International Journal of Otorhinolaryngology and Head and Neck Surgery
Shishodia S et al. Int J Otorhinolaryngol Head Neck Surg. 2021 Aug;7(8):1297-1305
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20212898

Original Research Article

Round window versus conventional bony cochleostomy technique in pediatric cochlear implantation: a randomized controlled double blinded trial

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Received: 08 May 2021
Accepted: 16 June 2021

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ABSTRACT

Background: Objective of the study was to investigate the outcomes of cochlear implantation when done via two different techniques namely, the round window or the bony cochleostomy.
Methods: A single-center, double-blinded randomized controlled trial including forty prelingual, bilateral severe to profoundly deaf children less than six years from the year 2014 to 2016 in a tertiary referral center in India were randomly allocated to round window and bony cochleostomy group. Our primary outcome measures were intraoperative neural response telemetry levels, behavioral threshold (t) and comfortable (c) loudness levels. The secondary subjective outcomes were measured via the category of auditory performance (CAP) and the meaningful auditory integration scale (MAIS) score. The cases were followed up for 9 months.
Results: Intra-operative, electrically evoked compound action potentials (ECAP) showed comparable mean thresholds for both the techniques except intermediate electrodes (p~0.04) showed lower values for the round window. Similarly, a lower threshold (p~0.03) and comfortable mean current levels (p~0.03) were noticed for the round window group at 6 months post-implantation. Secondary speech perception outcome scores measured via category of auditory performance (CAP) and MAIS score were comparable.
Conclusions: The round window insertion technique has physiological benefit as compared to the bony cochleostomy as evidenced by better stimulation levels in the intermediate electrodes and lower mean threshold and comfortable levels in the round window with more beneficial peri-modiolar position of electrode arrays. However, comparable speech perception outcomes revealed no clinical benefit in the cochlear implant performance depending on the technique of electrode insertion.

Keywords: Cochlear implantation, Round window cochleostomy, Bony cochleostomy, Neural response telemetry

INTRODUCTION

Globally, approximately 1-6/1000 newborns suffer from profound prelingual deafness affecting their speech, communication, intellectual development thereby deteriorating their quality of life.[1,2] It can be categorized into two types, congenital and acquired. Congenital prelingual deafness is most commonly of non-syndromic, autosomal recessive type whereas acquired causes broadly includes prenatal infections (cytomegalovirus, herpes, rubella), administration of ototoxic medications, fetal distress, hyperbilirubinemia etc.[3,4]

Early detection and intervention are critical for the successful rehabilitation which is being enabled by universal neonatal hearing screening and timely referral for appropriate management.[5] The mainstay beneficial treatment for bilateral severe to profoundly deaf children and adults both who exhibit minimal benefit from the usage of hearing aids is Cochlear implantation (CI).[6] First pediatric cochlear implantation was performed in late 1980's only after receiving optimistic results and ensuring the safety of the procedure in the adults.[7]

Major factors deciding the post cochlear implantation outcomes are age at implantation, duration of use of Cochlear implant, preimplant hearing levels, and age of hearing aid use. These factors seem to affect the auditory speech recognition and intelligibility.[8]

Another significant factor affecting the postoperative outcome is the technique of cochlear implant electrode insertion which can be done either via bony promontory cochleostomy or the round window approach (RW).[9] Round window insertion (RWI) is considered less traumatic attributed to the requirement of less drilling making it a superior technique for hearing preservation.[10] Moreover, decreased acoustic trauma, minimal loss of perilymph, and reduced entry of bone dust into the scala tympani are some of the other advantages of round window approach.[11] However, difficult visualization, probability of its absence and variable anatomy are some of the limitations of this approach making it less desirable than expected.[10]

After electrode insertion, electrically evoked compound action potentials (ECAP) are measured with the help of neural response system which was developed by Cochlear ltd and the university of Zurich.[12] It is a non-invasive objective method which consists of sending an electrical signal to intracochlear electrode and recording the evoked action potential.[13] Telemetry results could be used as an indirect measure of intracochlear trauma thus can help in assessing which approach is better in preservation of residual hearing.[14] Other primary outcome parameters used for comparison were threshold (T) levels and maximum comfortable (C) current levels. Changes in behavior were measured in response to electrical stimuli for the estimation of T and C levels therefore making it difficult and challenging in young children as compared to adults.[15]

The postoperative speech perception scores were calculated using MAIS and CAP score. MAIS is a parental interview with 10 questions asked by the audiologist to evaluate the perception of sound by children in everyday life and their ability to understand the speech according to the parents. The results of this questionnaire are subjective and are meant to compare the child only to himself or herself as an indicator of progress.[16] Another tool introduced by O'Donoghue et al, in 1999 was category of auditory performance (CAP) score in which extent of auditory perception in terms of utility of auditory mechanisms to pursue day to day task is assessed.[17]

Although various studies comparing the electrode array insertion approaches in adult cochlear implantation has been performed but not much data is available in cases of pediatric population therefore, we are carrying out this study. The purpose of this study is to comprehensively analyze the neural response measurements, cochlear implant performance levels and behavioral levels post cochlear implantation to differentiate between the two techniques of electrode array insertion in the pediatric population.

METHODS

Study design and subjects

We conducted a double blinded, randomized controlled trial in the department of otorhinolaryngology in a tertiary referral center, in India which included forty children, up to six years of age with bilateral profound sensorineural hearing loss who underwent cochlear implantation from the year 2014 to 2016. All the participants were enrolled in the study according to the inclusion criteria and then were subjected to similar preoperative workup with detailed history and clinical examination followed by systematic audiological workup by battery of tests which included pure tone audiometry, free field audiometry, impedance audiometry, otoacoustic emissions, aided audiogram, brainstem evoked response audiometry and auditory steady state response. To rule out any anatomical abnormality and to confirm the status of the vestibulocochlear nerve and facial nerve detailed radiological evaluation was performed with the aid of high-resolution computed tomography of temporal bone and MRI brain with 3D reconstruction of the cochlea. After enrollment and obtaining informed consent from the parents of all the participants, simple randomization was done via computer generated number sequence and was contained in sequentially opaque envelopes to ensure blinding of the participants and the investigators. All the patients were allocated to two groups of twenty children each, out of which the former group underwent cochlear implantation via bony cochleostomy (BC) and the latter group via round window approach. Altogether all the participants were implanted by the team of two surgeons, unilaterally with straight array Cochlear™ Nucleus® implant which consists of 22 electrode arrays and was followed by intraoperative evaluation of neural response telemetry levels. Electrode insertion was complete in all the implantations which was confirmed by post implantation, modified Stenver's view of X-ray skull. For each individual, initial switch on was done at 21 days as the part of protocol.

Primary and secondary outcomes

We used nucleus cochlear implant which is a multichannel implant with 22 electrodes, and divided all the electrodes into three categories, 1st one being the basal (1-7) electrodes, 2nd group consisted of intermediate electrodes from 8 to 15, and the last group comprised of rest of the apical electrodes (16-22). This categorization was adopted as it divides the electrodes into high, mid and low frequency categories as measuring the value of each electrode individually was not feasible statistically.[18]

Primary objective outcomes calculated were intraoperative neural response telemetry levels, hearing threshold and maximum comfortable levels. Neural response telemetry levels were measured by using cochlear custom sound 4.0, an automated system for all the electrodes. Hearing threshold (t) levels and maximum comfortable (c) levels were noted using behavioral/ objective measures at 6 and 9 months. Intraoperative recordings were done in operation theatre after the complete electrode insertion into the cochlea and during the incision closure. Impedance levels and ECAP thresholds were measured but, in our study, we only recorded the ECAP levels for each electrode.

Secondary subjective outcomes were assessed by means of MAIS at 3, 6 and 9 months.

The protocol of the trial was approved by the human's ethic committee of the Ganga Ram institute for post-graduate medical education and research (GRIPMER) and was carried out according to the principles of declaration of Helsinki. The registration number of the trial in the Indian national board is 128-20147-141-200758.

Data was reported as per consolidated standards of reporting trials (CONSORT) statement, which is a twenty-five-item checklist which ensures the precision, transparency and wholeness of the study design.[19]

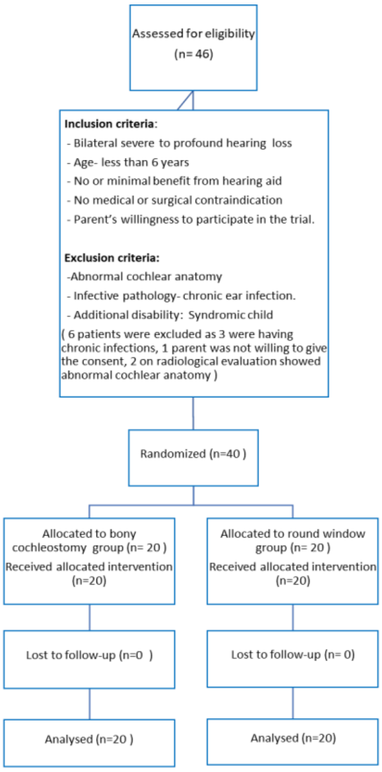

Figure 1: CONSORT flowchart for enrollment.

Sample size calculation

We defined a relevant difference of 20% in performance between two groups as per prior experience and using a two tailed alpha value (0.05), beta value (0.2) and a power of 80%, we calculated 60 observations per group for the detection of significant difference. Since the study was time bound and according to previous data, twenty participants per group were enrolled.

Statistical analysis

Statistical testing was conducted with the statistical package for the social science system version SPSS 22.0. Categorical variables (age and sex) were expressed as percentages and the continuous variables were presented as mean±standard deviation with minimum and maximum values if the data is unevenly distributed. The comparison of normally distributed continuous variables between the groups were performed using unpaired Student's t test. For all statistical tests, p value of less than 0.05 was taken to indicate the significant difference.

RESULTS

Subjects

Out of the all the participants, approximately half the patients were below 2 years of age (42.5%), eleven implanters were between 2-4 years (27.5%), and rest of the patients were implanted at the age of 4-6 years (30%). Details of technique wise age distribution has been further given below in Table 1. Sex distribution was equal with male to female ratio as 1:1. Basic patient's characteristics were similar (Table 1). Hearing competences were comparable in both the groups with severe to profound hearing loss bilaterally. All the patients were non syndromic with no medical or surgical contraindication. As better speech intelligibility is noted in right ear implantation when compared to left ear therefore most of the patients were implanted in right ear except three patients, out of which two had ossified cochlea in right ear and one had unclear anatomy.[20] These three patients were implanted in left ear (Table 1).

Enrollment and data completion

All the patients were enrolled after taking the informed consent from the parents of the respective children according to the inclusion and exclusion criteria and were tested under similar conditions. All the objective and subjective tests were performed by the single audiologist. We ensured the blinding of audiologist by not disclosing the technique of electrode insertion which was adopted while doing cochlear implantation. As all the patients were under the same center of rehabilitation affiliated to the hospital, no loss to follow up was noted and we were able to record the data up to 9 months. Follow up period of 9 months was chosen due to limited time as the research was a part of postgraduate degree completion and had to be completed by March 2016. Last patient enrolled in the study was implanted in June 2015 to give adequate time for follow up.

Bony cochleostomy versus round window

Primary objective outcomes

Intraoperative NRT levels

In all the group of electrodes the mean values of NRT thresholds were calculated and p value for estimating significant difference was measured by unpaired t test. Lower electrically evoked compound action potentials (ECAP) were noted in RW group in all the electrodes although significant difference (p~0.04) was specifically noted only in the intermediate group of electrodes. Another observation worth appreciating is the decrease in mean current values as we go from basal to apical electrodes irrespective of the technique of electrode insertion although it hasn't been calculated statistically in our study (Table 2).

Behavioral levels (threshold and comfort levels)

Statistical analysis of all the electrodes in both the groups showed lower mean values of both threshold (t) and comfort (c) levels in round window group (RW). Though significant difference with p=0.03 was noted in t and c levels at 6 months post implantation, nonetheless these differences became statistically insignificant at 9 months (Table 3 and 4).

Secondary subjective outcomes

We recorded the CAP scores and calculated the median scores for both the groups at 3, 6 and 9 months which were noted to be increasing as the duration of use of implant increases. On comparison of median CAP scores amongst both the groups by unpaired t test, comparable results were noted with p value more than 0.05 at all the times (p~0.58 at 3 months, p~0.41 at 6 months and p~1.00 at 9 months). At 9 months, mean CAP scores became 6.60 in both the categories with no difference at all (Table 5).

The MAIS score was calculated similarly as CAP scores at 3,6 and 9 months and showed similar pattern of increase in scores as post implantation follow up period increases. In BC category, mean MAIS score was 27.35 at 3 months, which increased to 37.30 at 6 months and became 40 at 9 months thereby reaching the highest possible score. Nevertheless, in RW group, MAIS score of 27.90 was noted at 3 months which further increase to 37.10 at 6 months followed by 39.50 at 9 months. However, on comparison of both groups, all the readings were statistically insignificant with p values of 0.82, 0.89 and 0.33 at 3, 6 and 9 months respectively (Table 6).

Table 1: Statistical comparison of intraoperative NRT levels between BC and RW.

Variables	BC (Mean current values)				RW (Mean current values)				P value (Unpaired t test)
	Mean	Mean±SD	Min	Max	Mean	Mean±SD	Min	Max	
NRT (electrode 1-8)	197.14	205.02	182.40	213	195.42	214.25	152	241	0.73
NRT (electrode 9-15)	188.33	200.27	165.57	218	180.89	191.45	149	196	0.04
NRT (electrode 16-22)	174.30	185.90	156.00	200	169.42	179.44	148	184.41	0.17

Table 2: Statistical comparison of threshold (t) levels between BC and RW.

Months	Bony cochleostomy				Round window				P value
	Mean	Mean±SD	Min	Max	Mean	Mean±SD	Min	Max	
t levels (6)	152.95	173.57	107.00	211.00	139.05	158.74	92.00	162.00	0.03
t level (9)	147.45	169.15	111.00	198.00	137.90	153.28	89.00	161.00	0.09

Table 3: Statistical comparison of maximum comfortable (c) levels between BC and RW.

Months	Bony cochleostomy				Round window				P value
	Mean	Mean±SD	Min	Max	Mean	Mean±SD	Min	Max	
c levels 6	152.95	168.88	143.00	223.00	139.05	160.70	136.00	203.00	0.03
c levels 9	182.50	199.25	136.00	203.00	174.85	192.42	129.00	200.00	0.15

Table 4: Statistical comparison of CAP scores between BC and RW.

Months	Bony cochleostomy				Round window				P Value
	Mean	Mean±SD	Min	Max	Mean	Mean±SD	Min	Max	
CAP (3)	3.30	4.52	1.00	5.00	3.10	4.07	1.00	6.00	0.58
CAP (6)	5.55	6.65	3.00	7.00	5.25	6.37	3.00	8.00	0.41
CAP (9)	6.60	7.28	5.00	7.00	6.60	7.20	5.00	7.00	1.00

Table 5: Statistical comparison of MAIS scores between BC and RW.

Months	Bony cochleostomy				Round window				P Value
	Mean	Mean±SD	Min	Max	Mean	Mean±SD	Min	Max	
MAIS (3)	27.35	35.30	10.00	40.00	27.90	35.45	10.00	40.00	0.82
MAIS (6)	37.30	42.16	25.00	40.00	37.10	41.33	28.00	40.00	0.89
MAIS (9)	40.00	40.00	40.00	40.00	39.50	41.74	30.00	40.00	0.33

DISCUSSION

Our study attempts to find the difference in the outcomes of cochlear implantation when done via two different techniques namely, the round window or the bony cochleostomy by measuring and analyzing the differences between the ECAP thresholds, behavioral levels and the speech perception scores in the children.

Assessment of both the approaches of electrode insertion is required as plenty of studies found RW insertion as the more advantageous technique in adults but lack of concrete evidence in pediatric group is apparent. Physiological, explanation given for this was the availability of increased length of spiral lamina for stimulation by electrodes as shown by the temporal bone dissection study.[11,22,23] Furthermore, it is considered more beneficial in residual hearing preservation due to less intracochlear trauma, decreased perilymph leak, and less bone dust entering in inner ear.[11,23] Thus, we did a comprehensive study to analyze the differences and how it influences the cochlear implant performance especially in children.

In all the patients straight array electrode was used and complete insertion was achieved. Our inclusion criteria included young children up to 6 years of age as numerous studies has suggested the importance of early age implantation and its role in achieving best speech and auditory outcomes.[8,24-26] Moreover, early implantation has been associated with improved quality of life and raised self-regard.[27,28] It has been illustrated that cochlear implantation before 3 years of age is associated with positive audiometric and speech outcomes.[29] Furthermore, comparatively inferior performance of cochlear implant was noticed when operated after 7 years of age due lack of spurt of growth which is usually exhibited before 2.5 years of age.[24] Another study showed that children benefits most from the implant when done before 6 years of age.[30] Nonetheless upper age limit of 6 years was chosen. Given the unequal age distribution in our study with nearly half of the patients below 2 years of age, we cannot deny its probable effect on the primary and secondary outcomes. All the participants with abnormal cochleovestibular anatomy were excluded due to the known difficulty in demonstrating suitable stimulation levels along with surgical difficulties and unpredictable cochlear anatomy.[31] Straight array Cochlear™ Nucleus® implant was implanted by the team of two surgeons. Due to the physical nature of surgical intervention, it was impossible to do blinding in surgeons hence possibility of performance bias might be present. Nevertheless, to avoid detection bias, investigators were blinded.

After electrode insertion we measured ECAP thresholds intraoperatively and mean current values of both the groups were calculated which showed decrease in mean threshold values as we go from basal to apical electrodes which could be associated with the smaller diameter at the apex, leading to convergence of the electrodes towards the spiral ganglion cells thus the lower NRT values.[32] Similar region specific NRT readings were found in another study which was reading the consequence of stylet removal on NRT.[33] When ECAP thresholds were compared between RW and BC, lower mean values were observed in RW however, statistically significant difference (p-0.043) was only noted in intermediate electrodes (9-15) as compared to another trial which found significant difference in ECAP values only in basal electrodes.[34] On the contrary, a study suggested no differences in the auditory nerve action potentials and insisted equal cochlear nerve stimulation in both the techniques but then inadequate sample size, poorly defined inclusion and exclusion criteria and weak study design with no randomization and blinding decreases the internal validity of this study.[18,35] Another factor contributing to lower electrical stimulation levels is the comparatively lower intracochlear basal trauma and more favorable peri-modiolar position in round window insertion.[23,36] Additionally, in RW, electrode enters scala tympani in more basal position leading to stimulation of basal neural fibers more effectively when compared.[22]

In RW insertion, the distances between the electrodes and neural elements are shorter and are in more proximity to modiolus as compared to BC due to which decreased threshold and comfortable levels are expected.[37,38] In our study, similar findings were observed with lower mean values of t and c levels for RW but statistically significant difference was only found at 6 months although it disappeared at 9 months. In addition, high intraoperative average NRT levels were followed by low T and C levels at 6 and 9 months which can be explained by the neural sensitivity repair and restoration of communication between matrix and electrodes immediately which can be as early as 24 hours post electrode insertion.[39] It has been found that T and C levels takes approximately 1 year to stabilize unfortunately due to shortage of time we could only follow up the patients for 9 months.[40] We did not determine the relationship of NRT with T and C levels as the part of research as plenty of studies have already showed the evidence of positive correlations between the two.[12,13,41] Another variable measured by some of the authors to differentiate between the two approaches was intra-operative electrically lower ESRT were measured in the RW group which means better the stimulation levels were noticed in the RW insertion corresponding to our study.[42]

Secondary subjective outcomes measured in the study were CAP score and MAISat 3, 6 and 9 months. We used CAP score for auditory performance measurement as it is easy to use, well validated tool with good test-retest repeatability.[43] The reliability and validity of MAIS has also been proved by a study done previously which showed the Cronbach's alpha coefficient more than 0.750.[44] The score of more than 0.7 is considered reliable.[45] However, use of MAIS is recommended only up to 4 years post cochlear implantation, after that probability of viewing ceiling effect is high as most of the participants show the best possible scores.[16,46] In our study, both the groups showed comparable cochlear implant performances as CAP and MAIS scores showed no statistical differences. Likewise, another study using consonant-nucleus-consonant test, Northwestern university children's perception of speech and hearing in noise test for comparing speech performance for both the approaches show comparable results.[47]

When CAP scores were observed over a period of time, they increased from 3.30 to 6.6 in BC and 3.10 to 6.6 in RW indicating that speech perception ability increases as duration of implant use increases irrespective of the electrode insertion technique. These findings could be confirmed by another study showing similar findings with median CAP scores increasing as post implantation time increases.[48]

MAIS score also increased implicitly from 27.35 at 3 months to 40 at 9 months in BC group and 27.9 at 3 months to 39.50 at 9 months in RW group. Another study using MAIS as a measure of cochlear implant performance in young children showed the rapid increase in MAIS score as the duration of implant use increases.[49]

Even though speech perception and understanding increases as evidenced by our findings and other studies supporting the evidence but when it comes to comparing the outcomes for both the technique, results were akin and showed no significant differences in outcomes after 9 months. Some studies calculated the speech perception scores with the follow up period of 1 year and as expected did not show any difference in their results.[50]

Some studies have been published which found bony cochleostomy electrode insertion technique accompanied by other factors like use of soft tissue for cochleostomy seal over fibrin glue and posterior tympanotomy over supra-meatal approach as more favorable for preservation of residual hearing.[51] Nonetheless numerous studies have showed the two techniques to be comparable in terms of telemetry findings, impedance of electrodes, speech perception, vestibular outcomes evaluated as per vestibular head impulse test and stapedial reflexes comparison.[42,53-55]

Certain radiological studies have also been carried out to answer this debatable question of which technique of insertion of electrode is better? One study showed the degree of displacement of electrodes from Scala vestibuli to Scala tympani which was found to be more in BC group when compared to RW insertions using a flat panel computed tomography scans therefore indicating RW as less traumatic technique.[55] Another retrospective cone beam computed tomographic evaluation showed no statistical difference in electrode-modiolus distance, insertion depth and angle.[56]

Strength and limitations

This trial has addressed a focused issue of finding out the better electrode insertion technique for pediatric population with clearly defined inclusion and exclusion criteria. Baseline characteristics were nearly equivalent in both the groups although age distribution was unequal with maximum patients under 2 years of age. Proper randomization and analysis of all the patients with minimal attrition bias was done. All the participant's guardians, investigators and audiologist were blinded, although blinding of surgeons was not possible. Performance bias cannot be ruled out due to two surgeons performing the implantation. All the patients were subjected to the same protocol starting from preoperative workup to postoperative rehabilitation except the electrode insertion technique was different. Some of the main limitations were smaller sample size as sixty patients were recommended as per the statistician but due to scarcity of time and previous experience in the trust, only forty patients were recruited in the study. This might increase the possibility of type 2 error.[57] We were able to follow up the patients only for 9 months and the follow up period of at least a year is suggested as it takes this much time for speech perception scores and threshold levels to stabilize, therefore we recommend longer follow up period for more reliable results.[40] Although we recorded the completion of electrode insertion, but depth and angle of insertion wasn't noted in this trial. Also, as only one of implant has been used for all the implantees, generalization of results for patients using other types of implants might be limited. Single center trials may show inappropriately larger treatment effect therefore in future multicenter trials are needed for more reliable and valid results.[58]

CONCLUSION

This study has shown lower ECAP thresholds in intermediate electrodes, lesser threshold levels and maximum comfortable levels at 6 months in round window group when compared to bony cochleostomy group suggesting physiological benefit of RW. However, comparable cochlear implant performance as shown by CAP and MAIS scores advocates minimal clinical benefit. Therefore, we recommend both the techniques of electrode insertion to be equivalent with no effect on the speech and hearing outcomes in children.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Shishodia S, Saurav D. Round window versus conventional bony cochleostomy technique in pediatric cochlear implantation; a randomized controlled double blinded trial. Int J Otorhinolaryngol Head Neck Surg 2021;7:1297-305.