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From:	"ENT Journal" entjournal@phillyent.com
Subject:	Your Submission

Ref.: Ms. No. 16-15R1
The value of ASSR threshold-based bilateral hearing aid fitting in children with difficult or unreliable behavioral audiometry.
Ear, Nose & Throat Journal

Dear Dr. Vlastarakos,

I am pleased to inform you that your manuscript has been ACCEPTED FOR PUBLICATION in Ear, Nose & Throat Journal. Editorial changes may be made to conform with the style and format of the journal and to correct errors in grammar, punctuation, and spelling. You will be contacted by an editor when editing is about to begin, and you will receive the edited text for your approval prior to publication. It is therefore essential that you inform us of any changes in your contact information.

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Comments from the Editor and Reviewers can be found below.

Sincerely,

Robert T. Sataloff, MD, DMA, FACS
Editor-in-Chief
Ear, Nose & Throat Journal

Comments from the Editors and Reviewers:

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The value of ASSR threshold-based bilateral hearing aid fitting in children with difficult or unreliable behavioral audiometry.

--Manuscript Draft--

Manuscript Number:	16-15R1
Full Title:	The value of ASSR threshold-based bilateral hearing aid fitting in children with difficult or unreliable behavioral audiometry.
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Author Comments:	Dear Prof. Sataloff, We would like to submit the enclosed manuscript for consideration of publication in the ENT Journal. The manuscript deals with the challenges in providing appropriate hearing aid fitting in infant - cochlear implant candidates, and monitoring their auditory/vocal preverbal progress. We believe that the presented paradigm would be very useful to your wide readership, as it involves a subpopulation of childrenwith significant discrepancies between ABR and ASSR testing, which may prove challenging for appropriate hearing aid fitting.The latter is of utmost importance, if we accept that a monitoring pre-implant period should exist in hard-of-hearing infants. The manuscript has been read and approved by all authors, and it is not under consideration or review elsewhere. Looking forward to hearing from you and thanking you in advance, Sincerely yours, Dr. Petros Vlastarakos, MD, MSc, PhD, IDO-HNS (Eng.)
Abstract:	The present case-series aimed to assess the relative contribution of auditory brainstem response (ABR) and auditory steady state response (ASSR) testing in providing appropriate hearing-aid fitting in hearing-impaired children with difficult/unreliable behavioral audiometry. From a total of 150 infants and children who had been referred for hearing assessment to the Clinic of Pediatric Hearing Loss, operating in the context of a Neonatal Hearing Screening and Cochlear Implant Program, five had significant discrepancies between click-ABR and ASSR testing and difficult/unreliable behavioral audiometry, and were, hence, included in the present study. Hearing aid fitting in pediatric cochlear implant candidates for a trial-period of 3 to 6 months is still commonly exercised in many implant programs. Nevertheless, monitoring the progress of the amplified infants and provision of appropriate hearing aid fitting are challenging. Nonetheless, if we accept that we can assess the progress of amplified infants with an acceptable degree of certainty, the auditory behavior that we are monitoring presupposes appropriate bilateral hearing aid fitting. This may become very challenging in young children, or even in older children with difficult/unreliable

	behavioral audiometry. This challenge could be addressed by using data from ABR and/or ASSR testing, as fitting attempts which only employ data from ABR testing provide amplification which involves the range of spoken language, and is not frequency-specific. In contrast, hearing aid fitting should incorporate and take into account ASSR data, as a different strategy might compromise the validity of the monitoring process. In conclusion, ASSR threshold-based bilateral hearing-aid fitting is necessary to provide frequency-specific amplification of hearing, and appropriate propulsion in the prelinguistic vocalizations of monitored infants.
Response to Reviewers:	Dear Prof. Sataloff, Thank you for the constructive comments of the Reviewer, and the proposed revision. We have revised our manuscript accordingly. In detail: 1)We have corrected the typographical errors throughout the text, as suggested by the Reviewer. 2)We have complied with the suggestions of the Reviewer and added relevant literature in our literature review (authors' references 21 & 23). The revised version of the manuscript has been read and approved by all authors. It is not under consideration or review elsewhere. Looking forward to hearing from you again, and thanking you again for the constructive comments of the Reviewer, Sincerely yours, Dr. Petros Vlastarakos, MD, MSc, PhD, IDO-HNS (Eng.)

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Drs. Vlastarakos and Vasileiou equally contributed to the preparation of the manuscript. Prof. Nikolopoulos critically reviewed and edited the manuscript.

The value of ASSR threshold-based bilateral hearing aid fitting in children with difficult or unreliable behavioral audiometry.

Vlastarakos PV, Vasileiou A, Nikolopoulos TP

Abstract

The present case-series aimed to assess the relative contribution of auditory brainstem response (ABR) and auditory steady state response (ASSR) testing in providing appropriate hearing-aid fitting in hearing-impaired children with difficult/unreliable behavioral audiometry. From a total of 150 infants and children who had been referred for hearing assessment to the Clinic of Pediatric Hearing Loss, operating in the context of a Neonatal Hearing Screening and Cochlear Implant Program, five had significant discrepancies between click-ABR and ASSR testing and difficult/unreliable behavioral audiometry, and were, hence, included in the present study. Hearing aid fitting in pediatric cochlear implant candidates for a trial-period of 3 to 6 months is still commonly exercised in many implant programs. Nevertheless, monitoring the progress of the amplified infants and provision of appropriate hearing aid fitting are challenging. Nonetheless, if we accept that we can assess the progress of amplified infants with an acceptable degree of certainty, the auditory behavior that we are monitoring presupposes appropriate bilateral hearing aid fitting. This may become very challenging in young children, or even in older children with difficult/unreliable behavioral audiometry. This challenge could be addressed by using data from ABR and/or ASSR testing, as fitting attempts which only employ data from ABR testing provide amplification which involves the range of spoken language, and is not frequency-specific. In contrast, hearing aid fitting should incorporate and take into account ASSR data, as a different strategy might compromise the validity of the monitoring process. In conclusion, ASSR threshold-based bilateral hearing-aid fitting is necessary to provide frequency-specific amplification of hearing, and appropriate propulsion in the prelinguistic vocalizations of monitored infants.

Keywords: ASSR, hearing loss, deafness, hearing aids, cochlear implants, infant

Introduction

Early cochlear implantation in children has a positive effect on the development of the auditory pathways, as well as on post-implantation outcomes [1-3]. Therefore, delays in detecting severe hearing impairment could significantly impair with the development of verbal communication skills and spoken language. Thus, the implementation of universal neonatal hearing screening is the only way to achieve very early detection of deafness, and timely referral to cochlear implant centers [4, 5].

A commonly exercised practice in pediatric cochlear implant candidates, who are identified by neonatal hearing screening programs, is to fit them with bilateral hearing aids for a trial period of 3-6 months, after which, should they not progress linguistically, cochlear implantation may follow. An additional rationale in fitting hearing aids to severely or even profoundly deaf infants during this period is to provide some access into the normal auditory spectrum, taking advantage of the critical periods of neuroplasticity [6, 7].

Nevertheless, the aforementioned practice in cochlear implant programs has two important prerequisites; provision of appropriate hearing aid fitting and monitoring the linguistic progress of the amplified infants. Both these aspects can be challenging in hard-of-hearing children.

The aim of the present case-series study is to assess the relative contribution of auditory brainstem response (ABR) and auditory steady state response (ASSR) testing in providing appropriate hearing aid fitting in hearing impaired children, in whom behavioral audiometry is difficult or unreliable.

Patients, Methods & Results

Between January 2009 and June 2014 a total of 150 infants and children had been referred for hearing assessment to the Clinic of Pediatric Hearing Loss, which operates in the context of the Attikon University Hospital Neonatal Hearing Screening and Cochlear Implant Program. The children were initially given a full ENT examination, and underwent tympanometry, transient-evoked otoacoustic emissions (TEOAEs), and automated ABR (a-ABR). Detailed past medical and family history were also taken.

Children failing the initial assessment were subsequently subjected to TEOAEs, click-evoked ABR, and mixed-modulation ASSR testing (90 Hz-sleeping child default mode) under sedation with 4% chloral hydrate (1mg/kg, max dose 1.5mg/kg), or hydroxyzine hydrochloride 10mg/5ml (for older children and under the guidance of a Pediatrician). Children with mild to moderate hearing loss were fitted with bilateral hearing aids, and were referred for speech and occupational therapy. The children were re-evaluated after three to six months.

Children with severe to profound or deteriorating hearing loss also received CT and MRI scanning, and were referred for genetic testing for connexin-26. These children were also referred for multidisciplinary assessment by the various specialties of the cochlear implant program, and fitted with hearing aids as a three to six month trial.

Among the total population of tested children, five presented with significant discrepancies between ABR and ASSR testing. The general and audiological characteristics of these children are summarized in Table 1. Behavioral audiometry was considered either too difficult to be performed in these children, or its results were rendered unreliable, therefore hearing aid fitting was based on the information obtained by both ABR thresholds and ASSR-predicted audiograms. The ensuing linguistic progress did not necessitate cochlear implantation in any of these children at the end of the study period.

Discussion

It is widely accepted that age of hearing aid fitting and cochlear implantation is a significant factor for the development of speech perception and intelligibility in deaf children [7-11]. This reality coupled with a growing body of evidence which supports the provision of implants in very young children (12 months of age or even younger) [1, 2], the improved technology [12], and the enhanced awareness regarding the safety of cochlear implants in young children [13], has led to an increasing trend to shorten the time-lag of auditory access to spoken language for pediatric cochlear implant candidates.

Nevertheless, hearing aid fitting in pediatric cochlear implant candidates for a trial period of 3 to 6 months is still commonly exercised in many implant programs, despite being frequently fraught with difficulty. This approach appears mandatory for children presenting with bilateral hearing loss between 65 and 85 dB, as findings of a recent study suggest that for severely deaf children, cochlear implantation results in an approximately 75% chance of improvement in hearing outcome, in comparison to bilateral hearing aid fitting. If such a chance of improvement is an acceptable probability of benefit for families and clinicians, then cochlear implantation could be considered, if the hearing-impaired child fails to demonstrate linguistic progress during the hearing aid trialing period [14]. Hence, following a hearing aid trial strategy the risk of an unnecessary implantation could be minimized, or the procedure itself postponed, should linguistic progress during the hearing aid trial period be demonstrated.

Drawing on the challenges of the hearing aid trialing practice, it should be noted that outcome measures of hearing amplification in infancy are usually considered as “soft”, as they are in the vast majority subjective, and often indirect (i.e. assessing parental views) [15, 16], or may even easily be reaching a ceiling effect in some cases [17]. Nevertheless, the development of communication in hearing impaired infants can be assessed by examining their preverbal communication skills [18]. These preverbal behaviors are the natural precursors of language development in all children, irrespective of their hearing status, and include appropriate eye contact, conversational-style turn-taking, autonomy and auditory awareness of the sound of speech [18]. They constitute the normal pattern of language development, which begins in early infancy. The Tait video analysis is a fine example of a methodology for the assessment of the preverbal communication in infants, and can be used to monitor the development of vocal and auditory preverbal skills in very young deaf children, who have been using acoustic hearing aids [19].

Hence, if we accept that we can assess the progress of amplified infants with an acceptable degree of certainty, despite the inherent limitations, the auditory behavior that we are monitoring presupposes appropriate bilateral hearing aid fitting. The latter may become very challenging in young children, or even in older children who are unreliable in behavioral audiometry, due to additional disabilities or limited cooperation. However, even this challenge could be addressed by using data from ABR and/or ASSR testing.

Taking into account the vague and non-frequency specific information obtained from click-ABRs, it becomes obvious that fitting attempts employing data from this testing method only may not address the hearing needs of amplified children, or even worse may mislead or cause unpleasant or even harmful hearing. Therefore, click-ABR should not be solely used to monitor children’s auditory/vocal preverbal progress, especially in cases where behavioral audiometry is unreliable. On the other hand, even though tone-burst evoked ABRs have been used to estimate the configuration of hearing loss in children, technical issues along with the time taken to record electrophysiological thresholds seem to limit their applicability [20]. Hence, hearing aid fitting should incorporate and take into account ASSR data, to ascertain the validity of the fitting and monitoring processes.

The paradigm which is conferred in the present case-series involves a subpopulation of hearing-impaired children, with significant discrepancies between ABR and ASSR testing, which may prove challenging for appropriate hearing aid fitting, when reliable behavioral audiometry could not be available. Drawing on case 3, the 70 dB ABR threshold waveform obtained, actually refers to the frequency of 4000 Hz only (Figures 1& 2), as the remaining frequencies appear to be normal or borderline. Fitting this child with a uniform 55-60 dB amplification in all frequencies is likely to result in intolerance towards the use of the hearing aids, with understandable hindering of the auditory/vocal progress of the child. And if this poses as a problem for a 2-year old child like case 3, the issue can be further perplexing in infants, due to the limitations mentioned above, and potentially compromise the validity of the monitoring process.

The notion that ASSRs may be a more accurate predictor of behavioral thresholds than ABRs in certain individuals with steeply sloping hearing losses, has also been previously supported by other investigators [21, 22]. ASSR thresholds can, hence, be used to predict the configuration of pure tone audiometry [23, 24], thus contributing to the appropriate bilateral hearing aid fitting in hard-of-hearing infants. However, the potential difference between pure-tone and ASSR thresholds in the hearing impaired population, which usually does not exceed 7 dB (± 5) depending on the frequency [25, 26], should also be taken into account, both during the fitting process, and in determining cochlear implant candidacy, as it can increase the “gray” area of the latter.

In conclusion, appropriate management of hearing impaired children should ensure that they will receive the maximum amount of auditory information during the critical periods for spoken language development, thus achieving age-appropriate spoken language skills, to the closest extent possible. Moreover, in the group of children who are under a hearing aid trial before cochlear implantation we must ensure that a reliable monitoring process is established. In order to achieve this, especially in children with unreliable behavioral audiometry, ASSR threshold-based bilateral hearing aid fitting is necessary to provide frequency-specific amplification of hearing, and appropriate propulsion in the prelinguistic vocalizations of monitored infants.

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Tables

Table 1

General and audiological characteristics of children presenting with significant discrepancies between ABR and ASSR testing

Number	*Age*[a]	*OAEs (R)*	*OAEs (L)*	*ABR*[b] *(R)*	*ABR*[b] *(L)*	*ASSR*[b, c] *(R)*				*ASSR*[b, c] *(L)*				*Remarks*
						500	1000	2000	4000	500	1000	2000	4000	
1	5	n.a.	n.a.	50	80	40	10	25	20	80	65	60	65	the child had received iv ABx for pneumonia
2	2.5	fail	Fail	60	60	30	40	40	40	30	35	45	40	the child has sisters with SNHL
3	2	n.a.	n.a.	70	70	25	15	35	70	20	20	30	65	the child had hyperbilirubinemia and was admitted in NICU
4	5	fail	Fail	40	50	35	45	60	55	75	65	80	55	the child had lower limb hypotonia/increased white matter signal
5	3.7	fail	Fail	60	80	35	15	20	10	90	90	90	90	one member with pediatric SNHL in the maternal family

Abbreviations: n.a.: not available, ABx: antibiotics, SNHL: Sensorineural Hearing Loss, NICU: Neonatal Intensive Care Unit

[a]in years, [b]in dB hearing level, [c]tested frequencies in Hz

Figure legends

Figure 1

ABR thresholds of child Nº 3(see also Table 1). Wave Nº V is clearly identified at 70 dB hearing level.

Figure 2

ASSR-predicted audiogram of child Nº 3 (see also Table 1). The difference with the ABR thresholds is clearly demonstrated (numbers at the bottom part of the figure refer to % probability to hear at the corresponding hearing level).

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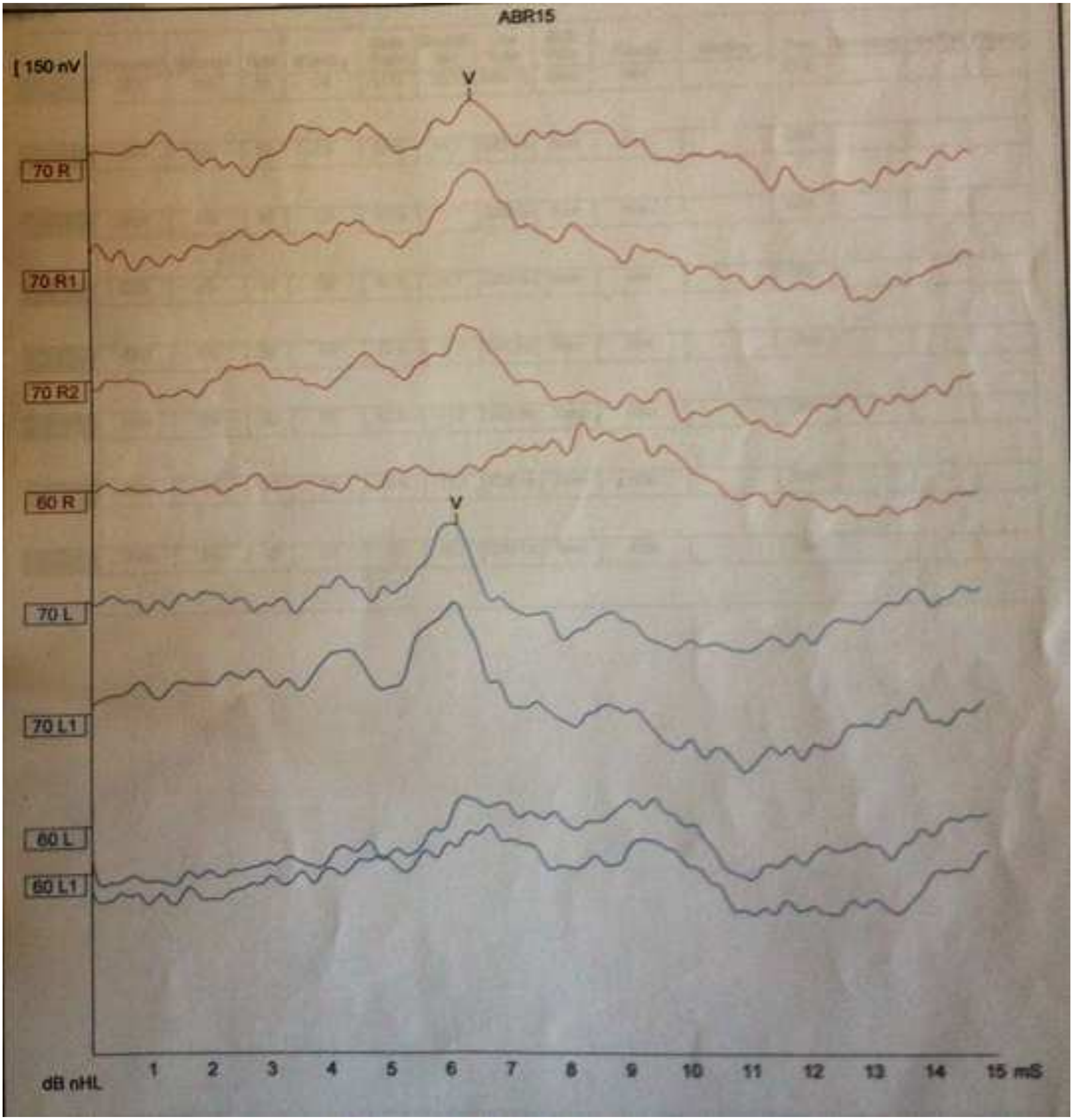

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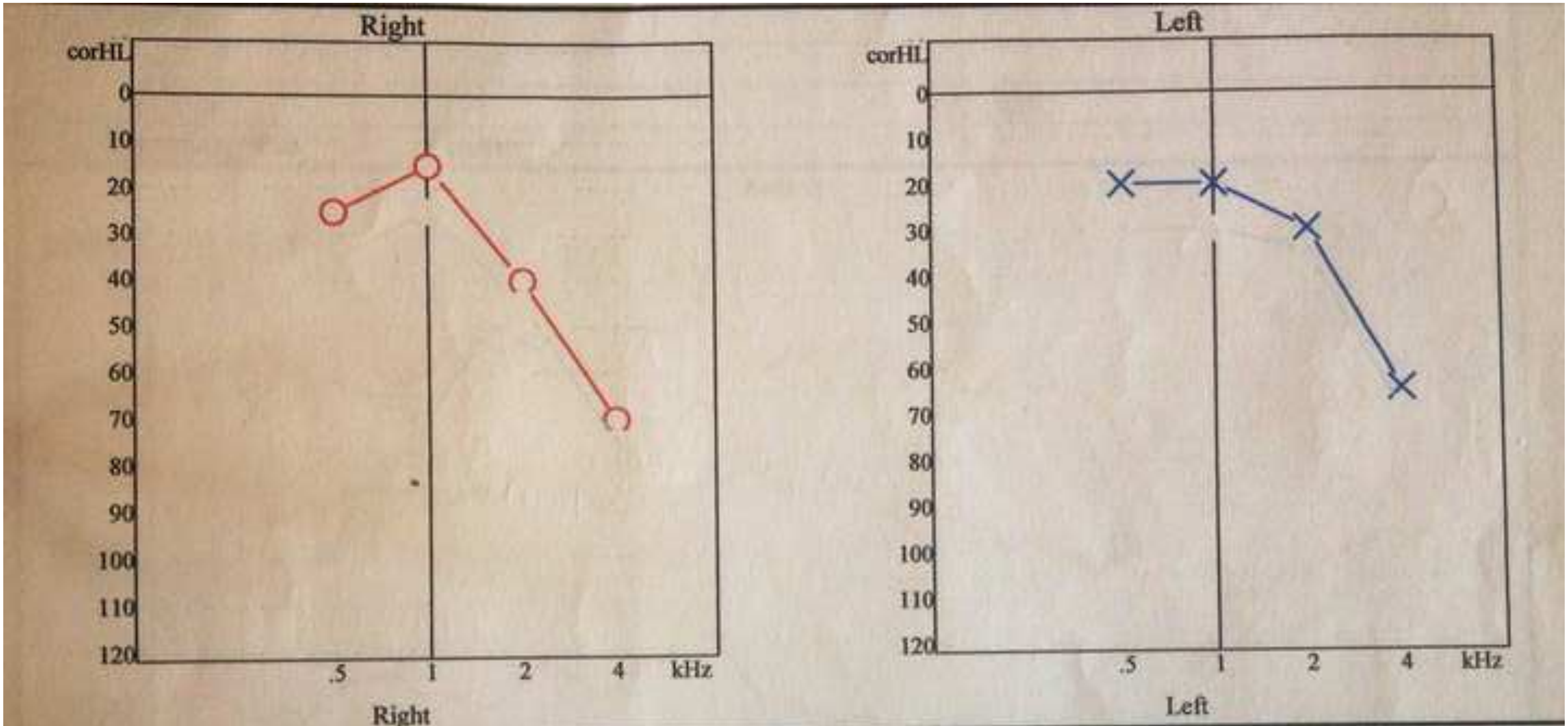

Right

25	87	100		
30				
35	100	100	27	
40			45	
45	100	100	100	
55	100	100	100	18
60				20
65	100	100	100	12
70				79
75				100

Left

25				
30	100	100	48	28
35			100	
40	100	100	100	12
45				
55				
60				9
65				89
70				100
75				