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SARA BARBOSA BAGANHA

Asymmetric Sensorineural Hearing Loss in Children: progression and involvement of the contralateral ear

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PROFESSOR DOUTOR ANTÓNIO CARLOS EVA MIGUÉIS

MESTRE TATIANA CARINA ANTUNES MARQUES

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ASYMMETRIC SENSORINEURAL HEARING LOSS IN CHILDREN: PROGRESSION AND INVOLVEMENT OF THE CONTRALATERAL EAR

Artigo Científico Original

Autores:
Sara Barbosa Baganha[1]
Tatiana Carina Antunes Marques[2]
António Carlos Eva Miguéis[3]

[1] Aluna do 6º ano do Mestrado Integrado em Medicina
Faculdade de Medicina, Universidade de Coimbra, Portugal
baganha.sara@gmail.com

[2] Departamento de Audiologia, Fisioterapia e Saúde Ambiental, Escola Superior de Tecnologia da Saúde de Coimbra, Instituto Politécnico de Coimbra, Coimbra, Portugal
tatiana.marques@estescoimbra.pt

[3] Clínica Universitária de Otorrinolaringologia, Faculdade de Medicina, Universidade de Coimbra, Coimbra, Portugal
amigueis@fmed.uc.pt

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ABSTRACT

Objective: Sensorineural hearing loss (SNHL) has a profound negative impact on children's lives. This study aims to examine the progression of asymmetric sensorineural hearing loss in children, according to the baseline hearing thresholds in the worst ear and to the technological level of the hearing aid fitted.

Methods: Eighteen children with asymmetric SNHL fitted with a nonlinear hearing aid for more than 2 years were selected for this retrospective study. The participants were interviewed and submitted to a pure tone audiogram at the age of 5 years (T0) and again at the age of 10 years (T1), performed as part of the usual medical follow-up. Children were divided into 3 groups, according to the technological level of the hearing aid fitted: low, middle, advanced.

Results: There were 3 cases of unilateral SNHL and 15 cases of bilateral asymmetric SNHL. A positive Pearson correlation was established between the hearing thresholds in the worst ear at T0 and in the best ear at T1: weak at 1kHz, moderate at 0.25kHz and at 2kHz, and strong at 4kHz. A Wilcoxon test for paired samples showed that in the worst ear there is no significant difference between the hearing thresholds at T0 and T1 regardless of the technological level of the hearing aid fitted; however, even though not statistically significant, there is an improvement of the hearing thresholds in the worst ear in children fitted with technologically advanced hearing aids. In the best ear, a Wilcoxon test showed a statistically significant progression of the SNHL in children fitted with low technological level hearing aids.

Conclusions: This study shows that the baseline hearing thresholds in the worst ear influence the progression of the SNHL in the best ear over time, especially at high frequencies. Even though the results were not statistically significant, technologically advanced hearing aids led to a slower progression of the SNHL and to an improvement of the hearing thresholds over time in controlled laboratory conditions.

KEYWORDS: Child; Deafness; Sensorineural hearing loss; Unilateral hearing loss; Hearing aids.

RESUMO

Objetivo: A surdez neurossensorial (SNS) tem um profundo impacto negativo na vida das crianças. Este estudo tem como objetivo avaliar a progressão da SNS assimétrica na criança, de acordo com os limiares auditivos basais do pior ouvido e com a gama tecnológica do aparelho auditivo equipado.

Métodos: Dezoito crianças com SNS assimétrica reabilitadas com um aparelho auditivo não linear há pelo menos 2 anos foram selecionadas para este estudo retrospetivo. Os participantes foram entrevistados e submetidos a um Audiograma Tonal Simples aos 5 anos de idade (T0) e novamente aos 10 anos de idade (T1), realizados no âmbito do seguimento médico habitual. As crianças foram divididas em 3 grupos, de acordo com a gama tecnológica do aparelho auditivo utilizado: baixa, intermédia, avançada.

Resultados: Foram detetados 3 casos de SNS unilateral e 15 casos de SNS bilateral assimétrica. Foi estabelecida uma correlação de Pearson positiva entre os limiares auditivos do pior ouvido em T0 e do melhor ouvido em T1: fraca em 1kHz, moderada em 0.25kHz e em 2kHz, e forte em 4kHz. Um teste de Wilcoxon para amostras emparelhadas demonstrou que, no pior ouvido, não há diferença estatisticamente significativa entre os limiares auditivos em T0 e T1 independentemente da gama tecnológica do aparelho auditivo utilizado; contudo, apesar de não ser estatisticamente significativa, houve uma melhoria dos limiares auditivos do pior ouvido das crianças reabilitadas com um aparelho auditivo de gama avançada. No melhor ouvido, o teste de Wilcoxon revelou uma progressão estatisticamente significativa da SNS nas crianças reabilitadas com um aparelho auditivo de gama baixa.

Conclusão: Este estudo mostra que os limiares auditivos basais do pior ouvido influenciam a progressão da SNS no melhor ouvido ao longo do tempo, sobretudo em frequências elevadas. Apesar dos resultados não terem sido estatisticamente significativos, os aparelhos auditivos de gama avançada associaram-se a uma progressão mais lenta da SNS e a uma melhoria dos limiares auditivos em condições controladas.

PALAVRAS CHAVE: Criança; Surdez; Hipoacusia neurossensorial; Hipoacusia unilateral; Aparelhos auditivos.

INTRODUCTION

According to the 2020 report on deafness and hearing loss from the World Health Organization (WHO), more than 34 million children worldwide suffer from disabling hearing loss, which in 60% of the cases arises from preventable causes.[1] This inability is manifested by a delay in language acquisition and development[2,3], which reflects in a difficulty in communication and interaction with others and leads to poorer school performance and loneliness. As such, the diagnosis and early intervention of hearing loss are essential for the correct neurodevelopment of the child.

The implementation of the Universal Neonatal Hearing Screening (Rastreio Auditivo Neonatal Universal - RANU) in 2005[4] in Portugal, allowed the early detection of congenital deafness cases. However, acquired hearing loss continues to be diagnosed too late. Gouveia et al. (2018) showed that unilateral and bilateral asymmetric hearing losses are diagnosed later than symmetric bilateral hearing loss[5], especially if the symmetric bilateral hearing loss is of profound degree.

Furthermore, the auditory rehabilitation of asymmetric unilateral hearing loss was devalued for many years, since it was believed that the child's development would not be affected as long as the best ear was within the normal limits of audibility. However, the literature demonstrates that asymmetric hearing leads not only to the worsening of bilateral hearing[6,7], with a negative impact on sound localization[8] and perception[3,9], but also to the adaptation of the auditory pathway to privilege the ipsilateral cortex to the healthy or more functional ear[7]. Moreover, it has been reported that in 11% of the children who were initially diagnosed with unilateral sensorineural hearing loss, there was a progression to a bilateral hearing loss within a 5-year follow-up period.[10]

Sensorineural Hearing Loss (SNHL) is a condition caused by an abnormality in the inner ear or in the auditory nerve.[11] According to the American Academy of Otolaryngology - Head and Neck Surgery, asymmetric sensorineural deafness is defined as the existence of a difference greater than 15 dB HL in the frequencies of 0.5, 1, and 2 kHz, or greater than 20 dB HL in the frequencies of 3, 4, and 6 kHz. This can be caused either by unilateral hypoacusis, a unilateral hearing loss in which the best ear shows normal hearing thresholds, or by asymmetric hypoacusis, a spontaneous asymmetric bilateral hearing loss in which the best ear is also injured.[12]

Auditory rehabilitation through hearing aids is the most used method to compensate for hearing loss. The technological level of the hearing aid is defined by the complexity and sophistication of its features, such as the number of compression channels, the directional microphones system, the adaptation to the environment, and the noise reduction algorithms[13,14]. Technologically advanced hearing aids are increasingly more automatic and adaptative to changes in different listening environments[14] and possess some features such as binaural data streaming[14] and pinna effect stimulation[15] that are not available in low technological level hearing aids. When compared to unaided listening, hearing aids were efficient at improving speech understanding[14], reducing listening effort[14], and altering the three most important cues for sound localization: interaural time difference, interaural level difference, and monaural spectra[15]. When compared to low technological level hearing aids, the literature shows that technologically advanced hearing aids can improve hearing in controlled laboratory conditions in adults with SNHL.[13-15]

Despite the scientific advances made to date, there is still a lot we do not know regarding unilateral or bilateral asymmetric hearing loss in children. Thus, this study aims to examine if the hearing thresholds in the worst ear influence the progression rate of the hearing loss in the contralateral ear in children with unilateral or bilateral asymmetric sensorineural hearing loss and analyze if the technological level of the hearing aid fitted influences the progression rate of the hearing loss.

METHODS

This study was approved by the Ethics Committee of the Faculty of Medicine, University of Coimbra, Portugal in September 2020 (approval number 110/2020) and by the direction of OuviSonus – clínica de reabilitação auditiva (hearing rehabilitation clinic), located in Coimbra, Portugal. Parents or legal representatives of the minor participants gave written consent prior to their participation in the study, and no test was performed without consent of the participant. The procedures applied were carried out in accordance with the Declaration of Helsinki.[16]

To respond to the investigation questions, a convenience sample was selected by recruiting children between the age of 5 and 16 years who suffer from unilateral or bilateral asymmetric sensorineural hearing loss, based on audiometric findings, and who had regular follow-up appointments at OuviSonus – clínica de reabilitação auditiva between 01/10/2009 and 31/01/2021.

To be eligible for this study, children had to have normal otoscopy findings and to have been rehabilitated with a nonlinear hearing aid (Behind the Ear hearing aid from a single manufacturer). This hearing aid had to have been equipped for at least 2 years with a mean time of 6 hours of daily use, that was monitored through the processing algorithm built into the memory of the hearing aid. Only children with a significant tonal gain, defined as a hearing gain greater than 10 dB HL[17], were considered. We excluded data from children with neurological disorders or attention deficit hyperactivity disorder (ADHD) since these situations affect collaboration and condition the credibility of the results. Children with conductive or mixed hearing loss were also excluded from this study.

This retrospective study consisted of the analysis of data obtained from interviewing participants and analyzing 2 pure tone audiograms (PTA) performed prior to this study: a baseline PTA performed at the age of 5 years (referred to as PTA at T0) and a follow up PTA performed at the age of 10 years (referred to as PTA at T1). The age of 5 years was determined for the baseline audiogram as children are collaborative and able to complete the evaluation in one session. The audiometric examination evaluated air conduction and bone conduction in the frequencies of 0.25kHz, 0.5kHz, 1kHz, 2kHz, and 4kHz. The results from these audiograms were compared to assess the evolution of the hearing thresholds over time. The PTAs, performed as part of the usual medical follow-up, confirmed the sensorineural hearing loss by revealing an air-bone gap lower than 15 dB HL and corroborated the asymmetric hearing by showing the existence of a difference greater than 15 dB HL in the frequencies of 0.5, 1, and 2 kHz[12] between both ears. The PTA also allowed the categorization of the degree of hearing loss, according to the Audiometric Classification of Hearing Impairments from the International

Bureau for Audiophonology (BIAP). According to this classification, the hearing level can be classified in: normal or subnormal hearing (average tone loss below 20 dB HL), mild hearing loss (average tone loss between 21 and 40 dB HL), moderate hearing loss (average tone loss between 41 and 70 dB HL), severe hearing loss (average tone loss between 71 and 90 dB HL), very severe hearing loss (average tone loss between 91 and 119 dB HL), total hearing loss/cophosis (average tone loss over 120 dB HL).[18]

The participants were split into 3 groups according to the technological level of the hearing aid fitted: low technological level, middle technological level, and advanced technological level. The hearing thresholds at T0 and T1 in the best and worst ear were compared to evaluate the influence of the technological level on the progression of the hearing loss.

At last, data obtained were processed and a statistical analysis was performed. Shapiro-Wilk tests were performed to evaluate if the hearing thresholds follow a normal distribution.

A Pearson correlation was tested to determine if the baseline hearing thresholds influence the progression rate of the SNHL. A One-way ANOVA test was performed to determine if there was a significant difference on the average hearing thresholds at T0 in the best or in the worst ear between the 3 technology groups. Finally, a Wilcoxon test for paired samples was performed to examine the relation between the progression of the SNHL and the technological level of the hearing aid fitted.

RESULTS

Table 1 provides information about the characteristics of the 18 participants. As shown in Table 1, the prevalence of unilateral SNHL was 16,7% (3 cases) and the prevalence of bilateral asymmetric SNHL was 83,3% (15 cases). The age of onset of aural rehabilitation ranged from 2 to 12 years of age, with an average of 5,11 ± 3,14 years. Three patients started aural rehabilitation after the age of 10 years. As such, and because only PTAs performed at the ages of 5 and 10 were considered, data from these 3 patients were excluded when evaluating the effect of the hearing aid on the hearing thresholds over time.

Table 1: Characteristics of the sample.

Variable		**N (%) or Mean (std. deviation)**	**Min**	**Max**
Sex	Male	6 (33,3%)	-	-
	Female	12 (66,67%)	-	-
Birth weight (kg)		2,85 (0,46)	1,96	3,75
Gestational age (weeks)		38,33 (2,17)	34	41
Etiology	prematurity	3 (16,7%)	-	-
	ICU stay > 5 days	1 (5,6%)	-	-
	infection	4 (22,2%)	-	-
	ototoxicity	0 (0%)	-	-
	inner ear malformations	1 (5,6%)	-	-
	family history of HL	2 (11,1%)	-	-
	other	7 (38,9%)		
Age of onset	congenital	6 (33,3%)	-	-
	< 2 years	5 (27,8%)	-	-
	2 – 5 years	7 (38,9%)	-	-
Age of diagnosis of SNHL (years)		3,39 (1,09)	2	5
Average hearing thresholds (dB HL)	best ear	52,85 (31,39)	7,50	108,75
	worst ear	82,50 (22,26)	43,75	115,00
Type of hearing loss	unilateral right ear	1 (5,6%)	-	-
	unilateral left ear	2 (11,1%)	-	-
	asymmetric (worst ear: right)	7 (38,9%)	-	-
	asymmetric (worst ear: left)	8 (44,4%)	-	-
Age of onset of aural rehabilitation (years)		5,11 (3,14)	2	12

Abbreviations: ICU: Intensive Care Unit; std: standard

All participants had been rehabilitated with nonlinear hearing aids for more than 2 years (mean duration of rehabilitation: 9 ± 3,43 years; min: 3 years; max: 15 years) with an average daily use greater than 6 hours (mean average hours of daily use of hearing aid: 11,67 ± 3,25 hours; min: 6 hours; max: 17 hours) prior to the study and had a functional gain greater than 10 dB HL (mean: 40,78±16,49 dB HL; min: 16,25 dB HL; max: 66,25 dB HL).

Table 2 shows the characteristics of the 15 children rehabilitated with a hearing aid before the age of 10 years, according to the technological level of the hearing aid fitted. The age of onset of aural rehabilitation in these 15 children ranged from 2 to 5 years, with an average of 3,8±0,94 years.

Table 2: Characteristics of aural rehabilitation.

	Technological level of the hearing aid N (%) or Mean (standard deviation)		
Variable	Low	Middle	Advanced
N	5 (33,3%)	4 (26,7%)	6 (40%)
Age onset of rehabilitation (years)	4,4 (0,55)	3,75 (1,26)	3,33 (0,82)
Average hours daily use (hours)	12,6 (3,78)	11,83 (3,87)	10,86 (2,54)
Average functional gain (dB HL)	43,50 (18,59)	42,75 (7,06)	41,13 (21,14)

From these 15 children, all 3 participants who suffer from unilateral SNHL are rehabilitated unilaterally in the worst ear. From the 6 patients who suffer from asymmetric SNHL with worse hearing thresholds in the right ear, 3 are rehabilitated bilaterally, 1 is rehabilitated unilaterally in the right ear and 2 are rehabilitated unilaterally in the left (best) ear. From the 6 patients who suffer from asymmetric SNHL with worse hearing thresholds in the left ear, 4 are rehabilitated bilaterally, 1 is rehabilitated unilaterally in the left ear, and 1 is rehabilitated unilaterally in the right (best) ear.

Both the average hearing thresholds in the best and in the worst ear follow a normal distribution (p=0,187 and p=0,244, respectively). There was no significant difference on the average hearing thresholds at T0 in the best or in the worst ear between the 3 technology groups ($F(2,12)=0,681$; p=0,525 in the best ear and $F(2,12)=1,137$; p=0,353 in the worst ear).

Shapiro-Wilk tests were performed to examine the normal distribution of the hearing thresholds in the worst ear at T0 and in the best ear at T1 at the frequencies 250Hz, 500Hz, 1000Hz, 2000Hz, and 4000Hz. The hearing thresholds in the worst ear at T0 follow a normal distribution at all frequencies tested (p=0,919 at 0.25kHz, p=0,820 at 0.5kHz, p=0,253 at 1kHz, p=0,058 at 2kHz, p=0,066 at 4kHz). The hearing thresholds in the best ear at T1 follow a normal distribution at 0.25kHz (p=0,773), 0.5kHz (p=0,264), 1kHz (p=0,098), and 4kHz (p=0,292). The only frequency in which there was not a normal distribution was 2kHz in the best ear at T1 (p=0,024).

A Pearson correlation was tested between the hearing thresholds at T0 in the worst ear and the hearing thresholds at T1 in the best ear at the frequencies 0.25kHz, 0.5kHz, 1kHz, 2kHz and 4kHz (Table 3). The test proved that there is a correlation between the hearing thresholds in the worst ear and the progression of the hearing loss in the contralateral ear over time.

Table 3: Pearson correlation between hearing thresholds in worst ear at T0 and best ear at T1.

Frequency	R_P	p value
0.25kHz	**0,623**	**0,006**
0.5kHz	0,464	0,053
1kHz	**0,476**	**0,046**
2kHz	**0,524**	**0,026**
4kHz	**0,717**	**0,001**

After excluding the data from the 3 children rehabilitated after the age of 10, Shapiro-Wilk tests were performed to examine the normal distribution of the hearing thresholds at the frequencies tested at T0 and T1 in each ear:

- At T0
  - worst ear: **0,410** at 0.25kHz; **0,812** at 0.5kHz; **0,132** at 1kHz; **0,065** at 2kHz; **0,078** at 4kHz;
  - best ear: **0,208** at 0.25kHz; **0,148** at 0.5kHz; **0,274** at 1kHz; 0,033 at 2kHz; **0,260** at 4kHz;
- At T1
  - worst ear: **0,718** at 0.25kHz; **0,409** at 0.5kHz; **0,081** at 1kHz; **0,198** at 2kHz; 0,033 at 4kHz;
  - best ear: **0,691** at 0.25kHz; **0,222** at 0.5kHz; **0,055** at 1kHz; 0,015 at 2kHz; **0,135** at 4kHz.

A Wilcoxon test for paired samples was performed to evaluate a possible relation between the progression of the hearing thresholds in each ear at the frequencies 0.25kHz, 0.5kHz, 1kHz, 2kHz, and 4kHz and the technological level of the hearing aid fitted. In the worst ear, there is no significant difference in the hearing thresholds at any frequency relating to the technological level of the hearing aid (Table 4).

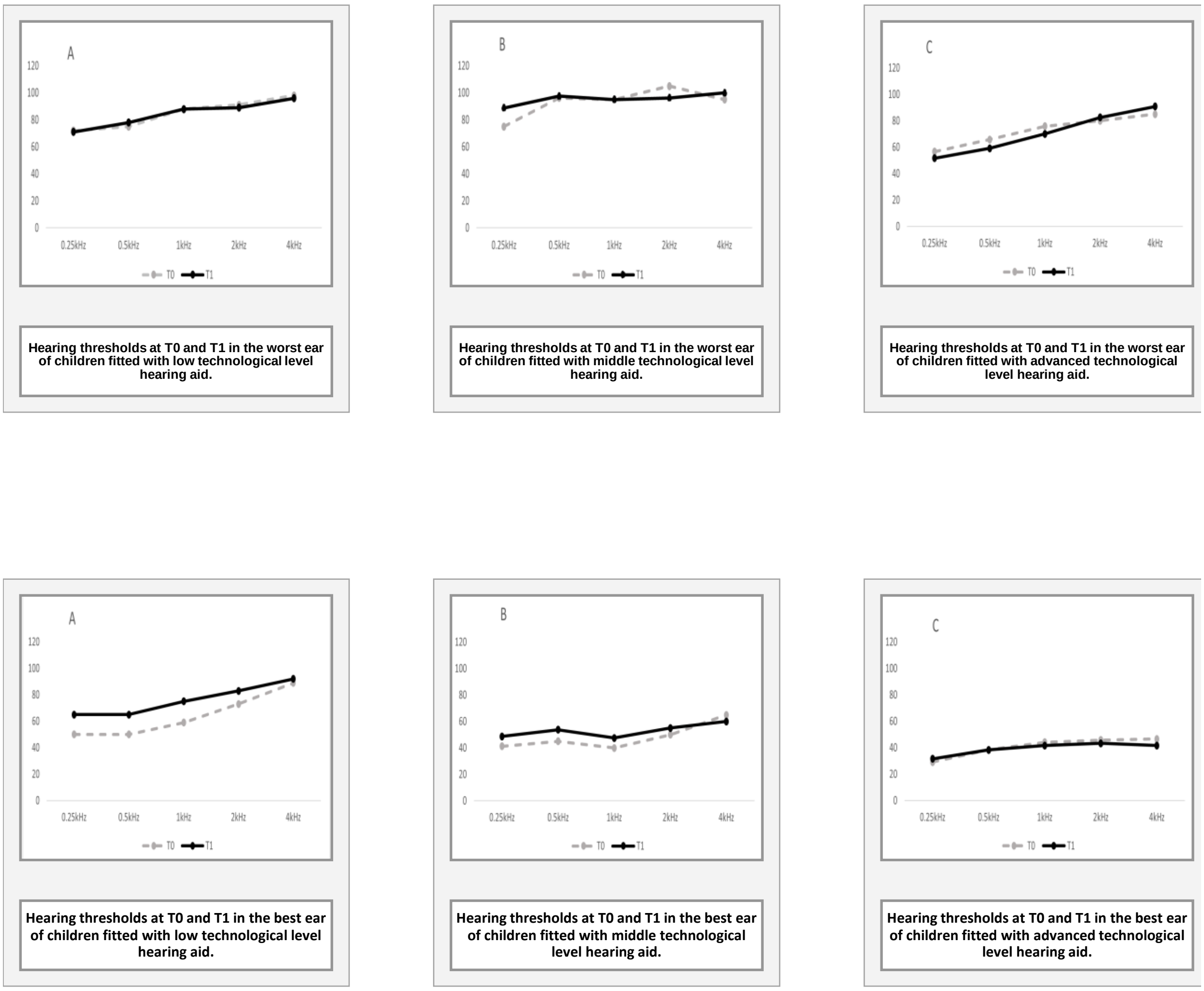
Table 4: Wilcoxon test for paired samples to evaluate hearing thresholds progression in the worst ear.

		Frequency				
		0.25kHz	**0.5kHz**	**1kHz**	**2kHz**	**4kHz**
Low technological level hearing aid	Z score	-0,447	-0,552	0,000	-0,412	-0,272
	p value	0,655	0,581	1,000	0,680	0,785
Middle technological level hearing aid	Z score	-0,730	-0,447	0,000	-1,069	-1,342
	p value	0,465	0,655	1,000	0,285	0,180
Advanced technological level hearing aid	Z score	-0,368	-0,447	-0,447	-1,342	-1,069
	p value	0,713	0,655	0,655	0,180	0,285

In the best ear, there is statistical significance in the hearing thresholds of children fitted with a low technological level hearing aid at the frequencies 0.5kHz, 1kHz, and 2kHz (Table 5). There is no statistical significance in children fitted with a low technological level hearing aid at the frequencies 0.25kHz or 4kHz. There is no statistical significance in the hearing thresholds in the best ear at any frequency in children fitted with a middle or advanced technological level hearing aid (Table 5).

Table 5: Wilcoxon test for paired samples to evaluate hearing thresholds progression in the best ear.

		Frequency				
		0.25kHz	**0.5kHz**	**1kHz**	**2kHz**	**4kHz**
Low technological level hearing aid	Z score	-1,826	**-2,032**	**-2,041**	**-2,041**	-0,816
	p value	0,068	**0,042**	**0,041**	**0,041**	0,414
Middle technological level hearing aid	Z score	1,069	-1,841	-1,604	-0,736	-1,134
	p value	0,285	0,066	0,109	0,461	0,257
Advanced technological level hearing aid	Z score	-1,134	0,000	-1,134	-0,184	-1,342
	p value	0,257	1,000	0,257	0,854	0,180



Hearing thresholds at T0 and T1 in the worst ear of children fitted with low technological level hearing aid.

Hearing thresholds at T0 and T1 in the worst ear of children fitted with middle technological level hearing aid.

Hearing thresholds at T0 and T1 in the worst ear of children fitted with advanced technological level hearing aid.

Hearing thresholds at T0 and T1 in the best ear of children fitted with low technological level hearing aid.

Hearing thresholds at T0 and T1 in the best ear of children fitted with middle technological level hearing aid.

Hearing thresholds at T0 and T1 in the best ear of children fitted with advanced technological level hearing aid.

Graphic 1: Hearing thresholds at T0 and T1 in the worst and best ear.

DISCUSSION

The results of this study are consistent with the findings of Haffey et al. (2013) on the devaluation of bilateral hearing rehabilitation on asymmetric hearing losses as it was believed that the child's development would not be affected as long as the best ear was within the normal limits of audibility.[7,10] From the 12 children diagnosed with asymmetric SNHL, only 7 were rehabilitated bilaterally. In this group of 12 children, 3 children were rehabilitated unilaterally in the best ear, which might indicate that the worst ear was severely damaged, and its rehabilitation would not result in any significant functional gain. These findings support Gordon et al. (2015) on the importance of an early diagnosis and bilateral intervention on bilateral asymmetric SNHL to avoid the progression to severe hearing loss[7] in early ages. The fact that 2 of the 12 children with asymmetric SNHL are rehabilitated unilaterally in the worst ear instead of being rehabilitated bilaterally legitimates that starting aural rehabilitation is a long and complex process for the family of the child, not only because it entails costs but also because it requires an acceptance and adaptation phase.

Even though the hearing thresholds in the best ear at T1 at 2kHz do not follow a normal distribution, parametric tests can still be used because of the normality in all the other frequencies tested. The positive correlation established between the hearing thresholds in the worst ear at T0 and in the best ear at T1 was weak at 1kHz ($0,3<R_P<0,5$), moderate at 0.25kHz and at 2kHz, ($0,5<R_P<0,7$), and strong at 4kHz ($0,7<R_P<0,9$).[19] These findings show that the baseline hearing thresholds in the worst ear influence the progression of the SNHL in the best ear over time, and that this dependence is stronger at 4kHz.

Despite the improvement not being statistically significant, children fitted with technologically advanced hearing aids had their hearing thresholds lowered in the worst ear at the 0.25kHz, 0.5kHz, and 1kHz frequencies after 5 years of hearing aid use.

In the best ear, the hearing thresholds of children fitted with technologically advanced hearing aids worsened slightly at 0.25kHz, remained unchanged at 0.5kHz and lowered at the 1kHz, 2kHz, and 4kHz frequencies after 5 years of hearing aid use. In contrast, children fitted with low technological level hearing aids had a statistically significant progression of the SNHL over 5 years at the 0.5kHz, 1kHz, and 2kHz frequencies.

Technologically advanced hearing aids are helpful to improve speech understanding[14] and sound localization[15] and are therefore more cost-effective in less severe cases of SNHL. This can explain why they are associated with not only a slower progression of the hearing loss but also with an improvement of the hearing thresholds over time in both ears. However, it is worth mentioning that the hearing improvement in controlled laboratory conditions does not ensure improvement in daily activities, as studies concluded that low and advanced technological level hearing aids provide equivalent improvement in speech understanding[14] and sound localization[15] in adults when the patient faces real world challenges.

However, in severe cases of SNHL the main therapeutic goal is to improve general hearing and patients might not benefit from the premium features that technologically advanced hearing aids offer, making them less cost-effective. For this reason, severe cases of SNHL are more commonly rehabilitated with low technological level hearing aids. Furthermore, the pathological process is harder to reverse in these cases, and a progression of the hearing loss is expected in both ears. This justifies the statistically significant worsening of the hearing thresholds over time at 0.25kHz, 0.5kHz, and 1kHz in the best ear of children fitted with low technological level hearing aids.

CONCLUSION

This study concludes that the baseline hearing thresholds in the affected ear in unilateral SNHL or in the worst ear in bilateral SNHL influence the progression rate of the hearing loss in the contralateral ear, especially at high frequencies.

Moreover, advanced technological level hearing aids were associated with a slower progression of the hearing loss and with an improvement of the hearing thresholds at some frequencies after a 5-year follow-up period, when tested in controlled laboratory conditions. However, the improvement might not be perceived by the patient when facing daily life challenges. Unfortunately, the literature on the impact of rehabilitation with different technological level hearing aids on children's lives is scarce.

Furthermore, this study shows that some children with bilateral SNHL are rehabilitated unilaterally, even after 3 years of aural rehabilitation. This finding reinforces the importance of the doctor-patient relationship to understand what has delayed the fitting of the second hearing aid and how those fears and obstacles can be overcome.

LIMITATIONS

The data collection process was severely affected by the pandemic caused by SARS-CoV2, as the participants' follow-up appointments were suspended for several months and some possible participants missed their appointments because of Covid19 restrictions. Moreover, the inclusion criteria of this study were strict to avoid bias. Consequently, the design of the study had to be slightly altered and the final number of participants was lower than expected.

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