The safety profile of cochlear implantation in children less than one year old

Brendan P. O'Connell MD Meredith A. Holcomb Aud Ted A. Meyer MD PhD David R. White MD



Disclosures

- No financial disclosures



Introduction

- Increased identification of young cochlear implant candidates
- Notion of critical period
- Improved outcomes with early implantation
- Children younger than 12 months old
- Safety profile remains unclear



Potential perioperative issues posed by early implantation

- Anesthetic factors
 - Hypoxia
 - Bradycardia
 - Exaggerated hypovolemic effects
- Surgical factors
 - Delicate tissue
 - Tip/stylomastoid foramen
 - Thin skull



Aim

 Determine if differences in complication rates exist in children undergoing implantation between 6 and 12 months when compared to children 12-18 months of age



Experimental Design

- Retrospective review 2002-2014
- Patients between 6 and 18 months of age undergoing cochlear implantation
- Single institution



Outcome Measures

- Primary outcome measure = surgical or anesthetic complications
 - Minor vs. Major
 - Infection, facial nerve injury, spinal fluid leak, wound breakdown, medical problems
- Secondary outcome measures = perioperative variables
 - Total operative time, anesthetic time, blood loss, time in the postoperative anesthesia unit, and length of post-operative hospital stay

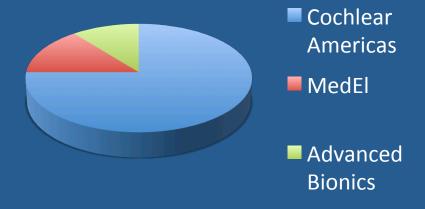
Patient Demographics

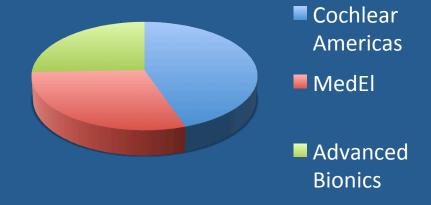
	Group 1 6-12 months	Group 2 12-18 months	<i>p</i> value
No. of Children	23	35	NA
No. of ears implanted	37	47	
Mean age at CI (months)	10.1 ± 1.2	15.0 ± 1.4	NA
Race Caucasian Other	17 (74.0%) 6 (26.0%)	22 (62.9%) 13 (37.1%)	0.55
Sex Male Female	14 (60.9%) 9 (39.1%)	24 (68.6%) 11 (31.4%)	0.75
Ear Right Left	23 (62.2%) 14 (37.8%)	31 (66.0%) 16 (34.0%)	0.90
Weight (kg)	8.8 ± 1.2	10.0 ± 1.0	0.002
Simultaneous bilateral	7	6	0.64

Devices Implanted

Device Manufacturer: 6-12 month group

Device Manufacturer: 12-18 month group





Average time to activation: 16.5 ± 7.1 days

Average time to activation: 20.3 ± 6.2 days

Results: Perioperative Metrics for unilateral implant cases

	Group 1 6-12 months	Group 2 12-18 months	<i>p</i> value
Total operative time (minutes)	127.2 ± 31.1	136.9 ± 46.7	0.74
Total anesthetic time (minutes)	162.3 ± 34.4	181.9 ± 53.7	0.27
Blood loss (cc)	10.9 ± 6.5	17.7 ± 19.3	0.16
Time spent in the PACU (minutes)	80.4 ± 31.5	83.0 ± 46.0	0.98
Length of hospital stay (days) *	0.07 ± 0.37	0.02 ± 0.15	0.75

^{*} All patients, except two, were discharged home after surgery from the PACU

⁻ No differences were observed between groups for bilateral implants (data not shown)

Results: Complications

- Overall rate of complication 6/84 (7.1%)
- Average follow-up of 3.7 ± 2.9 years

	Group 1 6-12 months	Group 2 12-18 months	<i>p</i> value
Total complications	3 (8.1%)	3 (6.4%)	1.0
Minor complications	2 (5.4%) - pressure ulcer - delayed FN paralysis	1 (2.1%) - swelling over implant	0.58
Major complications	1 (2.7%) - seroma drainage in OR	2 (4.3%) - abscess required I+D - abscess required I+D	1.0

2 device failures in each group

Conclusions and Significance

- Cochlear implant surgery appears to be safe in infants under 12 months of age
- Surgery requires meticulous care with hemostasis, soft tissue dissection, and drilling of the well
- Can be performed in outpatient setting
- Future studies with increased sample size are needed

MEDICAL UNIVERSITY of SOUTH CAROLINA