**ORIGINAL ARTICLE** 



# Non-Users and Limited Users of Cochlear Implants in Pediatric Patients: A Retrospective Cross-Sectional Study

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#### Abstract

To determine the prevalence of non-use and limited use of cochlear implants. To find out the reasons for the same. This study was carried out among the paediatric patients who underwent cochlear implantation under the SHP\* scheme in Civil Hospital, Ahmedabad between 2013 and 2020. Study Design: Retrospective cross-sectional study. Study Setting: Civil Hospital Ahmedabad. Sample Size: 150 paediatric patients. Patients were selected based on a random number generator. The data was collected through a telephonic interview based upon a preformed questionnaire. The study indicates that out of a total 150 participants, 109 (72.7%) used their cochlear implant regularly while 41 (27.3%) did not. Major issue faced by the participants was in the external device -damage to the device and monetary issues for its repair. The participants who have dropped the usage of their implants faced issues mostly after 2 years of usage. The age group of less than 3 years showed 15.6% of non-usage, while the age group of 3–6 years showed an increase to 34.5% of non-users. The age group of more than 6 years showed an even higher proportion (41.3%) of non-users. It is recommended that the government ensures the follow-up of the patients undergoing cochlear implantation for at least 2 years after the surgery. The proportion of non-users in the consecutive increasing age groups saw a rise in number. Therefore, it is recommended to divert the resources towards lower age groups to facilitate a better outcome.

Keywords Cochlear implant · Cross-sectional · RBSK · Non-use/limited use · Congenital deafness · SHP · External device

## Introduction

A cochlear implant is an electronic device that can provide useful hearing and improved communication abilities for people who have severe to profound sensorineural hearing loss and who cannot benefit from hearing aids [1].

As per WHO estimates, in India, there are approximately 63 million people, who are suffering from Significant Auditory Impairment; this places the estimated prevalence at 6.3% in Indian population [2].

Development of speech can only be possible when optimum skill for hearing is ensured. The child born with congenital deafness cannot achieve optimum development due to undeveloped hearing skill. The only treatment for the

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congenital deafness is cochlear implant surgery. Most of the parents are unable to take this treatment due to high cost and due to lack of treatment. As a result, the child permanently becomes deaf and dumb.

Ministry of Health and family welfare started "Screening of congenital deafness" program for providing quality and timely treatment for such children. The state of Gujarat provides free cochlear implant surgery and speech therapy in such cases, irrespective of socio-economical level. The implant and speech therapies are given free of cost to any child under 6 years of age who is having profound congenital deafness.

Screening of new born at delivery points, both government as well as private, with the help of Indian Association of Paediatrics, FOGSI and RBSK Mobile Health Teams. Primary screening of congenitally deaf child by RBSK Mobile Health Team at home, SNCU, DEIC and Aanganwadis. The suspected child is referred with Verified Referral Slip (Sandarbh card) to the hospitals for diagnosis by ENT specialist to rule out ear disease.

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The suspected cases of profound hearing loss found by SHRBSK Mobile Health Teams are referred to higher centres with a Referral Card. Monitoring is done through a special software developed in convergence with GERMIS. The District Team submits the details of the suspected cases in the Cochlear Implant Software and forwards it to tertiary care hospitals for further diagnosis. This enables paperless (digital) referral of the cases and parents/guardians do not need to carry the referral card or any other proof/document.

Diagnostic screening is carried out at DEIC, SNCU and empanelled hospitals. The overall management package includes screening, diagnosis, necessary investigations like CT SCAN, MRI BRAIN, BERA. Cochlear implant surgery and 100 speech therapy sessions are given free of cost [3].

Despite of all the efforts put in by the government, there are many possible reasons of non-compliance in the users of cochlear implants. The reasons vary depending on external or internal device issues, social issues or monetary issues.

Non-use and limited use of implants is a recognized phenomenon but there is little published in the literature. The majority of reports of non-use are anecdotal and isolated. As the cohort of cochlear implant recipients grows this may well be an unwelcome evolving phenomenon. It therefore becomes imperative to monitor instances of non-use and identify their antecedents [4].

## **Materials and Methods**

This cross-sectional study was carried out among the paediatric patients who underwent cochlear implantation under the School Health Programme (SHP) scheme in Civil Hospital, Ahmedabad. Study approval was taken from Institutional Ethics Committee of Civil Hospital Ahmedabad (CHA). Patients were enrolled as per inclusion criteria. The data was collected through a telephonic interview based upon a preformed questionnaire and all the necessary information was collected and recorded.

*Study Design* Retrospective cross-sectional study. *Study Duration* Three months. *Study Site* Civil Hospital Ahmedabad. *Sample Size* 150 paediatric patients.

## **Inclusion Criteria**

- 150 random patients who underwent cochlear implant surgeries from 2013 to 2020 in Civil Hospital, Ahmedabad.
- 2. All patients operated under School Health Programme scheme.

## **Exclusion Criteria**

(1) Unwilling to give informed consent.

#### **Patient Compliance**

Divided into regular users and non-regular users.

Non regular users are further divided into limited users and non-users.

*Limited users*- Duration of cochlear implant usage is further divided into less than 4 h and 4–8 h.

Non-users- No usage of cochlear implant.

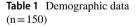
### **Data Collection**

The data was collected by contacting the patients or their guardians (if unavailable) in the paediatric age group with their cochlear implantation done under the SHP scheme at Civil Hospital Ahmedabad. It was performed solely on the basis of telephonic interview. Proper consent was taken before collecting the data. The data was collected during a single instance when the participant agreed to enrol in the study. All the information of the participants is kept confidential.

The participants were selected using a random number generator to avoid selection bias. The conversation was done in the vernacular language or whichever language the participant was comfortable with. The study was continued until 150 satisfactory results were obtained so that the objectives of this study can be met successfully.

#### **Data Analysis and Statistics**

The data was entered in Microsoft Excel Sheet. Percentage of responses were calculated for each question. The questions which had yes/no answers are represented in the form of pie charts, while the participant data is represented in the form of bar charts (Table 1).



63 (42%)
58 (38.6%)
29 (19.3%)
84 (56%)
66 (44%)

Table 2Usage of cochlearimplant (n = $150$ )	Do you use your cochlean implant? (n = 150)	
	Yes 72.99	% (109)
	No 27.39	% (41)
<b>Table 3</b> Duration of usage of cochlear implant per day (n = 109) <b>Table 4</b> Reasons for non-usage (n = 41)	How long is the device us per day? $(n=109)$	sed
	4–8 Hours 8.3%	(9)
	All the time 91.7%	% (100)
	External device issues	38
	Social/financial issues	6
	Internal device issues	3
	Others	2
Table 5External device issues $(n = 38)$	External device issues (n	=38)
	External device issues (n Damage and monetary issues for repair	=38)
	Damage and monetary	
	Damage and monetary issues for repair	27

## Results

Table 2 indicates that out of a total 150 participants, 109 (72.7%) used their cochlear implant regularly while 41 (27.3%) did not.

According to Table 3, 0 (0%) participants used their implants for < 4 h, 9 (8.3%) participants used their implants for 4–8 h and 100 (91.7%) used their implants for all the time.

Table 4 indicates the reasons for not using the device. Major issue faced by the participants was in the external device.

Table 5 indicates the different external device issues faced by the participants. Damage to the device and monetary issues for its repair was the major problem faced by the participants. Other problems include lost device and battery problems.

Internal device issues are rare. The issues include skin or local infection, Explant, decreased hearing and damage of device.

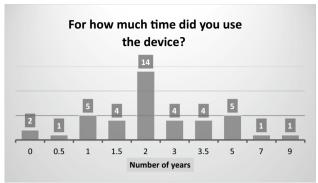


Fig. 1 Time of effective device usage (n=41)

If patient using disability certificate? $(n = 150)$		
Yes	25.3% (38)	
No	74.7% (112)	
Purpose of disability certificate (n=38)		
School/college admissions	16	
Travel reservations	31	
Income tax	1	

Social/Financial issues include embarrassment or bullying, unavailability of parents/guardian for therapy, inconsolable crying of child.

According to Fig. 1, the time range for which the device was used before stopping the usage of the cochlear implant was from a few months to 9 years.

Table 6 indicates 25.3% participants used disability certificate and 74.7% participants did not.

Maximum usage of the disability certificate is done for travel reservations (31). It is also used for admission in educational institutions and sometimes for income tax.

According to Fig. 2, the proportion of non-users in the consecutive increasing age groups saw a rise in number.

# Discussion

This study was done among 150 participants who had undergone cochlear implantation under the RBSK scheme in Civil Hospital Ahmedabad within the time period of 2013–2020. The results indicate that 109 participants used their cochlear implant regularly while 41 did not. This shows that despite all the efforts put in by the government for the benefit of the people, a large proportion, that is, 27.3% of the beneficiaries have not been able to take the intended advantage of the scheme. Similar research have been done in the UK by J Ray et al. which showed 2.9% non/limited users in the

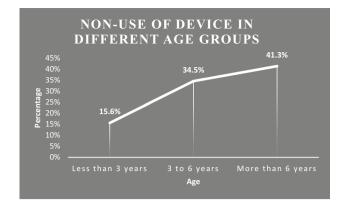


Fig. 2 Non-use of device in different age groups

paediatric age group [4]. While another study done in the UK by SM Archbold et al. showed 3% non-users [5]. This indicates the proportion of non-users in our study is relatively much higher.

The alarming rate of non-users can be attributed to various factors.

- 1) Quality of the government-issued devices
- 2) Monetary issues regarding its repair
- 3) Availability of the components of the device
- 4) Inadequate follow-up

In the past years, data on the post-operative outcomes following cochlear implantation have identified a wide spectrum of variables known to affect post-implantation performance. These variables relate to the device itself, including electrode design, speech processing strategies, and device reliability, as well as individual patient characteristics such as cochleo-vestibular anatomy, presence of associated disabilities, age at implantation, gender of candidate, hearing aid usage and the cause of deafness. Social and educational factors, such as mode of communication, parents/family expectations, demographical background of the patient, post implantation rehabilitation, and socio-economic status are additional variables shown to affect post-operative performance [6].

A total of 109 participants who used the cochlear implant, a majority (91.7%) of the participants used the device for all the time. They faced some issues ranging from very minor to none at all. The major issues faced by the non-users was of external device. Social issues like bullying, embarrassment, biased behaviour towards the patients also need to be addressed and accounted for a notable proportion of reasons of non-usage. Monetary issues for the repair of the external device prevailed among other minor reasons.

The participants who have dropped the usage of their implants faced issues mostly after 2 years of satisfactory

usage. Though the duration of proper and satisfactory usage ranged from as small as a few months to 9 years. There were 2 participants who had cerebral palsy and were not benefitted by the surgery.

It is well established that as there is an increment in the age group of patients undergoing the cochlear implantation surgeries, the benefit reaped from the procedure reduces drastically due to various reasons including the inability to develop proper speech. When these devices are used with children who are deafened early in life, the scope of the benefits are substantially broader due to the importance of audition in the acquisition of spoken language [7]. Blamey and colleagues reported that a group of children implanted at an average age of 3.2 years demonstrated speech production and language skills after three years of cochlear implant use that were similar to children with unaided pure tone average thresholds of 78 dB HL; this would place the paediatric implant users' performance above that of children in the gold hearing aid category in the prior studies. Thus, it appears that children implanted with newer technology and newer clinical practices (earlier age of implantation) may have better speech production outcomes [8]. The results of this study is in strong concordance of the above statement. The age group of less than 3 years showed a modest 15.6% of non-usage, while the age group of 3-6 years showed an alarming increase to 34.5% of non-users. The age group of more than 6 years showed an even higher proportion (41.3%)of non-users. This implies that on progressive increase in the age group, the benefit to investment ratio of the cochlear implantation surgery is adversely affected.

Numerous studies have concluded that prelingual deafened children who receive CI early (with or without CVM) will have better auditory and speech performance than children implanted at a later age [9, 10]. A study by Govaerts et al. [11]. showed that intervention before the age of 4 years seemed critical to avoid irreversible loss of auditory performance. Children who were implanted before the age of 2 years were shown to achieve optimal results, with 90% of them being able to get integrated into mainstream kindergarten and reach good CAP scores [12].

UDID card or Unique Disability Identity Card is an initiative by the Government of India used to issue UDID cards to any citizen of India with partial or complete disability with a view of creating a national database for PwDs. This aims to encourage transparency, efficiency and ease of delivering the government benefits to the person with disabilities. The disabilities included under this initiative are blindness, cerebral palsy, low vision, locomotor disability, leprosy-cured, mental retardation, mental illness and hearing impairment. Hearing impairment here is defined as loss of sixty decibels or more in the better ear in conversational range of frequencies. 25.3% of the participants in this study used disability certificate and 74.7% participants did not. Majority of the patients used the disability certificate to gain travel reservation benefits from government transport services. A substantial number of patients also used it to reap academic benefits from the government in the form of school/college admission. There needs to be a better-defined criterion for issuing disability certification for such implanted patients.

# Conclusion

There is a substantial proportion of participants who after cochlear implantation surgery are stopping the usage of the device. The duration of the proper usage is mostly around 2 years after which there are some issues faced by the participants. One of the main reasons is device malfunctioning. There is an increase in the proportion of non-users on progression of the age at which the surgery is done. It is also noticed that there are patients who have been using disability certificates and reaping their benefits even after undergoing a cochlear implant surgery.

It is recommended that the government ensures the follow-up of the patients undergoing cochlear implantation for at least 2 years after the surgery. Spending more on such costly devices and at a higher age for prelingual deafness cases leads to lesser compliance and hence misdirection of government resources. This leads to a substantial proportion of non-users despite all the efforts put in by the government. It is also recommended to divert the resources towards lower age groups to facilitate a better outcome. The government should also keep a check on the issuance of disability certificate to the people using cochlear implants.

We had a data of 700 patients but we have conducted this study on 150 random paediatric patients. On increasing the sample size, we can get a more realistic overview. Therefore, we are keen to continue this study. Also, there are very few such studies done, so there is a need of more such researches which can help address such issues and recommend positive reforms. Collaborative efforts of the authorities and the patients' parents/guardians will together help achieve good compliance of cochlear implants in the future.

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#### Declarations

Conflict of interest No any conflicts of interest involved.

**Ethical Approval** The following study has been done in compliance with the ethical standards. Reference number: EC/ Approval/33/2023/12/06/2023.

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