An Evaluation of the Surgical Trauma to Intracochlear Structures After Insertion of Cochlear Implant Electrode Arrays: A Comparison by Round Window and Antero-Inferior Cochleostomy Techniques

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Received: 4 August 2016 / Accepted: 2 May 2017 / Published online: 5 May 2017
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Abstract To evaluate the extent of intracochlear damage by histologic assessment of cadaveric temporal bones after insertion of cochlear implants by: round window approach and cochleostomy approach. Cochlear implantation was performed by transmastoid facial recess approach in 10 human cadaveric temporal bones. In 5 temporal bones, electrode insertion was achieved by round window approach and in the remaining 5 bones, by cochleostomy approach. The bones were fixed, decalcified, sectioned and studied histologically. Grading of insertion trauma was assessed. In the round window insertion group, 2 bones had to be excluded from the study: one was damaged during handling with electrode extrusion and another bone did not show any demonstrable identifiable cochlear structure. Out of the 3 temporal bones, a total of 35 sections were examined: 24 demonstrated normal cochlea, 4 had basilar membrane bulging and 7 had fracture of bony spiral lamina. In the cochleostomy group, histology of 2 bones had to be discarded due to lack of any identifiable inner ear structures. Out of the 3 bones studied, 18 sections were examined: only 3 were normal, 4 sections had some bulge in spiral lamina and 11 had fracture of bony spiral lamina. The fracture of spiral lamina and bulge of basement membrane proportion is relatively higher if we perform

cochleostomy as compared to round window approach. Therefore, round window insertion is relatively less traumatic as compared to cochleostomy. However, our sample size was very small and a study with a larger sample is required to further validate these findings.

Keywords Cochlear implants · Round window · Electrodes

Introduction

Cochlear implantation is standard and established treatment for severe to profound hearing loss in both select pediatric and adult population. The electrode insertion techniques have been widely studied and standardized. There is a debate in literature regarding the exact placement of cochleostomy for insertion of cochlear implant arrays. The project was aimed to evaluate the extent of intracochlear damage by histologic assessment of cadaveric temporal bones after insertion of cochlear implants by two widely practiced methods of insertion: Round window approach and cochleostomy approach.

Methods

Ten human temporal bones were harvested from the unclaimed cadavers. Due permission was available from Medical Superintendent (No F.15/Misc/2013/Estt (H)). Institute ethics clearance was obtained. The harvesting was performed by standard techniques and monitored personally by project investigator and co-investigator. Bones were preserved in 10% formaldehyde solution. Each temporal bone was dissected in the Department of

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Fig. 1 End stage drilling demonstrating the cochleostomy

Fig. 2 The drilled and nibbled out temporal bone with cochlear implant electrode in place

Otolaryngology specialised temporal bone dissection lab under high power magnification. The standard cortical mastoidectomy was performed followed by facial recess exposure of middle ear. The anatomy of the temporal bone was preserved similar to that during live surgeries (transmastoid insertions to reproduce the normal operative surgical approach). The drilling was with adequate sized burr respecting the inner endosteum and removing it gently with pick to avoid any non electrode damage. The standard cochlear implantation was performed with Hi Focus 1 J Demonstration electrode. Standard insertion tool provided by company (Clarion insertion tool MMT-6111) was used to guide the electrode. All cochleostomies and electrode insertions were performed slowly and by single surgeon experienced in cochlear implant surgery (Fig. 1). 5 bones received the cochleostomy insertion (anterior to round window) and 5 received round window insertions. The electrode array was secured by bone cement at site of insertion. The bones were fixed and decalcified using EDTA. The decalcification process took time (almost 5 months) and was serially monitored by investigators. During the process of decalcification the excess unrequired components of temporal bones were nibbled or drilled out to facilitate focussed decalcification. The decalcification procedure was duly guided by Head, Department of Anatomy. The ultimate decalcification was completed and bones were nibbled and cochlea was drilled out atraumatically to facilitate the embedding (Fig. 2). The bones were embedded in paraffin and serially sectioned at a thickness of 20 microns. The sections were taken with electrode array in place but due to extremely thin sectioning, it was not possible to get the electrode array in sections. The slides were mounted and stained with H and E and studied. All slides were studied personally by principal and co-investigator. Grading of insertion trauma was assessed using scale from 0 to 4 [1].

Grade	Description
0	No trauma
1	Elevation of basilar membrane
2	Rupture of basilar membrane or spiral ligament
3	Dislocation into scala vestibule
4	Fracture of osseous spiral lamina or modiolar wall

Results

A total of 10 temporal bones were dissected. 5 bones received cochleostomy antero-inferior to round window and 5 bones received round window insertions. One of bones in round window group had electrode extrusion and handling damage so that was excluded from histological studying. All bones were gradually decalcified and embedded in paraffin. The bones were sectioned and multiple slides made (sectioning parallel to modiolus). Of 9 temporal bones, total of 113 slides were made and screened. Only the good quality slides demonstrating reasonable staining and demonstrable anatomy were selected. The grading of cochlear trauma was modified as electrode arrays could not be demonstrated in sections. Three grades of temporal bone trauma were used.

Grade 1: Normal (Fig. 3).

Grade 2: Bulge of basilar membrane (Fig. 4).

Grade 3: Fracture of osseous spiral lamina (Fig. 5).

Round Window: Group A

One of bones was not considered for result analysis as it was damaged in handling with electrode extrusion. 1 bone did not show any demonstrable identifiable cochlear structure so was excluded from the result analysis. Out of 3 temporal bones, total of 35 sections were examined. 24

Fig. 3 Sectioned and stained temporal bones demonstrating normal (asterisk represents scala vestibule, single arrow: basilar membrane and double arrow: Reissner's membrane)

Fig. 4 Sectioned and stained temporal bone showing distorted basilar membrane (arrow)

Fig. 5 Stained temporal bone section showing disruption of cochlear structures and fractured osseous spiral lamina

demonstrated normal cochlea, 4 had basilar membrane bulging and 7 had fracture of bony spiral lamina.

Cochleostomy: Group B

Histology of 2 bones had to be discarded due to lack of any identifiable inner ear structures. Out of 3 bones studied, 18 sections were examined. Only 3 were normal. 4 sections had some bulge in spiral lamina and 11 had fracture of bony spiral lamina. The results are summarized in Table 1.

Statistical Analysis

A 3×3 contingency table was framed taking 2 surgical approaches and damage groups as attributes (Table 1). Numbers were based on distribution of total number of slides that were seen. The empirical observation that could be drawn on basis of contingency table was that fracture of spiral lamina and bulge of basement membrane proportion is relatively higher if we perform cochleostomy. If we perform round window, greater number of normal findings were observed.

Discussion

Cochlear implantation is now established first line treatment of profound congenital sensorineural hearing loss and over these years its benefit has been extended to severe hearing loss. The treatment with cochlear implantation is now standard of care for prelingually deafened children and also in many adults with acquired deafness. The indications are fast expanding and internationally, the patients with residual hearing at some frequencies are being considered for cochlear implantation [2]. The idea behind implanting these patients is that these patients with high frequency hearing loss with preserved low frequency hearing can be effectively benefitted by electroacoustic stimulation. The basal cochlear turns being benefitted with the implant and low frequencies with preserved hearing can be amplified with hearing aids.

The cochlear implant design and surgical technique has traditionally been “hearing destroying” with significant damage to delicate intracochlear structures and fluids [3]. The scope and need of residual hearing preservation has however been realized in recent years. This has led to research and innovations in this field. The cochlear implant companies have evolved various hybrid designs and models that penetrate limited depth of cochlea and hence preserve the unpenetrated structures [4].

These hybrid designs have enabled low frequency preservation of hearing to large extent. Still the need for

Table 1 Grades of trauma in round window versus cochleostomy electrode insertion in our study

	Round window	Cochleostomy
Fracture of lamina	7 (20%)	11 (60%)
Bulge in basilar membrane	4 (10%)	4 (20%)
Normal	24 (70%)	3 (20%)
Total sections	35	18

near perfect surgical technique to prevent iatrogenic damage to delicate inner ear structures cannot be underestimated. Over the years, different surgical techniques have evolved to preserve the residual hearing loss in such patients.

In 1993 Lehnhardt described a technique which he termed ‘soft surgery’ to minimize traumatic access to the inner ear and permit insertion of electrode array with preservation of inner ear structures and their biological environment and function [5].

Scala tympani of cochlea is considered the preferred intracochlear compartment for multi electrode array implantations. This is because scala tympani insertions provide a closer and more direct access to excitable elements [6]. The best method of cochleostomy site that guides the implant electrode into scala tympani with minimum collateral damage is debated. The world literature provides debatable statistics on histological and clinical results after two techniques of insertion. Richard C et al. have suggested that implantation through the round window minimizes initial intracochlear trauma and subsequent new tissue formation, whereas the RW extension technique used at the time of these implantations produced the greatest damage. The authors have suggested future studies to clarify whether today’s techniques and electrodes will produce these same patterns of damage [7].

Our study is first of its kind to be conducted in the subcontinent and the ambitious methodology was aimed at answering the big question of superiority of round window versus cochleostomy. Although our results suggest round window approach to be less damaging to normal cochlear structures, the statistical bias of less number of cases exists.

Some earlier histologic and clinical studies, have recommended different sites around round window as preferred sites of implant insertion [8, 9]. The immense debate on the topic has further intensified over last couple of years and the topic of best site of insertion has continued to mark significant space in Otology, Neuro-otology and cochlear implant related journals. Various major prospective studies and systematic reviews have recently been published on the issue. Even 2 metaanalysis and systematic reviews have provided conflicting conclusions. In metaanalysis on Hearing preservation surgery in cochlear Implantation,

Santa Maria et al. [10] have suggested cochleostomy to be better than round window. The systematic review from Netherlands by Havenith et al. [11] however have concluded “no benefit of one approach over the other regarding preservation of residual hearing”.

India is having the 2nd largest population in the world and thus harbours large population of deaf. None of studies till now have been done to evaluate insertion related trauma in the Indian population. Indian skulls are morphologically different from Caucasian population. This study was planned to evaluate for any trauma to any inner structure and grade them according to grading system used in other similar studies. Many studies have been centred to evaluate this trauma but all these studies were performed in Caucasian race. It is known for a very long time that skulls of different human races have different morphology but none of the investigators till now have answered this question regarding trauma with insertion in any race other than Caucasian [12]. This study is focused on evaluating electrode insertion related trauma in the Indian population. Also, the study is aimed at answering the query regarding appropriate site for insertion of cochlear implant electrode array.

Conclusion

This study concludes that there is intracochlear trauma with cochlear implantation and trauma is more with cochleostomy than round window insertions. Further studies, both clinico radiological and histological, with larger sample size should be undertaken to further study this aspect.

Acknowledgements Authors sincerely acknowledge the funding received from Research section, AIIMS (Code: A-171) and thank Director, AIIMS, Dean and Subdean, research section, AIIMS.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving cadavers were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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