

Complications of Cochlear Implant Surgery: A Public Implant Centre Experience

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ABSTRACT

Objectives: To determine the prevalence of complications of cochlear implant surgery in children with congenital profound sensorineural hearing loss.

Methods: This study retrospectively & consecutively reviewed charts of children who underwent cochlear implantation from July 2015 to July 2019 at Cochlear Implant Centre of Otolaryngology Department of Capital Hospital, Islamabad Pakistan. These included cases of both genders aged one to 12 years operated at least one year before the time of data collection. Basic demographic data, complications including major and minor complications and treatment received was noted and statistically analyzed using SPSS-23. Results were presented using descriptive statistics.

Results: Current study included a sample of N=251 having a mean age of 4.05±2.15 years including 154(61.4%) males and 97(38.6%) females revealed a prevalence of complications of 16(6.4%) with 4(1.6%) major and 12(4.8%) minor complications. Wound infection and acute otitis media with frequency of 3(1.2%) each were the commonest complications, followed by , facial nerve twitching, tinnitus and vertigo, infection and extrusion; and device failure in 2(0.8%) each. However, there was no significant association of complications with age group and gender with P=0.344 and P=0.519 respectively.

Conclusion: Present public sector implant program is characterized with a very low prevalence of complications of 16(6.4%) with 4(1.6%) major and 12(4.8%) minor complications. Wound infection and acute otitis media were the commonest complications.

KEYWORDS: Cochlear Implantation, Complications, Hearing Loss, Prevalence.

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INTRODUCTION

Severe to Profound Hearing Loss has a prevalence of 6.7% in clinical population and 0.7% in general population as reported for United Kingdom's National Health Service clinic¹ and a

prevalence of 1.6 per 1000 cases with profound hearing loss alone has been reported from Pakistan.² Cochlear implantation is arguably the best possible option for non-serviceable sensorineural hearing loss (SNHL) with appropriate case selection having paramount importance.³ A big population is now receiving cochlear implants with 78% of deaf children receiving cochlear implants in Belgium alone⁴ and according to US Census 2000, there were 12,816 children aged 1 to six years eligible for cochlear implantation.⁵

In cases with severe or profound hearing loss (HL), quite a high prevalence of inner ear malformations (IEMs) of around 15 to 20% has been reported in a

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study.⁶ Though cochlear implantation in cases with IEMs has favorable surgical and speech results⁷ and is a safe procedure in experienced hands,⁸ however difficulties and intraoperative complications do occur.⁹ Complications ranging from pain, minor bleed, infection, breakdown of skin, facial palsy, taste changes, vertigo, cerebrospinal fluid leak, device failure as well as mal-placement, skull base and brain damage to complete deafness and death may occur.³ Hence knowledge of associated risks is very important since it is not a lifesaving procedure rather it is responsible for reduction of disability and hence significantly improves quality of life (QoL).¹⁰

Cochlear implant surgery started in Pakistan in the year 2000, in the private sector alone and the only available small published study gave a complication rate of 11.5% for private sector program.¹¹ With a high prevalence of congenital hearing loss in Pakistan,¹² dearth of local literature on the subject and recent development of cochlear implant facility in the public sector in Pakistan was the stimulus to conduct this study on a larger population hailing from all over the country with the objective determine the prevalence of complications of cochlear implant surgery in children with congenital profound sensorineural hearing loss.

This study is important since it will cover the local literature gap being the only study of its type in Pakistan and will be helpful in provision of reliable local data regarding complications of cochlear implantation in patients with congenital HL and planning of effective management strategies.

METHODS

This study retrospectively conducted chart reviews of children who consecutively underwent cochlear implantation for congenital sensorineural hearing loss, over a period of four years from July 2015 to July 2019. These included cases of both genders aged one to 12 years who were operated at Cochlear Implant Centre of Otolaryngology Department of Capital Hospital, Islamabad Pakistan. All cases were more than one year postoperative at the time of data collection, hence cases operated after 30th June 2019 were not included in the study. Basic demographic data, complications including major and minor complications and treatment received was noted.

Complication of Cochlear Implant surgery was labelled when there was any medical issue arising

due to the surgery, which was not expected, resulting in increased morbidity or mandating addition surgical procedure.¹³ Also these were classified as major when there was significant medical problem requiring removal of implant, re-exploration, facial nerve paralysis or paresis or other complication which was serious with continuous dysfunction or discomfort; while minor complications were those requiring no intervention or minor one, resolve by themselves, or easily overcome by little medical or audiologists management.¹⁴

Study was initiated after obtaining ethical approval of the research from Ethical Review Committee of Capital Hospital PGMI, Islamabad vide Registration No. 2020-03-003 dated 10th March, 2020. Following data collection, tabulation was done in Microsoft Excel and statistical analyzed performed using Statistical Package for Social Studies (SPSS) Version-23. Statistical analyzed were done using descriptive statistic including frequencies, percentages, mean, and standard deviation. Chi-square test was used for assessment of age and gender association. Data was further examined besides national and international literature and deductions made were finally discussed.

RESULTS

N=251 cases of cochlear implantations performed at this public Cochlear implant Centre from July 2015 to July 2019, were included in the study. With a mean age of 4.05±2.15 years, the study population comprised 154(61.4%) males and 97(38.6%) females. The prevalence of complications was 16(6.4%) (Fig.1).

Minor complications were predominant with frequency of 12(4.8%), followed by major

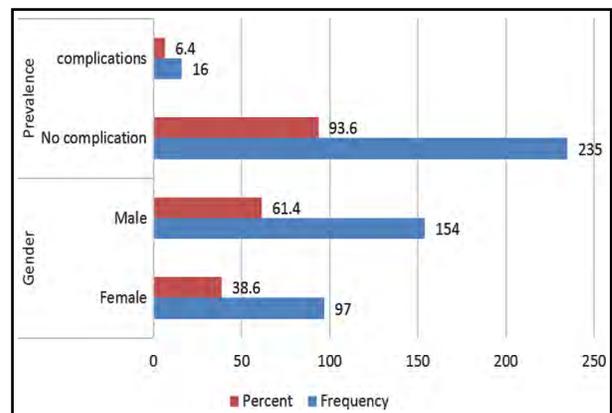


Fig.1: Gender Distribution and Prevalence of Complications (n=251).

Table-I: Complications * Age Group & Gender. Cross Tabulation (n-251).

Complications (N, %)	Age Group				Gender	
	>1-3 (81)	>3-5 (144)	>5-18 (25)	>18 Yr (1)	Female (97)	Male (154)
No complication (235, 93.6%)	74	138	22	1	92	143
Major Complications 4(1.6%)	Implant infection & extrusion (2, 0.8)	2	0	0	0	2
	Device failure (2, 0.8)	0	2	0	0	2
	Facial Nerve Twitching (2, 0.8)	1	1	0	0	2
	Wound Infection (3, 1.2)	2	0	1	0	1
Minor Complications 12(4.8%)	AOM (3, 1.2)	2	1	0	1	2
	Pain/Headache (1, 0.4)	0	0	1	0	1
	Mastoiditis (1, 0.4)	0	1	0	0	0
	Tinnitus & Vertigo (2, 0.8)	0	1	1	0	1
Chi-Square (value, P-value)	26.178, 0.344				7.160, 0.519	

complications 4(1.6%). Wound infection and Acute otitis media predominated with frequency of 3(1.2%) each; followed by facial nerve twitching and Tinnitus & vertigo with frequency of 2(0.8%); and Pain/headache & mastoiditis being least common with frequency of 1(0.4%) each (Table-I). Major complications included implant infection & extrusion and Device failure in 2 (0.8%) cases each. There was no significant association of complications with age group and gender with $P=0.344$ and $P=0.519$ respectively.

DISCUSSION

Current study being the largest study from Pakistan involving 251 cases of Government funded cochlear implant surgeries in the public sector revealed a prevalence of complications related to cochlear implant surgery among one to 12 year old children being 16(6.4%) with no death report and with 4(1.6%) major complications and 12(4.8%) minor complications. In contrast an Egyptian study by Sefein IK,¹⁵ revealed a high complication rate of 18.75% with 8.03% minor and 10.71% major complications with no death. Another study by Farinetti A et al. also reported a high complication rate of 19.9% with minor complications in 14.9% and major in 5% cases. They also noted significant higher complication rate in adults.¹⁶ Achiques MT has reported a prevalence of 11.38%.¹⁷ While, Awad AH et al¹⁸ reported complication rate of 10.43%

with 6.75% minor and 3.68% major complications. Dodson KM et al reported a complication rate of 9.3%, with 59% related to device failure and 3 intracranial complications including two with minor dura leak which was repaired with fascia and one with acute hematoma treated by evacuation.¹⁹

In a previous study conducted in Pakistan, in the private sector comprised of only 52 cases and revealed much higher prevalence of complications of 11.5% with 3.8% failure rate of the device.¹¹ Current study has the advantage of being conducted for a population in which implant and surgery was government funded resulting in a sample hailing for all provinces and areas of Pakistan, while the previous study was in the private sector in which funding was a substantial issue.¹¹ The difference in the complication rate of the two studies might be due to better audiological, surgical and follow up of cases in current study. In a study by Saunders & Barrs,²⁰ to make recommendations for implantation in developing countries, while studying challenges in developing nations, authors reported that most respondents (83%) agreed that audiologist was most important requirement and limitation of audiological services was the most important postop concern compared to postoperative care and infection. It must also be noted that over the years, Pakistan has developed better audiological services. In quite similarity to our study, Binnetoglu A et al. in a large study with 2597 cases and mean

age of 6.48 years reported a very low complication rate of 3.7% with 3% minor and 0.7% major complications.²¹ However in study bin Binnetoglu A et al. vertigo was the commonest minor complication while implant extrusion was the major complication and authors supported the closure of the cochleostomy or round window with muscle to avoid complications.²¹ In present study also among major complications implant infection & extrusion and device failure were noted among the major complications. To avoid electrode extrusion and or migration, Kubo T et al. have also advocated tight packing of cochleostomy, split bridge technique and canal wall reconstruction.²² It has also been highlighted that vertigo with non-improvement in hearing should arouse suspicion of mal-placement of electrodes.²³ Also in a study by Yi J et al.,²⁴ out of 1065 implantations 28 (2.63%) developed complications with 7 (0.66%) major and 21 (1.97%) minor and only two re-implantations were required with no case of severe infection, necrosis of flap or extrusion of device. The Major complications included magnet and electrode displacement, traumatic failure of implant and minor CSF leak.²⁴ High frequency of complications of 13.25 was reported by Júnior LRPL et al. including 8% minor and 5.2% major complications.²⁵ Compared to these, the current study had a low prevalence of 4(1.6%) major and 12(4.8%) minor complications and with regards individual complications of surgery, Wound infection and Acute Otitis Media were the commonest complications noted in 3(1.2%) each. Facial nerve twitching/ stimulation occurred in 2(0.8%). Implant infection & extrusion and device failure occurred in 2(0.8%) each. Sefein IK reported 12 cases with major complications including misplaced electrodes in two, cerebrospinal fluid leak in four, labyrinthitis ossificans, magnet displacement, central perforation, seroma and hematoma in, wound infection, and persistent pain/discomfort in one case each.¹⁵ Study by Farinetti A et al.¹⁶ and Awad AH et al.¹⁸ also revealed that in children infections like AOM were the commonest complication, while common major complication was device failure. While, Halawani R et al. for a sample of adults and children reported a complication rate of 10.2% with 9.5% being minor with hematoma/ seroma being commonest complication.²⁶ Other studies have also reported hematoma, infection,²² and device failure¹⁷ as the commonest complications.²⁵ Infection can even progress to meningitis, however most respond to medications, however skin breakdown may

warrant surgical intervention.²² A Saudi study by Al Shaikh AM et al.,²⁷ revealed a prevalence of 11.4% in children including 7.7% major and 4.8% minor complications including spontaneous device failure 2.8%, traumatic device failure 2.1%, Wound infection and dehiscence 1.4% each, hematoma 0.7%, post-operative vertigo, facial twitching, and otitis media in 0.7% each.

Some other complications may also rarely occur. Facial Nerve stimulation occurred in just 0.8% of our cases and was not related to IEM's, According to Kubo T et al this commonly occurs in ears with anomalies and can be dealt with reprogramming some electrodes, however decrement in speech recognition may occur.²² Rarely, auditory nerve may give poor response as a result patient becomes aware of only environmental sounds and avoids implant use.²² Also rarely complications like periorbital ecchymosis can occur, hence avoidance of undue extensive periosteal elevation and dissection of other subcutaneous tissues.²⁸

Depending on specific individual anatomical considerations of patient preoperative planning and adoption of soft surgical techniques result in reduction of surgical complications.²⁴ Preoperative protocol followed, safe surgical techniques and post-operative care are responsible for reduction in complications.²⁶ Hence continued surgeon education and training is emphasized.²⁵

CONCLUSIONS

Present public sector implant program is characterized with a very low prevalence of complications of 16(6.4%) with 4(1.6%) major and 12(4.8%) minor complications. Wound infection and acute otitis media were the commonest complications.

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Authors Contribution:

JA: Did the data collection, analysis and interpretation of results.

GS: Was responsible for conception of work, writing of manuscript and is responsible for integrity of research

IJK: Did the critical revision of the manuscript

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