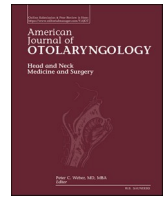




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Health-related quality of life perspectives of cochlear implanted children, their hearing peers, and their parents: a prospective case-control study

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ABSTRACT

Background: Hearing loss is one of the most common sensory alterations in humans. Cochlear implants in children provide significant benefits from a clinical point of view. However, the benefits in the health-related quality of life have been seldom studied.

Objective: To assess whether the health-related quality of life of 5-18 old children with cochlear implants, as measured with the PedsQL pediatric quality of life questionnaire version 4.0, is comparable with the perception of their parents/caregivers.

Design: Prospective, observational, cross-sectional and analytical study.

Setting(s): Hearing loss Unit of the Hospital Universitario Insular Materno-Infantil (Mother and Child University Hospital), León y Castillo Infant and Primary Education Center and La Minilla Secondary Education Institute.

Participants: 140 pediatric subjects (108 with cochlear implants, 32 hearing) plus one of their parents or guardians.

Methods: The original and Spanish-validated PedsQL™ pediatric quality of life questionnaires version 4.0 were used.

Results: Cochlear implantation yielded statistically significant results in terms of physical functioning and psychosocial health in children of 5-18 years of age.

Conclusions: The health-related quality of life of cochlear implanted pediatric patients (5-18 years old) evaluated with the PedsQL™ pediatric quality of life questionnaire version 4.0, is comparable to the perception of their parents/caregivers.

What is already known:

- Untreated severe sensorineural hearing loss at an early age has a major impact on language development and quality of life.
- Cochlear implants are currently the only treatment shown to be effective in severe sensorineural hearing loss.

What this paper adds:

- Cochlear implant significantly impacts children's quality of life, beyond the widely known benefits derived from improved hearing.

- From a cost-benefit perspective, cochlear implant surgery is positive, since it provides children with a health-related quality of life similar to that of their normal-hearing peers.

1. Background

Hearing is one of the main physiological processes that enable humans to learn, and is important for the overall neuropsychological development of the individual [1]. Hearing loss is one of the most common sensory alterations in humans [2,3].

According to the definition of the World Health Organization,

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“quality of life” is a multidimensional concept that includes not only personal aspects such as health, autonomy, independence and satisfaction with life, but also aspects of the person’s environment, such as support networks, social services and others. It refers to the way individuals perceive their position in life based on the current cultural context and system of values [4,5].

The term “health-related quality of life (HRQoL)”, in turn, refers to patients’ perception of their disease, which also involves “non-medical” factors like their goals, personal expectations, family characteristics, and other conditions in their lives [6]. The main objective of using and measuring health-related quality of life parameters is to pursue interventions aimed at promoting the greatest possible wellbeing, and to provide a comprehensive and valid assessment of an individual’s or a group’s health status, and of the possible benefits/risks of the care provided to them [7,8].

It is now well established that cochlear implant is the only effective treatment for severe-profound sensorineural hearing loss. Currently, there is a growing interest in the use of specific tools designed to assess the impact of these implants on pediatric health-related quality of life, beyond clinical evaluation of hearing or spoken language outcomes [9,10].

The information obtained through health-related quality of life questionnaires, parents’ observations or implanted patients’ comments, may serve as guidance for health professionals to design post-cochlear implantation follow-up or potential interventions [10,11].

The Pediatric Quality of Life Inventory (PedsQL™) is a reliable and validated pediatric health-related quality of life measuring tool, that can be used in both healthy children and children with different conditions [12].

The aim of this study is to analyze and compare the perception of health-related quality of life of cochlear implanted subjects aged 5 to 18 years, their parents and their hearing peers.

2. Methods

Observational prospective analytical study including pediatric subjects (5-18 years of age) either cochlear implanted or normal hearing and one of their parents.

2.1. Participants

The sample included a total of 280 subjects: 140 pediatric subjects (108 cochlear implanted and 32 normal-hearing) and one parent per child. The pediatric subjects had to meet the following inclusion criteria:

- Age between 5 and 18 years.
- Normal hearing.
- Children with cochlear implants (unilateral implantation, simultaneous bilateral implantation or sequential bilateral implantation with interim implantation time ≤ 7 years), with full electrode insertion.
- Twelve-month or longer use of speech processor.

The exclusion criteria were:

- Subject or parent unable to attend the visit established for the study.
- Psychological, mental or any other additional disability that prevented the completion of the health-related quality of life questionnaire.

2.2. Data collection

The subjects’ data were recorded in an Excel database. Participating parents and children completed the PedsQL™ Pediatric Quality of Life questionnaire (version 4.0 –European Spanish) on the same day, although independently. The PedsQL™ questionnaire is designed to

measure the quality of life in the last four weeks, considering four scales: physical functioning, emotional functioning, social functioning, and school functioning [12].

Responses are scored from 0 to 4, with 0 = never, 1 = almost never, 2 = sometimes, 3 = often, and 4 = always. These elements can be transformed into a linear 0-100 scale as follows: 0 = 100; 1 = 75; 2 = 50; 3 = 25 and 4 = 0. The maximum possible health-related quality of life values in the emotional, social and school functioning scales is 500, while that of the psychosocial health scale (emotional and social functioning) is 800. Higher scores indicate better health-related quality of life. The score of a certain scale is not calculated unless $>50\%$ of the items in that scale have been completed. The mean result of the psychosocial health scale is calculated using the number of its items plus the number of completed items in the emotional, social and school functioning scales. The physical health score is the same than the physical functioning scale score. The mean total result was calculated as the sum of all items over the number of completed items in all scales.

2.3. Data analysis

The statistical analysis was carried out through descriptive, exploratory and inferential analytical techniques, using the IBM SPSS Statistics software for Windows v25.0. Categorical variables were expressed as absolute frequencies and percentages; numerical variables were expressed as mean and standard deviation, or median and interquartile range (IQR = P75-P25), depending on whether or not the criteria for data normality were met. Percentages were compared with the Chi-squared test, means were compared with the Student’s *t*-test and medians were compared with the Wilcoxon or the Mann-Whitney test (for dependent or independent samples as corresponding). For comparing means/medians from more than two groups, ANOVA or the non-parametric Kruskal-Wallis test for independent samples were used.

2.4. Human research ethics approvals

This study was approved by the Ethics Committee of our Hospital (ID Number 2022-256-1) and was conducted in accordance with the Declaration of Helsinki and the Standards of Good Clinical Practice [13,14]. The researchers informed the subjects and/or guardians about the risks and benefits of taking part in this study and all of them gave their consent before the start of their participation.

3. Results

A total of 140 children (108 cochlear implanted and 32 normal hearing) plus one parent per child (140) were included in the study. Pediatric participants were subdivided into age groups: 29 subjects (20.71 %) of 5-7 years of age, 43 (30.71 %) of 8-12 years, and 68 (48.58 %) of 13-18 years; 47.14 % of the pediatric subjects were male and 52.86 %, female; 20.71 % of implanted children had received unilateral devices while 56.43 % had received bilateral implants. Table 1 shows the age distribution of the pediatric subjects (implanted and hearing) and the distribution of implanted children per implant type.

An evaluation of the different dimensions of the PedsQL™ questionnaire showed that the parents of both implanted and hearing pediatric subjects had lower mean values than their children (Table 2).

Table 3 shows the scores of the domains “psychosocial health” (emotional and social functioning) and “total score”, where children, both implanted and control, show higher scores than the parents. Furthermore, implanted children show higher mean scores than hearing children in both psychosocial health and overall score (80.42 and 80.86 in implanted children versus 76.97 and 79.84 in hearing ones, respectively).

The comparison (with Student’s *T*-test) of scores in the different domains showed significant differences between implanted children and their parents in psychosocial health ($p = 0.002$) and total score ($p =$

Table 1

Distribution of implanted and hearing children per age-group, sex and implant type.

Age group (years)	Subjects with unilateral cochlear implant				Subjects with bilateral cochlear implant				Hearing subjects			
	Boy		Girl		Boy		Girl		Boy		Girl	
5-7	5	23.81 %	1	12.5 %	8	23.53 %	4	9.89 %	3	27.27 %	8	38.10 %
8-12	5	23.81 %	2	25.00 %	10	29.41 %	16	35.55 %	3	27.27 %	7	33.33 %
13-18	11	52.38 %	5	62.50 %	16	47.06 %	25	55.56 %	5	45.46 %	6	28.57 %
Total	21	100 %	8	100 %	34	100 %	45	100 %	11	100 %	21	100 %

Table 2

Distribution of implanted and hearing children and their parents in the different evaluated health-related quality of life dimensions.

			Physical functioning		Emotional functioning		Social functioning		School functioning	
Implanted	Parents n = 108	Minimum	20.00		25.00		0.00		0.00	
		Maximum	100.00		100.00		100.00		100.00	
		Mean	80.88		72.69		84.03		73.61	
		SD	19.73		18.30		20.13		23.17	
	Children n = 108	Minimum	25.00		12.50		41.67		33.33	
		Maximum	100.00		100.00		100.00		100.00	
		Mean	82.17		76.56		87.42		77.27	
		SD	16.71		19.71		16.49		18.90	
Hearing	Parents n = 32	Minimum	40.00		43.75		50.00		16.67	
		Maximum	100.00		100.00		100.00		100.00	
		Mean	86.56		68.75		86.20		67.19	
		SD	15.05		15.87		16.61		25.66	
	Children n = 32	Minimum	35.00		25.00		25.00		16.67	
		Maximum	100.00		100.00		100.00		100.00	
		Mean	88.44		69.73		88.02		76.18	
		SD	13.94		19.58		18.07		26.16	

Table 3

Psychosocial health and total score results of implanted and hearing children and their respective parents.

Implanted	Parents (n = 108)		Children (n = 108)	
	Psychosocial health	Total score	Psychosocial health	Total score
Minimum	34.72	37.19	34.72	38.54
Maximum	100.00	100.00	100.00	100.00
Mean	76.77	77.80	80.42	80.86
SD	17.53	16.84	15.06	14.46

Hearing	Parents (n = 32)		Children (n = 32)	
	Psychosocial health	Total score	Psychosocial health	Total score
Minimum	38.89	48.33	26.39	28.54
Maximum	100.00	100.00	100.00	100.00
Mean	74.05	77.17	76.97	79.84
SD	16.57	14.73	17.54	15.41

0.008), whereas no such differences were found between hearing children and their parents (Table 4).

4. Discussion

Recently, researchers from all over the world have taken a great interest in the definition of health and in the creation of tools that measure the different dimensions of the health-related quality of life, such as social health, mental health and physical health. Taking into account the definition of quality of life, it is appropriate that individuals, including children, have the opportunity to assess their quality of life and provide information about it. This requires tools validated for the pediatric population [4,5].

Table 4

Analysis of the questionnaire scales in the total sample.

	Scale	Inferior	Superior	Mean	SD	p*
Implanted	Physical functioning	1.82	4.41	1.30	16.33	0.411
	School functioning	0.21	7.53	3.66	20.29	0.063
	Psychosocial health	1.35	5.94	3.64	12.03	0.002
	Total score	0.80	5.32	3.06	11.84	0.008
Hearing	Physical functioning	5.16	8.91	1.87	19.50	0.590
	School functioning	1.61	13.60	5.99	21.09	0.118
	Psychosocial health	3.10	8.95	2.93	16.70	0.329
	Total score	2.75	8.08	2.67	15.02	0.323

* p value of Student's *t*-test.

Several studies have shown a positive effect of cochlear implants on children's health-related quality of life, not only in terms of communication and language acquisition, but also in psychosocial outcomes. Furthermore, parents were found to perceive an improvement in their children's quality of life, especially in communication and social relationships. These data are in line with our results, in which parents were objective in assessing the quality of life of their cochlear implanted children [15–18]. These results however, contrast with those of Alegre-de la Rosa and Villar-Angulo [19] who reported that the self-assessed quality-of-life of implanted children differed from their parents' perceptions [20].

Loy et al. [21] concluded in their study that: early cochlear implantation and prolonged use of the implant resulted in higher quality of life scores, implanted children had a similar quality of life than their hearing peers, and parents were reliable informants of their children's overall quality of life. These conclusions are in line with our finding that parents and children showed similar results in the evaluated health-related quality of life dimensions. Haukedal et al. [22] in a study using the generic Pediatric Quality of Life Inventory (health-related

quality of life) questionnaire, found that the quality-of-life perception of most of their cochlear implanted 5-13-year-old subjects was comparable to that of their hearing peers. This is in agreement with our PedsQL™ results of similar health-related quality of life perception in implanted versus hearing children.

In the social and school functioning domains, Haukedal et al. [22] found that implanted children expressed certain concerns, which consistent with the differences found in our psychosocial health and school functioning results.

Stacey et al. [23] and Yang et al. [24] in their studies demonstrated that pediatric cochlear implantation was associated with improvements in oral communication skills, as well as in some aspects of educational achievement, personal independence, social interaction, and other quality of life parameters. Their results are similar to ours, since we observed the greatest benefits in the psychosocial domain. Furthermore, as in the study by Suneel et al. [25] no differences were found in our results between children with different implant configurations of cochlear implant use (unilateral or bilateral).

4.1. Strengths and limitations of the study

4.1.1. Strengths

Having access to the entire sample at the Implanting Center, according to the inclusion criteria of the study.

Use of a reliable validated tool, the PedsQL™ Pediatric Quality of Life questionnaire, applicable to parents, healthy children and implanted children, which facilitates comparisons.

4.1.2. Limitations

Difficulty establishing collaboration between the research center and the different educational centers, in which the study participants were educated, in order to facilitate the collection of data.

5. Conclusions

Children with cochlear implants reported improvements in the dimensions of Physical Functioning and Psychosocial Health. However, no differences in total score were found between subjects with cochlear implants and subjects with normal hearing.

The cochlear implant configuration, namely unilateral or bilateral, was not a factor influencing the quality-of-life perception in cochlear implanted children. Parents proved to be objective in assessing their children's quality of life, with consistent results across the different analyzed dimensions.

CRediT authorship contribution statement

Debora d.P. Jiménez Montesdeoca: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft. **Juan C. Falcón González:** Conceptualization, Data curation, Formal analysis, Methodology, Resources, Supervision, Validation, Writing – review & editing. **Silvia A. Borkoski Barreiro:** Conceptualization, Formal analysis, Methodology, Project administration, Supervision, Validation, Writing – review & editing. **Angel M. Ramos Macías:** Project administration, Resources, Software, Supervision, Validation, Visualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence

the work reported in this paper.

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Data availability

The primary data set collected and analyzed in this study is available upon request to the corresponding author. Secondary data is not available due to ethical and privacy restrictions.

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