sinusoidal tones presented at 0.5, 1, 2 and 4 kHz starting at 110 dB HL. Behavioral thresholds were acquired with warble tones presented at 0.5, 1, 2 and 4 kHz in each ear through insert or head phones at maximum presentation level of 120 dB HL.
Results: Behavioral thresholds were obtained in 36.7% (185/504) of all frequencies in all subjects, 9% in intensities $>$110 dB HL. Among 504 ASSR measurements, 53 thresholds were obtained (10.5%). Overall 89.5% of the tested frequencies did not show any response at 110 dB HL. Most responses were at 500 Hz. Mean differences between behavioral and ASSR thresholds varied from 0.09 to 8.94 dB. Twenty-seven comparisons of behavioral and ASSR thresholds were obtained: 12 at 0.5 kHz, 9 at 1 kHz, 5 at 2 kHz and 1 at 4 kHz. Absent responses were observed in both tests in 38.1% at 0.5 kHz, 52.4% at 1 kHz, 74.6% at 2 kHz and 81.0% at 4 kHz. Specificity was $>$ 90% at 1, 2 and 4 kHz. In ears with no behavioral response at 120 dB HL all ASSR thresholds were in the profound hearing loss range, 90% of them were $\geq$110 dB HL.
Conclusion: Among 63 pediatric CI candidates, absent responses to high-intensity ASSR was the major finding (specificity $>$ 90%) predicting behavioral thresholds in the profound hearing loss range. These findings can be helpful to confirm the decision for cochlear implantation.

1. Introduction

Newborn hearing screening and early identification of hearing loss shows clear benefits. So diagnostic evaluation should follow as soon as possible to provide hearing-impaired children with adequate amplification and follow-up. Children with mild-to-moderate hearing loss may benefit from hearing aids; those with severe-to-profound hearing loss are candidates for cochlear implantation (CI) [1–4].

Behavioral hearing tests such as visual reinforcement audiometry (VRA) and play-audiometry provide accurate information in children above the age of 6 months but can be unreliable for younger children or those with developmental delay or visual disorders [5–7]. Therefore, physiologic hearing measures are essential to confirm hearing loss.

Auditory evoked potentials permit separate ear-and frequency-specific hearing evaluation. The most widely used procedure is the click and tone burst Auditory Brainstem Response (ABR). However, due to the transient nature of stimuli employed to evoke ABR, in clinical practice the maximum presentation level usually does not

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exceed 95 dB HL to avoid saturation. Absent ABR is consistent with significant hearing impairment but cannot distinguish between severe and profound hearing loss [8,9].

Auditory steady-state responses (ASSR) allow frequency-specific stimulation at intensities up to 120 dB HL. The investigation of residual hearing in young children with objective measures contributes to appropriate selection and fitting of hearing aids before surgery and to confirm profound hearing loss [10].

Although Gorga et al., Small et al., and Picton et al. [11–13] observed artifactual responses to high-intensity ASSR, especially at 500 and 1000 Hz, these issues were corrected for the MASTER system [13].

Nevertheless, few studies used ASSR to evaluate children with severe-to-profound hearing loss since 2004. Swanepoel and Hugo [14] studied 15 children aged between 10 and 60 months with suspected severe-to-profound hearing loss. They tested four frequencies (0.5, 1, 2 and 4 kHz) bilaterally in intensities between 120 and 128 dB HL. They found that 87% of thresholds measured were at intensities equal or higher than 100 dB HL and 47% were at 115 dB HL or higher.

Swanepoel et al. tested 10 children between 10 and 15 years with severe-to-profound hearing loss and found close relation between pure-tone thresholds and recorded ASSR thresholds [15].

In adults, comparing ASSR and warble tone audiometry, Ramos et al. [16] found high sensitivity and specificity for ASSR. Some previous data from our group showed no artifactual responses among children in intensities up to 110 dB HL [17,18]. In this study we showed that ASSR underestimated behavioral hearing thresholds obtained by instruments in 7/42 pediatric patients [18]. So there is a clear need for more data to compare high intensity ASSR with behavioral pure tone tests among the pediatric population.

The objective of this study is to compare ASSR thresholds and behavioral test results at 500, 1000, 2000 and 4000 Hz in young children prior to cochlear implantation.

2. Methods

2.1. Subjects

The research was approved by the Ethics Committee of the University of São Paulo School of Medicine (41225/2012). Sixty-three pediatric CI candidates (126 ears), aged between 6 and 72 months (mean 29.14 ± 13.5 months, 30 girls), were enrolled in the study. All parents signed the informed consent according to the Helsinki's Declaration.

Inclusion criteria were: normal otomicroscopy findings, absent otoaccoustic emissions, absent click air-conduction ABR at 90 dB HL and bone conduction at 55 dB HL. We excluded children with vestibular or cochlear malformations seen on MRI or CT, such as enlarged vestibular aqueduct or cochlear nerve deficiency. Subjects with auditory neuropathy spectrum disorder or who did not complete the behavioral evaluation or achieve electroencephalographic noise under 30 nanovolts (nV) during the ASSR test were also excluded.

2.2. Methods

2.2.1. Visual reinforcement audiometry (VRA)/pure tone audiometry (PTA)

Two audiologists conducted VRA in a double-walled, sound attenuated room using the Interacoustics AC33 clinical audiometer (Assens, Denmark). Behavioral air conduction thresholds were obtained with warble tones presented at 500, 1000, 2000 and 4000 Hz in each ear through ER-tone 5A (Etymotic Research, Elk Grove Village, IL) or TDH-39 (Telephonics Corporation Huntington, NY) calibrated according to ISO 389-2 and 389-1, respectively.

Threshold was obtained using a 10 dB down, 5 dB up technique with the upper limit at 120 dB HL for each frequency.

The investigators judged the responses, which were considered consistent if positive in at least 2 of 3 attempts.

For older children, over 3 years old, traditional pure tone audiometry was performed to obtain thresholds.

All but 2 patients were evaluated after using hearing aids for at least 6 months.

2.2.2. Auditory steady-state responses

In our hospital all pediatric ABR tests are performed under light general anesthesia (Sevofluorane). The ASSR procedure was carried out during routine evaluation after otomicroscopy, click ABR and otoaccoustic emissions. Each child performed all tests in one session.

2.2.2.1. ASSR stimulus. The multiple auditory steady-state response (MASTER) software (version 2.04.i00) running on the Bio-Logic Navigator Pro System (Natus Medical Incorporated, San Carlos, CA) was used for the ASSR measurements.

The stimuli used to evoke air-conduction ASSR were continuous sinusoidal tones modulated 100% in exponential amplitude and 20% in frequency. These sinusoidal tones were presented through ER-3A insert earphones (Etymotic Research, Elk Grove Village, IL). The carrier frequencies of 500, 1000, 2000 and 4000 Hz were tested, modulated at 66.797 Hz in the left ear and 69.141 in the right ear. The stimulation was dichotic for a single frequency in each run [12]. Maximum presentation level was 110 dB HL for all frequencies.

Air-conduction stimuli were calibrated in dB HL, according to ANSI S3.6-1996 standard, using a Quest Electronics model 1700 sound level meter with Brüel & Kjær DB0138 2 cm^3 coupler.

2.2.2.2. ASSR recordings. Recordings occurred in a sound-attenuated, electrically shielded room. The same physician, without prior knowledge of the behavioral thresholds, performed all tests.

Surface electrodes were positioned at high forehead (Fz, non-inverting), nape (Oz, inverting) and on the right shoulder (Pz, ground). All electrode impedances were less than 5 k Ω.

Electroencephalographic activity was filtered using a band-pass filter of 30 to 300 Hz and amplified by a gain of 10,000. The responses were recorded in epochs lasting 0.8533 s. Sixteen data epochs were collected and linked together to form one sweep with an overall duration of 13.653 s.

Data epochs containing excessive noise were excluded when amplitudes exceeded artifact rejection level of 60 μV. Epochs that contained electrophysiological activity exceeding 90 nV were rejected [17]. The maximum amount of sweeps was determined according to the pre-set specifications of the equipment: 10 sweeps in intensities above 100 dB HL, 12 sweeps between 90 and 99 dB HL and 18 sweeps between 80 and 89 dB HL.

Once completed each sweep was averaged in the time domain and subsequently submitted to a fast Fourier transform. The resulting amplitude spectrum enabled steady-state responses to be analyzed in the frequency domain. The software determined whether the response amplitude at the modulation frequency was significantly different from the mean amplitude of the electroencephalographic background noise in adjacent frequencies and analyzed the frequency spectrum automatically. The significance of the signal-to-noise ratio was assessed by F-ratio with a confidence interval of 95% for each sweep collected. A response was considered to be "present" when the F-ratio was significant at a level of $p < 0.05$, for at least five consecutive sweeps [5]. Consequently, a "no-response" was considered when the signal-to-noise ratio did not reach significance ($p < 0.05$) after the maximum number of sweeps.

2.2.2.3. ASSR threshold evaluation. The ASSR measurement started at 110 dB HL at the carrier frequency of 500 Hz, followed by 1000, 2000 and 4000 Hz. Thresholds were determined using a 10 dB down and 5 dB up technique, until no responses could be collected. All thresholds or absent responses were confirmed with retest. ASSR threshold was defined as the lowest intensity at which a significant response was detected, and a no response was found 5 dB below this level.

2.2.2.4. Analysis. The relationship between presence or absence of behavioral responses and ASSR was examined at 500, 1000, 2000, and 4000 Hz in each evaluated ear. Behavioral and ASSR responses were classified as absent responses, thresholds between 90 and 110 dB HL and responses <90 dB HL. VRA or PTA thresholds >110 dB HL were included among absent responses.

Agreement between the methods was tested using weighted Kappa (confidence interval 95%). Sensitivity and specificity were calculated considering VRA or pure tone audiometry as the gold or best possible standard for the identification of residual hearing. Data were analyzed using SPSS 20.0 software (IBM, Armonk, NY, USA).

3. Results

3.1. Behavioral test results

Behavioral thresholds were obtained in 36.7% (185/504) of all evaluated frequencies for all subjects. Most of them were at 500 Hz, decreasing among the higher frequencies (Fig. 1).

Nine percent of the behavioral thresholds were obtained above 110 dB HL (included in the absent responses group), predominantly at 500 Hz, 38% between 100 and 110 dB HL and 51.8% were at levels equal or lower than 95 dB HL.

3.2. ASSR thresholds

Overall, 504 measurements from 63 subjects (4 frequencies x 126 ears) were acquired. Fifty-three ASSR thresholds (10.5%) were obtained Fig. 2.

The distribution of the ASSR responses was similar to the behavioral test results. No significant differences were found between right and left ears in both tests.

At the frequency of 500 Hz, 22 thresholds were found. Sixteen thresholds were found at 1000 Hz, nine at 2000 Hz and six at 4000 Hz. Mean thresholds and standard deviation are summarized in Table 1.

3.3. Comparison of ASSR and behavioral thresholds

Means and standard deviations of behavioral and ASSR thresholds in ears with measurable responses are summarized in Table 1. The mean differences between behavioral and ASSR thresholds varied from 0.09 to 8.94 dB. There was no statistical difference for any frequency (Table 2).

Overall, 27 comparisons of behavioral and ASSR thresholds were obtained from 63 subjects (126 ears): twelve at 500 Hz, nine at 1000 Hz, five at 2000 Hz and one at 4000 Hz. Absent responses were not included in this analysis.

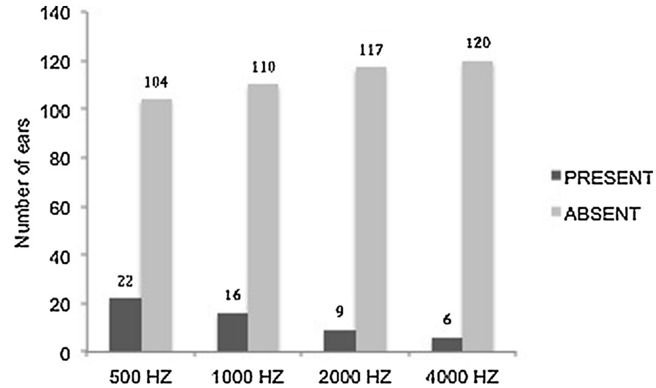

Fig. 1. Present and absent ASSR responses for each frequency.

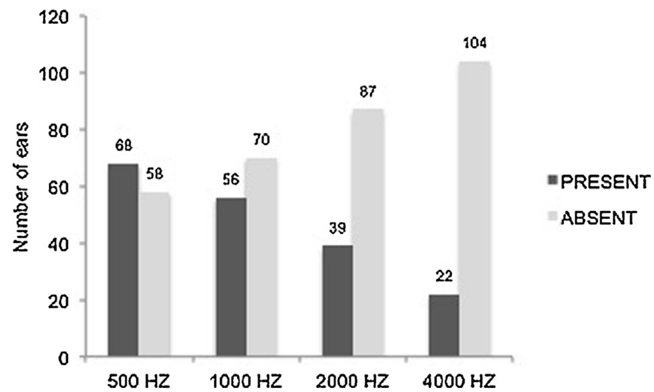

Fig. 2. Present and absent behavioral responses for each frequency.

ASSR thresholds were obtained close to the behavioral hearing levels. The maximum difference was 15 dB. In 38.9% of tested frequencies, behavioral thresholds were equal or higher than 100 dB HL and 9% were higher than 110 dB HL.

Absent responses were observed in both tests in 38.1% at 500 Hz, 52.4% at 1000 Hz, 74.6% at 2000 Hz and 81.0% at 4000 Hz.

In ears with no behavioral responses at 120 dB HL, all ASSR thresholds were in the profound hearing loss range. Among these values, about 90% were equal or worse than 110 dB HL.

The sensitivity and specificity were calculated considering the behavioral responses, obtained by VRA or PTA as the gold standard for detection of residual hearing. Specificity was higher than 90%, especially at 1000, 2000 and 4000 Hz (Table 2).

4. Discussion

Absent responses to high-intensity ASSR was the major finding of this study. Eighty-nine percent of the tested frequencies did not show any response at 110 dB HL. ASSR showed high specificity as compared to behavioral test results in 1000, 2000 and 4000 Hz,

Table 1
Mean thresholds, standard deviation and mean difference between thresholds in different methods.

Frequency (Hz)	Behavioral thresholds Mean ± SD (dB HL)	*N* (ears)	ASSR thresholds Mean ± SD (dB HL)	*N* (ears)	Mean difference
500	92.42 ± 14.5	68	101.36 ± 6.9	22	−8.94
1000	96.69 ± 13.0	56	101.87 ± 6.3	16	−5.18
2000	101.02 ± 15.0	39	101.11 ± 7.3	9	−0.09
4000	96.13 ± 15.7	22	100 ± 14.1	6	−3.87

Table 2
Comparisons between ASSR and VRA thresholds.

Frequency	ASSR	Behavioral evaluation								Weighted Kappa (IC 95%)	Sensitivity %	Especificity %
		Absent		110 dB - 90 dB		< 90 dB		Total				
		N	%	*N*	%	*N*	%	*N*	%			
500 Hz	Absent	48	38.1	42	33.3	14	11.1	104	82.5	0.000 (−0.101; 0.100)	17.6	82.8
	110–90 dB	9	7.1	9	7.1	3	2.4	21	16.7			
	<90 dB	1	0.8	0	0.0	0	0.0	1	0.8			
	Total	58	46.0	51	40.5	17	13.5	126	100.0			
1000 Hz	Absent	66	52.4	35	27.8	9	7.1	110	87.3	0.082 (−0.053; 0.216)	17.0	90.4
	110–90 dB	7	5.6	8	6.3	1	0.8	16	12.7			
	<90 dB	0	0.0	0	0.0	0	0.0	0	0.0			
	Total	73	57.9	43	34.1	10	7.9	126	100.0			
2000 Hz	Absent	94	74.6	18	14.3	5	4.0	117	92.9	0.182 (−0.005; 0.368)	17.9	95.9
	110–90 dB	4	3.2	3	2.4	2	1.6	9	7.1			
	<90 dB	0	0.0	0	0.0	0	0.0	0	0.0			
	Total	98	77.8	21	16.7	7	5.6	126	100.0			
4000 Hz	Absent	102	81.0	11	8.7	7	5.6	120	95.2	0.003 (−0.104; 0.109)	5.3	95.3
	110–90 dB	5	4.0	0	0.0	0	0.0	5	4.0			
	<90 dB	0	0.0	1	0.8	0	0.0	1	0.8			
	Total	107	84.9	12	9.5	7	5.6	126	100.0			

VRA thresholds > 110 dB HL were included among absent responses.

demonstrating that absent ASSR responses at 110 dB HL are a strong predictor of profound hearing loss, which helps in the decision for cochlear implantation.

These results are consistent with the report of Rance et al. [9], who showed that the absence of ASSR at maximum stimulation levels is a reliable indicator of profound hearing loss. In 73 of 126 tested ears (58%) the behavioral and ASSR thresholds were consistent with profound hearing loss: Forty-two with absent responses in both tests and 31 with absent ASSR responses and behavioral thresholds ≥90 dB HL.

Swanepoel and Hugo [14] studied 15 children between 10 and 60 months (mean 29 months) with suspected severe-to-profound hearing loss. In this study the stimuli were delivered up to 120–128 dB HL according to each frequency. They found that 87% of ASSR thresholds measured were equal or above 100 dB HL and 47% were at 115 dB HL or higher. The frequency of 500 Hz did evoke fewer responses.

According to Swanepoel et al. [15], ASSR could assist in cochlear implant candidacy when audiological tests are unavailable as in infants or in difficult-to-test subjects. They studied 10 subjects between 10 and 15 years and found thresholds for all the evaluated frequencies close to behavioral thresholds, at maximum ASSR intensity of 120 dB HL [15].

Our results differ from the aforementioned studies as we limited the maximum stimulus output to 110 dB HL for all frequencies, since all recordings were carried out without prior knowledge of the behavioral thresholds. We refrained from using higher intensities to avoid cochlear damage. The only audiological data available prior to the ASSR test was absent click ABR at 90 dB HL. It is well known that this finding cannot differentiate between severe and profound hearing loss or may be related to delayed maturation of auditory pathways in premature infants. We were also concerned about the possibility of artifactual responses in intensities above 110 dB HL as previously described [11–13].

According to Swanepoel et al., the use of insert phones can minimize the possibility of somatosensory responses [14] in high intensities, so we used insert ear phones in all tests.

Different from Swanepoel and Hugo [15] who obtained behavioral thresholds for only one subject, in our casuistic 41 children showed responses in at least one frequency during the behavioral evaluation. Some of them were evaluated more than once to obtain reliable results. We used 120 dB HL as maximum output for the behavioral evaluation, with a 10 dB up seeking procedure. This may explain why we obtained more behavioral than ASSR thresholds.

Since 2004 there are few studies about ASSR in children with severe-to-profound hearing loss, exclusively.

Kandogan and Dalgic evaluated 20 children aged between 19 and 41 months with ABR and ASSR. They observed that ASSR thresholds could be obtained in patients with absent ABR, and this information can be used for a true hearing aid trial [19].

Ramos et al. [16] found 202/320 (63.1%) thresholds using high-intensity ASSR up to 120 dB HL in 40 subjects with severe-to-profound hearing loss. However, they tested teenagers and adults who were able to complain if the stimulus intensity was bothersome. In this study ASSR demonstrated high sensitivity (96%) and specificity (91.6%) as compared to pure tone audiometry.

In our study, sensitivity was low for all tested frequencies when compared to behavioral audiometry. At 500 Hz it was 17.6%, 17.0% at 1000 Hz, 17.9% at 2000 Hz and 5.3% at 4000 Hz. There was no correlation between the methods due to the reduced number of ASSR responses. As most patients were in the profound hearing loss range, only a few number of ASSR responses were available for analysis (53/504). In very young children it is questionable if VRA test results can be considered a true audiological gold standard. In fact, this is the most widely used tool for frequency-specific behavioral evaluation in this age group and so the best possible standard.

As absent ASSR is a strong indicator of profound hearing loss [5] we can assume that our patients are good candidates for cochlear implantation. This was shown previously by Rance and Briggs [5] who reported that in the absence of ASSR behavioral responses were equal or greater than 115 dB HL in 93.4% of the thresholds. Also Ramos et al. [16] reported that in 93.2% of the occasions with no detectable ASSR neither a behavioral response was found. This is more valuable information before CI than absent click ABR, which cannot exclude the possibility of residual hearing [20].

All children should have a hearing aid trial prior to cochlear implantation, but in the absence of ASSR responses the family should be advised that useful aided hearing might not be achieved.

In contrast, with present ASSR and absent ABR responses the child may have residual hearing at amplifiable levels [5,14]. In this case ASSR thresholds can be used for proper hearing aid fitting.

Comparisons between ASSR and behavioral tests have shown strong correlation of thresholds in subjects with hearing loss. The difference between ASSR and tonal thresholds decreases as the severity of hearing loss increases [20–22]. So when ASSR thresholds are measurable, they provide important information for early hearing aid fitting in very young children when behavioral tests are not reliable and for the selection of the ear for CI, if unilateral CI is desired.

Although some researchers raised the concern about artifactual responses at high stimulus levels in 2004 [11–13], few studies were conducted since using ASSR to determine residual responses in cochlear implant candidates. Similar to the present study, Beck et al. [17,18] did not found spurious responses at any frequency at the maximum stimulus presentation level of 110 dB HL, applying the high analog–digital conversion rate of 1200 Hz and selecting rates for which the carrier frequency of the stimulus was not an integer multiple [12,13]. Using the same conversion rate and stimulus intensities up to 120 dB HL, Ramos et al. [16] observed that ASSR responses in the absence of behavioral responses were uncommon among their study population accounting for only 3.1% of the frequencies tested, less than expected by chance [23].

Some factors might have contributed to fewer ASSR thresholds and lower ASSR sensitivity in the present study. First of all, we limited the maximum output to 110 dB HL, so less ASSR responses are expected in comparison to other authors who used higher intensities. As ASSR thresholds in sensorineural hearing loss may be 6 to 11 dB higher than tone ABR thresholds in children, ASSR responses at 110 dB HL may indicate hearing levels of 100 dB HL or better [24]. The behavioral test detected 89/504 responses at intensities equal or greater than 100 dB HL that could not be obtained with ASSR stimuli limited to 110 dB HL. Although this strategy may have missed about 17% of possible ASSR responses, we considered it more important to avoid cochlear damage. Clinicians should be cautious about high intensity ASSR stimulation, especially in children without previous behavioral tests, premature infants and in cases of auditory neuropathy spectrum disorder.

ASSR amplitudes are usually small at threshold levels, so we may have missed some responses due to insufficient signal-to-noise ratio. The noise level depends on EEG amplitude and recording time and usually decreases during the test. At stimulus levels of 100 dB HL or higher no more than 10 sweeps are collected at each intensity. In view of the small amplitudes near threshold and possibly elevated noise levels, it may be difficult to collect responses with a significant signal-to-noise ratio with the reduced number of 10 sweeps (1 sweep contains 16 epochs of 1.024 s, so the recording time was 163 s for each frequency, less than 3 min). Thus a longer recording time as used with Chirp stimuli is expected to produce larger response amplitudes and a better signal-to-noise ratio [25].

The subject's state of arousal contributes to a significant noise level interfering with response detection. In our experience light anesthesia with sevofluorane permits a smooth EEG and helps to achieve acceptable noise levels even in high intensity stimulation.

Previous studies in adults showed that 80-Hz-ASSR-response amplitudes might be 5 times smaller than 40 Hz responses. Tlumak et al. [26] confirmed the data and found smaller 80-Hz-ASSR amplitudes as compared to the 40 Hz repetition rates in children [26]. Nevertheless, sometimes 10 sweeps are not enough to reduce the noise level under 30 nV, so we suggest extending the recordings up to 12 sweeps in these cases. Another approach could be the 40 Hz stimulation rate as suggested by Mühler et al. [27]. There is no data yet for the use of narrow band chirps at high-intensity ASSR stimulation above 80 dB HL.

Although our casuistic of 63 children with severe-to-profound hearing loss is among the largest in the literature, most children were in the profound hearing level range, accounting for a reduced number of ASSR responses at high intensities. A multicentric study including more subjects with residual hearing would help to improve stimulus and detection parameters for the pediatric population with severe-to profound hearing loss.

5. Conclusion

Among 63 pediatric CI candidates, absent responses to high-intensity ASSR was the major finding (specificity $> 90\%$) predicting behavioral thresholds in the profound hearing loss range. These findings can be helpful to confirm the decision for cochlear implantation.

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