Reducing cochlear implant complications with a cochlear implant care protocol: a 5-year prospective closed loop audit

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Background

Patients with profound sensorineural hearing loss may be offered unilateral or bilateral cochlear implantation, which has been found to be both a safe and effective method of hearing restoration¹. Though there are now a considerable number of publications on complications in cochlear implantation, none have elaborated on the impact of standard operating procedures for surgical implantation and the management of complications.

Objectives

1. Establish our cochlear implant complication rates
2. Formulate a Cochlear Implant Care Protocol
3. Determine the effect of this protocol on the rates of complications over consecutive years

Methods

A preliminary retrospective audit was conducted for the years 2009 to 2012 using patient notes. Complications were divided in to major and minor as outlined in Hansen et al 2010². Following a literature search and through consultation with the departments of Infectious Diseases and Paediatrics, a Cochlear Implant Care Protocol (figure 1) was formulated. This standardised care pre-, intra- and post-operatively and included guidelines for managing complications. Once the protocol was introduced, a yearly prospective audit was done between 2013 and 2017. The protocol flowchart (figure 2) was disseminated and ensured that all cochlear implant related problems were picked up regardless of where they presented to. Rates were recorded for each year and the effect of the protocol demonstrated.

Cochlear Implant Care Protocols
Theatre Aseptic Protocols <ul style="list-style-type: none">• Strict theatre aseptic discipline to be enforced by most senior scrub sister/nurse• Signs on doors to prevent entry. Masks to be worn by all staff at all times.• Minimise number of individuals and movement in theatre.• Any breaches in theatre discipline to be documented by scrub sister/nurse
Antibiotic Prophylaxis Adults – Teicoplanin 400mg iv [0,12hrs] + Meropenem 1g iv [0,8,16hrs] (if penicillin-allergy – give Ciprofloxacin 400mg iv [0,12hrs] instead of Meropenem) Paediatric (weight-dependent dosing)– Teicoplanin [0,12hrs] + Meropenem [0,8,16hrs]
Intraoperative Standard Operating Procedure (SOP) <ol style="list-style-type: none">1. Cochlear implants to be first on list unless otherwise authorised by consultant2. Reconfirm side & device with notes, audio and scan(s) during WHO checklist3. Use templates to mark implant site and incision (1.5cm from front edge of implant & 45°-60° to horizontal depending on size/shape of skull) [skin marker]4. Povidone before methylene blue to mark bone (centre of implant) & LA infiltration5. Prep with povidone again when draping - use 3M iodine-impregnated sheet on skin6. Saline washout of mastoid and periosteal pocket before cochlear implantation7. Before handling implant - scrub nurse and surgeons to change gloves8. Muscle plug to seal cochleostomy and secure electrode array (bone wax/cement)9. Half-povidone/saline washout of pocket and mastoid after implantation10. Betadine spray/washout to musculo-periosteal layer closure11. Betadine spray/washout + Vicryl-plus subcutaneous/subcuticular layer closure12. Glue for skin closure (no clips)
Complications Protocol <ol style="list-style-type: none">1. All suspected implant infections or other complications to be escalated for urgent review by registrar/staff grade oncall and discuss with an implant surgeon & consultant (of the week) oncall.2. All infections to be swabbed if possible and started on empiric therapy:-<ul style="list-style-type: none">• Superficial infection limited to the wound only – Flucloxacillin PO for 7 days. Review after 3 days (ideally with CI team). If unresponsive, or deterioration, admit for iv antibiotics.• All other infections (or unresponsive superficial infections) – admit, discuss with ID, swab and commence 2 weeks of iv Teicoplanin + Meropenem (if penicillin-allergy – give Ciprofloxacin iv instead of Meropenem) and handover to CI team.<ul style="list-style-type: none">◦ Followed by 4 weeks of oral antibiotics - usually Rifampicin + Ciprofloxacin (informed by swab results & consultation with ID)• Acute otitis media – <i>No watchful waiting policy in CI patients</i>. Immediate commencement of oral Augmentin for 7 days with review by implant surgeons within 3-4 days in OPD.<ul style="list-style-type: none">◦ If any cochlear malformation – admit for iv Ceftriaxone (as higher meningitis risk) and discuss with ID.

Fig. 1
Cochlear Implant Care Protocols available in theatre and ENT Casualty

References

1. Farinetti A, Gharbia DB, Mancini J, Roman S, Nicollas R, Triglia J-M. Cochlear implant complications in 403 patients: Comparative study of adults and children and review of the literature. European Annals of Otorhinolaryngology, Head and Neck diseases 2014;131(3):177-182.
2. Hansen S, Anthonsen K, Stangerup SE, et al. Unexpected findings and surgical complications in 505 consecutive cochlear implantations: a proposal for reporting consensus. Acta Otolaryngol 2010;130(5):540-9.

Fig. 2
Flowchart outlining pathway for patients to contact North East Region Cochlear Implant team

Results

Between 2009—2012, 215 implants were done in 173 patients, with complication rates found to be 7.5% and 14.5% for major and minor respectively. From 2013—2017, a total of 403 implants were implanted in 291 patients. Major and minor complication rates were 10.64% and 53.19% respectively in the first year, followed by an overall decline in rates to 2.7% and 4.1% respectively (figure 3). The disparity in rates between those recorded for 2009—2012 and the initial complication rates recorded in 2013 were likely due to the introduction of a new and robust method of reporting complications.

Fig. 3
Graph depicting complication rates 2013—2017

Conclusion

The adoption of a cochlear implant protocol has been demonstrated to be efficacious in reducing complication rates. We propose the use of both a protocol which ensures the standardisation of care pre-, intra- and postoperatively and the introduction of a pathway for cochlear implant patients to contact their local cochlear implant team. The method through which this protocol is formulated is inherently important to ensure it is tailored to the local population, so considered consultation with the appropriate specialties is necessary.