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Complications in a series of 4400 paediatric cochlear implantation

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ABSTRACT

Objectives: The purpose of this study is to retrospectively review the complications of paediatric patients undergoing cochlear implantation at four major Iranian cochlear implant centres.
Methods: A retrospective analysis was performed of all patients who underwent primary cochlear implantation from January 1991 to December 2013. The patients were reviewed for demographic information, and complications including cerebrospinal fluid leak, meningitis, facial palsy, and wound infection.
Results: 4400 records were reviewed. Fifty-four patients were lost to follow-up; therefore, 4346 records were analysed. The most common aetiology of hearing loss was non-syndromic genetic sensori-neural hearing loss (69%). Other less common aetiologies of hearing loss included TORCH (Toxoplasmosis, Other infections, Rubella, Cytomegalovirus, Herpes) (11%), syndromic hearing loss (7%), ototoxicity (5%), and autoimmune inner-ear disease (4%). The most common major complications were CSF leak (0.4%), skin necrosis (0.2%), meningitis (0.1%), facial paralysis (0.07%) and massive haemorrhage (0.05).
Conclusion: Cochlear implantation continues to be reliable and safe in experienced hands, with a very low percentage of severe complications.

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1. Introduction

Congenital severe-to-profound hearing loss has been shown to limit children's ability to develop effective auditory and oral linguistic capabilities and communication skills [1]. Cochlear implants provide people with severe-to-profound hearing loss greater access to sound and improvement in their auditory abilities, speech understanding, and linguistic development [2]. Cochlear implant surgery in children may present additional risks that are not present in adult patients [3]. Preoperative evaluation in a child also has challenges. Before consideration for cochlear implantation the degree of hearing loss needs to be established. Current objective testing with sedated auditory brainstem responses, auditory-evoked potentials, auditory steady-state responses and play audiometry has enabled more accurate evaluation of hearing. Post-operative device programming can also be difficult in the paediatric patient.

It is important that the thresholds are accurate and the device is set at comfortable levels to enable optimal functioning of the cochlear implant [4]. The procedure continues to be performed with increasing frequency, although cochlear implantation (CI), like any other surgical procedure, has some minor or major complications [5]. Since the introduction of newborn hearing screening in Iran in 2001, more than 85% of newborns are screened for hearing loss within the first few days of life. Consequently, more patients are being detected with hearing loss early in life, and more paediatric patients are getting cochlear implants in the course of their hearing rehabilitation. On average, children achieve higher linguistic, academic, and social skills when management of hearing loss is implemented earlier [6]. The purpose of this study was to evaluate major complications and safety of cochlear implantation in children through a multi-centric study in Iran. Although surgical techniques have improved since the first CI procedure, there are

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still some complications, both major and minor. Major surgical complications necessitate hospital admission and intervention, while minor complications can be managed conventionally [7].

2. Methods

The national review board's permission was obtained. We performed a retrospective analysis of all patients who underwent cochlear implantation from January 1991 to December 2013 at four major academic centres to find out the leading aetiologies for paediatric cochlear implantation and also major complications of this procedure. The patients were reviewed for demographic information, cochlear implant device, and major complications including meningitis, wound infection, cerebrospinal fluid leak and facial palsy. Minor surgical complications such as magnet sore, stitch abscess, local pain and facial numbness were locally managed and were not included in this analysis. Fifty-four patients were lost due to insufficient follow-up or death unrelated to CI. Selection criteria for the child population in this study were age between five months and 12 years, bilateral severe-to-profound hearing loss with pure tone average of 90 dB SPL or more, minimal benefit from hearing aids (defined as detection of less than 20–30% on single-syllable word test) or for younger children, a bilateral profound sensori-neural hearing loss over a time period of 3 months or more, no medical contra-indications, and realistic expectations on the part of the parents. Surgical contraindications were central auditory lesions, cochlear aplasia and persistent chronic ear infection with otorrhoea. Pre-operative temporal-bone CT scans were analysed and anomalies were noted.

3. Results

4400 records were reviewed. Fifty-four patients were lost due to emigration or death unrelated to CI; therefore, 4346 records were analysed. All patients were followed for at least one year after implantation. The predominant aetiology of hearing loss was non-syndromic, genetic hearing loss (69%). Table 1 demonstrates the aetiologies of hearing loss in this series. Male to female ratio is 1.

Intra-operative complications, such as CSF leak, massive haemorrhage due to rupture of under diagnosed very high jugular bulb, and severe facial nerve trauma, were few, and managed in the same session. A summary of the complications is given in Table 2. The most common post-operative complication was flap necrosis (0.2%). The first patients had the traditional C-shaped post-auricular incision, and all of the flap failures belonged to this group. Other patients had small straight or hockey-stick post-auricular incisions without flap failures.

Flap and wound disorders were managed with local care and, in case of complete failure, rotational musculo-cutaneous or free forearm flap were used (eight cases) (Fig. 1). Skin necrosis and wound dehiscence occurred within six months of implantation. Magnet sores were managed with weaker magnets and local care in 170 patients (4%).

The rate of post-operative meningitis in our series was 0.1% and the causative organism was proven to be pneumococcus only in one of the earliest cases. We have routinely used pre- and intra-operative antibiotics, and until recently pre-operative pneumococcal vaccination was not mandatory.

Fig. 1. Device extrusion from necrosed skin.

Inner-ear anomalies can play a role as a predisposing factor. The overall rate of inner-ear anomalies which were diagnosed pre-operatively in CT scans was 3.9% (rate of meningitis = 0.1%). Structural anomalies were as follows: large vestibular aqueduct (n = 75, 1.7%); Mondini dysplasia (n = 36, 0.8%); common cavity (n = 25, 0.6%); cochlear hypoplasia and abnormal communication between IAC to cochlea or vestibule (n = 21, 0.5%); cochlear ossification (n = 13, 0.3%). Pneumococcal meningitis was the most common aetiology of cochlear ossification. Overall, in 4345 CI patients, the major complication rate was 0.8% (n = 34).

4. Discussion

Cochlear implantation has been done successfully in the paediatric population for several years. Surgeons have to know several areas of potential risk. As reported in the literature, the most common aetiology for reoperation is device failure [8], our results is 2.3% and are comparable to the reports of Chung et al. [9] and Donatelli and Tresa [8]. Recently, Trotter et al. [10] reported that the rate of device failure has been reduced; this might be the result of improvements in the manufacturing process. We noticed that the bulk of our reimplantations belonged to the old generation of MED-EL combi40 devices; very few device failures were diagnosed with new released devices, so we can confirm this finding.

Very young children have a thin skull and scalp. Although it has been claimed that thin scalp may increase the risk of wound breakdown [11], flap failures have not been seen in very young kids. Post-operatively, parents or baby carers need to daily observe the magnet strength and scalp appearance over the receiver, and early skin-colour change or flap problems can then be managed with local wound care; reduction of magnet strength could prevent breakdown. According to Brito et al. [12], complications related to flap problems seem to be decreasing in incidence compared with

Table 1
Aetiologies of paediatric hearing loss.

Aetiology	%
Non-syndromic genetic	69
TORCHS	11
Syndromic	7
Ototoxicity	5
Autoimmune inner ear disease	4
Others	4

Table 2
Major intra and post operative complications.

Aetiology	No.	%
Intra operative CSF leakage	17	0.4
Flap (skin) necrosis	8	0.2
Post operative meningitis	4	0.1
Severe facial nerve damage	3	0.07
Massive haemorrhage	2	0.05
Total	34	0.8

older reported data. The decrease in complications is related to improvement in technology, anatomy-based flap design, and learning curve of medical staff. These days, as the devices have become thinner and smaller, less soft-tissue damage is incurred [13]. Earlier large C-shaped flaps have been replaced with small, straight anatomical-based flaps to save blood supply and venous drainage to the flaps, so skin necrosis and flap failures have been dramatically decreased, as reported by Ajalloueyan et al. [14]. In our series all of the flap failures were among the old large C-shape designs; we believe improve learning curve resulted in decrease in flap necrosis. We found no flap failure with small straight incisions; this is comparable to the results of Bajaj et al. [15].

Intra-operative CSF leakage mostly occurs after cochleostomy in cases with inner-ear anomalies [16], but may occur in cases with intact labyrinth in pre-operative CT scan too. In our series it occurred in 0.4% of cases, mostly with inner-ear anomalies, and was managed during surgery without long-term complication; Daneshi et al. [17] reported the same management and results. This leakage, which usually stops after a while with hyperventilation, sometimes continues as CSF rhinorrhoea for two to three days. A conservative approach solved this problem in all of our cases without any need for second intervention. This means intra-operative CSF leakage from cochleostomy sites is not a major concern.

We had two cases of trauma to major vessels and massive bleeding was controlled in the same session, though Gastman and Hirsch [18] reported potential risk of carotid damage in CI.

Inadvertent burr trauma to facial nerve in facial recess occurred in three cases with training surgeons and was managed on site by cable graft. Long-term results are not satisfactory and some synkinesis and disfiguration has occurred. This awful complication should be prevented in any surgical setting by close observation and care by expert surgeons. Transient facial palsy (paresis) occurred in about 7% of the cases, with spontaneous or steroid-supported complete recovery. This may be due to thermal damage to the nerve during drilling or may be related to viral or stress-induced Bell's palsy. This problem continues to be occurring after introduction of continues irrigation technique when drilling around facial recess and using cutting burrs. We may conclude that this is some sort of Bell's palsy and should be medically managed. Fayad and Wanna [19] reported the risk of facial nerve damage during CI and made some useful comments to prevent this complication.

Risk of meningitis as a horrible complication in Western countries was reduced after the introduction of pneumococcal vaccines. It was reported to be as much as 4% in the pre-vaccine era but has been reduced to near zero in recent years, as reported by Moore et al. [20]. In our experience, total risk of pneumococcal meningitis has been less than 0.1% with the same distribution in the pre- and post-vaccine eras. Although, according to the latest Iranian national health guideline for CI, pneumococcal vaccination is mandatory before CI, we cannot conclude that pneumococcal vaccination has reduced risk of meningitis in our series. Afsharpaiman et al. [21] reported the same results.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijporl.2015.05.035.

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