Original Article

Cochlear Implantation in Infants: Evidence of Safety

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Abstract

The aim of this study was to investigate surgical, anesthetic, and device-related complications associated with cochlear implantation (CI) in children younger than 1 year of age. This was a multicenter, retrospective chart review of all children with severe-to-profound sensorineural hearing loss who underwent cochlear implantation with a Cochlear Nucleus Implant System before 1 year of age. Endpoints included perioperative course, major and minor surgical, anesthetic and device-related complications, and 30-day readmission rates. One hundred thirty-six infants (242 ears) met criteria. The mean age at implantation was 9.4 months (standard deviation 1.8). Six-month follow-up was reported in all patients. There were no major anesthetic or device-related complications. Adverse events were reported in 34 of implanted ears (14%; 7 major, 27 minor). Sixteen adverse events occurred $\leq$30 days of surgery, and 18 occurred $>$30 days of surgery. The 30-day readmission rate was 1.5%. The rate of adverse events did not correlate with preexisting medical comorbidities or duration under anesthesia. There was no significant difference detected in complication rate for patients younger than 9 months of age versus those 9 to 11 months of age. This study demonstrates the safety of CI surgery in infants and supports reducing the indication for cochlear implantation to younger than 1 year of age for children with bilateral, profound sensorineural hearing loss obtaining a Cochlear Nucleus Implant System.

Keywords

cochlear implantation, congenital hearing loss, deafness, profound hearing loss, infants

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Cochlear implants (CIs) are a revolutionary technology that enables deaf children to develop spoken language on par with their normally-hearing peers (Dettman et al., 2007). In 1990, CIs were first approved by the U.S. Food and Drug Administration (FDA) for children 2 years of age or older. In 2000, the FDA approved lowering the minimal age of CI to 1 year. The diagnosis of hearing loss before 1 year of age has increased due to implementation of the universal newborn hearing screen (Busa et al., 2007). Many centers in the United States routinely implant infants (<1 year of age) off-label per FDA guidelines and outcomes in these children have demonstrated superior receptive and expressive language development (Dettman et al., 2007, 2016; Miyamoto et al., 2008; Roland et al., 2009; Waltzman & Roland, 2005).

Despite advantages of early implantation, concerns unique to very young children have decreased the enthusiasm for CI in infants. Perioperative safety of CI in infants has been demonstrated in several prior series, though limitations to these studies largely revolve around small sample size and single-institutional experiences (Colletti et al., 2012; Das Purkayastha et al., 2011; Dettman et al., 2007; Holman et al., 2013; Karltorp et al., 2020; Waltzman & Roland, 2005). Population-

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level studies using national registries have also demonstrated safety of CI younger than 1 year (Kim et al., 2017; O'Connell et al., 2016; Patel et al., 2018). However, use of these databases is limited by short-term follow-up (capturing only up to 30 days postoperatively). In addition, CI-specific adverse events such as facial nerve paralysis, cerebrospinal fluid (CSF) leak, and mastoiditis are not reported. Consequently, the lack of sufficient granularity of data in population-level studies prohibits informing change to clinical practice and FDA device labeling.

Herein, we report results of the retrospective, multicenter clinical study leading to the U.S. FDA approval to lower the age of cochlear implantation from 12 months to 9 months for children with bilateral, profound sensorineural hearing loss obtaining a Cochlear Nucleus Implant System.

Materials and Methods

This was a multicenter, retrospective review to determine the safety of CI in children younger than 1 year. The institutional review board from each of the five sites approved this study. To minimize bias, the selected sites included both large, urban university hospitals and average-sized independent clinics with a geographic spread across the United States and Canada. The CI surgeons who participated in this study have more than 10 years of experience performing this procedure and are part of well-established CI centers. A board-certified pediatric anesthesiologist delivered anesthesia in all cases.

The electronic medical record at each study site was queried to identify all patients younger than 1 year of age with severe-to-profound sensorineural hearing loss who underwent CI surgery with a Cochlear Nucleus Implant System between January 1, 2012, and December 31, 2017. Both unilateral and simultaneous bilateral CI surgeries were included. Medical records were reviewed for demographic information and comorbidities.

Primary study endpoints included anesthetic, surgical, and device-related adverse events within 6 months of surgery. *Adverse events* were any unintended physical injury resulting from the medical care that requires additional monitoring, treatment, or hospitalization. *Early* adverse events were defined as any issue occurring $\leq$30 days from the date of surgery. *Late* adverse events were defined as any issue occurring >30 days from surgery. *Major* adverse events were defined as those incidences requiring a surgical intervention to resolve (Cohen & Hoffman, 1991). *Minor* adverse events were defined as incidences managed nonoperatively (e.g., observation, supportive care, local wound care, or oral antibiotics). Outcomes were analyzed by considering the group as a whole as well as subdividing them into two groups (younger than 9 months and 9 to 11 months).

Secondary study endpoints included intraoperative blood loss, total duration under anesthesia, recovery time in the postanesthesia care unit (PACU), and 30-day hospital readmission rates. Intraoperative blood loss was recorded from the surgeon's operative note. Time under anesthesia was measured as the time between induction and extubation. Duration in the PACU was measured as the time elapsed between entering and leaving the PACU. Some of the centers participating in this study discharge infants home the day of surgery, while others admit for observation. Thus, postoperative length of stay was not included as a major endpoint in this study.

Subjects

Across all five study sites, 136 infants met criteria for the study. There were 74 (54%) male and 62 (46%) female children. The mean age at CI surgery was 9.4 months (standard deviation [*SD*]: 1.8 months; range: 3.6–11.9 months; Figure 1). Patient comorbidities and additional demographic data are shown in Table 1. Of the 136 total surgeries, 106 cases (78%) were bilateral simultaneous implantations and 30 cases (22%) were unilateral implantations. Therefore, 242 individual ears were implanted. All patients had follow-up data to at least 6 months postimplantation, which was the study time frame to identify adverse events.

Statistical Analysis

Data on all subjects were analyzed using Microsoft Excel. Descriptive statistical analysis included summary of continuous variables with means, medians, and ranges and categorical variables with frequency counts and percentages. Demographic data, intraoperative events, and anesthetic complications were analyzed per patient ($n = 136$), while surgical complications were analyzed per implanted ear ($n = 242$). Associations were analyzed with a Fisher's exact test for comparing two binomial proportions and t test when comparing continuous data. A p value of less than .05 (two-tailed) was considered statistically significant.

Results

Perioperative Outcomes

All 136 patients underwent successful placement of either unilateral or bilateral CI electrodes. There were no major complications related to anesthesia. There were no reports of sustained bradycardia, cardiac arrhythmias, hypotension, hemodynamic instability, desaturation, bronchospasm, laryngospasm, or difficulty

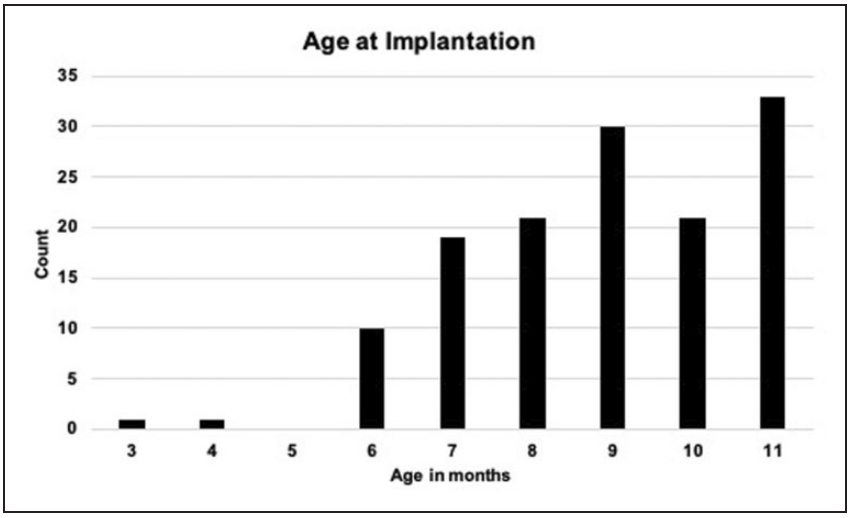

Figure 1. Histogram Showing the Age of Implantation for All 136 Patients.

with the airway. Intraoperative hypothermia was noted in eight cases (5.9%); all eight of these children received bilateral CI, and all resolved with use of warming blanket (Table 2). Blood loss data were available on 77 patients. The average blood loss in bilateral CI cases was 1.8 ml/kg (*SD*: 1.9 ml/kg; range: 0.1–13.0 ml/kg) compared with 1.4 ml/kg (*SD*: 0.7 ml/kg; range: 0.2–2.6 ml/kg) for unilateral CI cases ($p > .05$). No cases were aborted early due to concern for significant blood loss. The average loss in circulating volume per case was 2.0% (*SD*: 0.02%; range: 0.2%–16%), which was calculated using the assumption that infants younger than 1 year of age have an average circulating volume of 80 ml/kg (Maertzdorf et al., 1991). All patients lost less than 10% of their circulating blood volume except for one patient with a congenital ear anomaly undergoing bilateral cochlear implantation where approximately 16% of the circulating blood volume was lost, though no hemodynamic instability was noted.

Data for time under anesthesia were available for 132 of the 136 patients. The mean duration under anesthesia for simultaneous bilateral CI cases was 3.8 hr (*SD*: 1.0 hr; range: 2.2–6.3 hr) and for unilateral CI cases was 2.5 hr (*SD*: 0.8 hr; range: 1.4–4.8 hr). Recovery time data were available for 128 out of the 136 patients. Mean recovery time in PACU for all patients was 2.6 hr (*SD*: 2.0 hr; range: 0.4–10.5 hr). No significant difference was detected in PACU recovery time when comparing unilateral versus bilateral CI cases ($p > .05$).

Performing CI in infants on an outpatient basis versus admitting for overnight observation varied among the study sites. Three of the sites routinely discharged the patients to home the same day, while two of sites admitted the children overnight for observation. In only six cases (4.4%) did a child stay longer than the typical

Table 1. Demographics ($n = 136$).

Age at CI (months)	
Mean (*SD*)	9.4 (1.8)
Range	3.6–11.9
Sex, *n* (%)	
Male	74 (54%)
Female	62 (46%)
Weight (kg)	
Mean (*SD*)	8.72 (*SD*: 1.2)
Range	6.1–11.8
Etiology of HL, *n* (%)	
Idiopathic or not tested[a]	110 (81%)
Meningitis	7 (5%)
Congenital CMV	5 (4%)
Mutation in a gene related to hearing loss	5 (4%)
Cochlear malformation[b]	4 (3%)
Hyperbilirubinemia	3 (2%)
Stroke	2 (1%)
Comorbidities, *n* (%)	
Meningitis (preimplantation)	7 (5%)
Seizure disorder	6 (4%)
Congenital CMV	5 (4%)
Known syndrome[c]	5 (4%)
Cardiac anomaly	5 (4%)
Pulmonary anomaly	4 (3%)
Hematologic anomaly	3 (2%)
Developmental delays/hypotonia	3 (2%)
Neonatal stroke	1 (1%)
Endocrine anomaly	1 (1%)
Total	40 (29%)

Note. CMV = cytomegalovirus; SD = standard deviation; CI = cochlear implant.
[a]Majority of patients did not have genetic testing reported.
[b]Mondini deformity ($n = 3$) and CHARGE syndrome ($n = 1$).
[c]One of each of the following known syndromes were represented: CHARGE, Usher Type 1, Waardenburg, DiGeorge, Noonan Syndrome.

Table 2. Intraoperative and Anesthetic Details.

	Total ($n = 136$)	Bilateral CI ($n = 106$)	Unilateral CI ($n = 30$)
Anesthesia duration (hours)			
Mean (*SD*)	3.5 (1.1)	3.8 (1.0)	2.5 (0.8)
Range	1.4–6.3	2.2–6.3	1.4–4.8
Recovery duration in PACU (hours)			
Mean (*SD*)	2.6 (2)	2.6 (2.1)	2.5 (2.0)
Range	0.4–10.5	0.5–10.5	0.4–9.2
Blood loss (ml/kg)			
Mean (*SD*)	1.7 (1.8)	1.8 (1.9)	1.4 (0.7)
Range	0.1–13.0	0.1–13.0	0.2–2.6
Anesthetic-related adverse events, *n* (%)			
Hypothermia	8 (5.9%)	8 (7.5%)	0 (0%)
Postoperative nausea/vomiting	4 (2.9%)	4 (3.8%)	0 (0%)

Note. SD = standard deviation; CI = cochlear implant; PACU = postanesthesia care unit.

protocol at a given center, and no stay was extended longer than 24 hr. Of these six cases, two patients had congenital syndromes warranting further observation, one patient was found to have a CSF leak on Postoperative Day 1 and was taken back to surgery to repair the leak, one patient was monitored to ensure adequate analgesia and oral intake, one patient had a fever on Postoperative Day 1 which was observed for an additional night and resolved spontaneously, and one patient had a concurrent ventral hernia repair done at the same operation which required an overnight admission.

There were minimal anesthetic-related postoperative symptoms. Four patients (2.9%)—all of whom underwent bilateral CI surgery—were noted to have significant nausea and vomiting. All patients had resolution of symptoms within 1 week of surgery, though one patient required readmission for supportive care due to poor oral intake.

Major Complications

There were a total of 7 (2.9%) major complications reported in the 242 implanted ears. Of these, two occurred within the early postoperative period ($\leq$30 days), while five occurred within the late postoperative period (>30 days). The specific event, timing of onset, and management are reported in Table 3. One patient with a cochlear malformation developed a CSF leak from the cochleostomy on Postoperative Day 1 which required revision surgery to seal the cochleostomy. There were no cases of CSF leaks from the site of the receiver-stimulator, despite drilling a bony well to recess the device ($n = 142$) or a linear groove for devices with a pedestal design ($n = 88$).

Three patients (from different clinical sites) developed a surgical site skin infection with wound breakdown. The earliest manifestation of this complication was at 18 days postoperatively. That patient was readmitted to the hospital for intravenous antibiotics and wound debridement and the device was salvaged. The other two patients with surgical site infections presented in the late postoperative period (Postoperative Day 31 and 68, respectively) with wound breakdown and purulent drainage with concern for a device infection. Both underwent device explant with staged reimplantation once the infection had resolved.

Three other patients developed mastoiditis during the late postoperative period (Postoperative Day 55, 66, and 107, respectively) which was managed successfully with device salvage by admitting to the hospital for intravenous antibiotics, incision and drainage, and placement of a myringotomy tube. There were no cases of meningitis after CI surgery. There were no instances of device failure or device-related complications.

Minor Complications

There were 27 (11.2%) minor complications reported across all sites, of which approximately half occurred during the early postoperative period (Table 3). Four patients had swelling or tenderness at the site of the magnet coil. These issues resolved by decreasing the magnet strength or with time under observation. No instances of skin breakdown over the magnet were observed. Uncomplicated middle ear effusion was noted on exam in three patients, and mild acute otitis media was evident in eight patients, all of which resolved with either oral antibiotics or observation.

One patient had a seroma over the receiver-stimulator site. This was drained by needle aspiration at the first postoperative appointment to facilitate magnet retention and prevent infection. Two patients developed a delayed facial nerve weakness. One of these patients had CHARGE syndrome with an anomalous facial nerve course, and the second patient had normal anatomy. Both patients were managed with oral prednisone and

Table 3. Surgical Complications in All 136 Patients (242 Ears Implanted) at 6 Months Postoperatively.

	Total ($n = 242$)	<9 mo ($n = 97$)	9–11 mo ($n = 145$)	Management	Onset of complication for each patient (postoperative day)
Major complications					
CSF leak	1 (0.4%)	0 (0%)	1 (0.7%)	Revision to plug cochleostomy	1
Wound breakdown/surgical site infection	3 (1.2%)	1 (1.0%)	2 (1.4%)	IV antibiotics, I&D, device explant (staged reimplant)	31, 68
				IV antibiotics, wound debridement, device salvage	18
Severe acute otitis media/mastoid abscess	3 (1.2%)	2 (2.0%)	1 (0.7%)	IV antibiotics, M&T, I&D	55, 66, 107
Subtotal	*7 (2.9%)*	*3 (3.1%)*	*4 (2.8%)*		Early: 2, Late: 5[a]
Minor complications					
Swelling at magnet site	4 (1.7%)	1 (1.0%)	3 (2.1%)	No intervention	28
				PO antibiotics	57
				Magnet strength decreased	75, 161
Uncomplicated acute otitis media	8 (3.3%)	3 (3.1%)	5 (3.4%)	PO antibiotics	12, 21, 23, 52, 72, 85, 92, 143
Fever	8 (3.3%)	4 (4.1%)	4 (2.8%)	Conservative management	2, 9, 24, 51, 58, 152
				Prolonged hospitalization	1
				PO antibiotics	11
Middle ear effusion	3 (1.2%)	0 (0%)	3 (2.1%)	PO antibiotics	8
				No intervention	52
				M&T	114
Wound swelling/irritation	1 (0.4%)	0 (0%)	1 (0.7%)	I&D seroma	5
Facial edema	1 (0.4%)	0 (0%)	1 (0.7%)	No intervention	1
Delayed facial nerve weakness	2 (0.8%)	0 (0%)	2 (1.4%)	PO steroids	2, 4
Subtotal	*27 (11.2%)*	*8 (8.2%)*	*19 (13.1%)*		Early: 14, Late: 13[a]
Total	34 (14.0%)	11 (11.3%)	23 (15.9%)		Early: 16 (6.6%), Late: 18 (7.4%)

Note. CSF = cerebrospinal fluid; IV = intravenous; I&D = incision and drainage; mo = months; M&T = myringotomy and tube; PO = per os (by mouth).
[a]Early is defined as presenting ≤30 days from surgery. Late is defined as presented >30 days from surgery.

were observed to have full recovery of facial function. There were no cases of permanent facial nerve paralysis.

Readmission Rates

The <30-day readmission rate was 1.5% (2 of 136) and included the patient with poor oral intake and the patient with an early surgical site skin infection. The 6-month readmission rate was 5.1% (7 of 136) which, in addition the two patients who were readmitted within 30 days, also included the two patients with surgical site infections and wound breakdown and the three patients with severe acute otitis media (Table 3).

Associations

The rate of adverse events was not affected by preexisting medical comorbidities or duration under anesthesia. Specifically, 11 out of the 40 patients (28%) with a medically complex history had an adverse event compared with 33 out of 96 patients (34%) without significant comorbidities ($p = .84$). Duration under anesthesia for patients with a surgical complication was 3.5 hr (*SD*: 1.0) versus 3.6 hr (*SD*: 1.1) for those without a surgical complication ($p = .75$). No differences were detected in rate of complication for cases done as simultaneous bilateral versus unilateral CI ($p = .64$). While all three patients with a surgical site infection and wound breakdown had undergone bilateral CI, the infrequency of this event (1.2%) and the fact that a larger number of bilateral CI cases were performed precludes determining how this factor impacts the rate of adverse events. In addition, due to the retrospective nature and differences in operative note reporting, it was not possible to identify if the surgical site infection occurred on the first or second operated side in cases of bilateral simultaneous CI. There were no significant differences in the frequency or severity of adverse events when stratifying between patients younger than 9 months old versus those 9 to 11 months of age at surgery ($p = .11$). Eleven patients (11.3%) who were younger than 9 months had an

adverse surgical event versus 23 patients (15.9%) between 9 and 11 months of age at surgery ($p = .09$).

Discussion

Results from this retrospective study demonstrate the safety of CI surgery in infants and supports reducing the indication for treatment to younger than 1 year of age. The outcomes reported represent real-world evidence gathered from several implant centers that have been implanting young children based on the published data showing long-term benefits of earlier treatment. To minimize bias, the centers chosen exhibit geographic diversity as well as diversity in practice size and practice type (e.g., academic vs. private). There were no significant anesthetic complications or device failures in the present study. There were 34 out of 242 implanted ears (14%) adverse surgical events reported, of which 27 out of 34 (80%) were minor. Major surgical complications were reported in only seven cases, all which were manageable and resolved after surgical intervention. All but six patients (4.4%) were discharged home the day of surgery or after overnight observation, depending on the protocol at the given center. The 30-day readmission rate was low at 1.5%. For reference, the readmission rate after pediatric endoscopic sinus surgery and tonsillectomy is 3% and 3.6%, respectively (Johnson et al., 2018; McKeon et al., 2019).

These findings are consistent with several prior series that have demonstrated the safety of performing CI in infants younger than 1 year of age (Colletti, 2009; Cosetti & Roland, 2010; Das Purkayastha et al., 2011; Hoff et al., 2019; Holman et al., 2013; James & Papsin, 2004; Karltorp et al., 2020; Roland et al., 2009; Valencia et al., 2008; Waltzman & Roland, 2005). The complication rate after CI in infants younger than 1 year of age ranges from 0% to 16%, the majority of which are minor (Colletti, 2009; Das Purkayastha et al., 2011; Hoff et al., 2019; Holman et al., 2013; James & Papsin, 2004; O'Connell et al., 2016; Roland et al., 2009). Studies analyzing a large pool of pediatric CI patients queried through the multi-institutional Pediatric American College of Surgeons–National Surgical Quality Improvement Program (ACS-NSQIP) database have reaffirmed the low rate of adverse events (around 3%–4%; Kalejaiye et al., 2017; Kim et al., 2017; O'Connell et al., 2016; Patel et al., 2018). The ACS-NSQIP captures only the first 30 days of postoperative events and does not report several CI-specific complications; hence, the reported complication rates are lower than institutional series. In a study on CI younger than 1 year of age, O'Connell et al. (2016) reported a 2.7% complication rate at 30 days postoperatively versus a 13.5% at a mean follow-up of 3.7 years. This is comparable to the 14% complication rate in the present series.

The complication rate after CI in infants is also similar to studies on CI outcomes in older children and adults, estimated at 15%–18% (Colletti et al., 2012; Dettman et al., 2007; Holman et al., 2013; Nisenbaum et al., 2020; O'Connell et al., 2016; Roland et al., 2009). Karltorp et al. reported no severe anesthesia or surgical complications and only a 7.8% minor complication rate (e.g., transient seroma or pain) in a cohort of children undergoing CI surgery. No correlation between complications and the age at surgery (5 to 11 months vs. 12 to 29 months) was identified (Karltorp et al., 2020).

The present study was unique in that it subdivided patients into younger than 9 months and those 9 to 11 months. There was no significant difference in complication rates between these cohorts. Studies to confirm these findings may encourage further reducing the age of CI even younger than 9 months.

Surgical Risks

Several surgical factors deserve consideration when performing CI in infants. Infectious complications are among the most concerning postoperative issues to arise in children. These range from a superficial skin infection, to wound dehiscence, to a mastoid abscess which may progress to a device infection. The most significant infectious complication is meningitis, which historically was associated with the use of a "positioner" which has now been taken off the market (Reefhuis et al., 2003). The positioner was a small silastic wedge that was inserted adjacent to the implanted electrode and designed to push the electrode against the inner wall of the cochlea, thereby improving the transmission of the electric signal. However, in 2002, the manufacturer recalled devices using a positioner after cases of meningitis in young children were reported and use of a positioner was associated with this complication. There were no instances of meningitis in the present study, but there were 14 (6%) infectious-related adverse events. This is consistent with prior literature that has found the rate of infectious complications after CI to be around 3% to 6.5% (Anne et al., 2016; Benatti et al., 2013; Cunningham et al., 2004; Nisenbaum et al., 2020; Terry et al., 2015).

One study found that infections in pediatric CI patients were greater in those younger than 5 years of age compared with those older than 5 years of age (Nisenbaum et al., 2020). Yet, when looking only at children younger than 5 years of age, there was no significant difference in infection rate among those younger than 1 year versus those 1 to 5 years of age (Nisenbaum et al., 2020). Based on these findings in conjunction with the findings from the present study, risk of infection should not prevent lowering the age of implantation younger than 1 year of age.

Many postoperative infections present as superficial skin infections, often due to the bacteria *Staphylococcus aureus* that resides on the skin (Nisenbaum et al., 2020). This may be a result of the thin skin and subcutaneous tissue in infants which is more susceptible to wound breakdown and device exposure (Das Purkayastha et al., 2011; Davids et al., 2009; R. W. Young, 1959). Poor hygiene or a compulsion to scratch or pick at the wound may also be causative factors in this very young population.

Postoperative infections may present during the early ($\leq$30 days) or late (>30 days) postoperative period. It is, thus, imperative that the surgeon and the implant audiologist have a close line of communication. Many complications may be detected early during routine programming visits and thus may be treated before progressing to more severe complications (Roland et al., 2009). In this study, five of the eight children with uncomplicated acute otitis media presented during the late postoperative period. Children are at greater risk for upper respiratory infections and acute otitis media which may account for some of the late postoperative infections observed (Teele et al., 1989; Vila et al., 2017). Mild cases of acute otitis media diagnosed and treated early often do not lead to a device infection (Vila et al., 2017). The fibrous capsule that forms over the receiver-stimulator unit isolates it from the middle ear and mastoid cavity (Nisenbaum et al., 2020). Sometimes, a tympanostomy tube is required which is generally safe in the presence of a CI and rarely leads to further complications (Javia et al., 2016). When untreated, a mastoid abscess may develop and involve the device, thereby comprising it due to biofilm formation (Im et al., 2015). Severe or recurrent infections whereby the device is involved often necessitate explantation, including cutting the electrode and leaving it in the cochlea as a placeholder. Once the wound bed is healed and sterile, typically 3 months later, reimplantation may be commenced (Roland et al., 2006).

Another surgical risk of particular concern during CI surgery in infants is CSF leak. The skull in infants is thin resulting in potentially exposing or injuring dura when drilling a bony well to secure the receiver-stimulator. The receiver-stimulator was secured by drilling a well in most patients in this series, yet there were no leaks attributable to this portion of the procedure. The sole case of a CSF leak occurred in a patient with a cochlear malformation (Mondini deformity), whereby a CSF pulser was encountered upon making the cochleostomy, signifying higher perilymphatic pressure and risk of CSF leak postoperatively. Carefully packing the cochleostomy with fascia will prevent a postoperative CSF leak and potential meningitis, given the communication between the middle ear and subarachnoid space.

The underdeveloped mastoid tip in infants may result in a more laterally located stylomastoid foramen, which may result in the facial nerve being vulnerable to injury during initial incision and flap elevation (Bhatia et al., 2004; Li et al., 2014). Use of a facial nerve monitor is routine and recommended in all cases to avoid iatrogenic injury. Temporary facial nerve injury is often related to heating of the nerve during drilling resulting in a neuropraxia. Prompt treatment with steroids, as observed in the two cases in this series, will aid the nerve is recovery over the subsequent 1 to 4 weeks.

In the present study, the length of the operative time (as measured by the duration under anesthesia) was not correlated with increased risk of complications or longer length of stay. However, prior studies have found longer operative time to be correlated with greater risk of infection in unilateral CI cases (Nisenbaum et al., 2020). Similarly, in a review of the ACS-NSQIP database, Kim et al. (2017) found that longer length of stay, surgical site infections, unplanned reoperation, and readmissions were all correlated with longer operative times. Further studies are needed to examine the relationships between underlying etiology of hearing loss, operative time, and postoperative infection rates.

Anesthesia Risks

Prior literature has shown that infants younger than 1 year have a higher rate of complications compared with older children after undergoing general anesthesia for a broad range of noncardiac procedures (Flick et al., 2019; Hawksworth & Ravury, 2015; Keenan et al., 1992, 1994; Yeh et al., 2011; N. M. Young, 2002). Cardiopulmonary events in the setting of an underdeveloped sympathetic nervous system account for the greatest risk of anesthesia in the infant population (Keenan et al., 1994). Episodes of laryngospasm or a misplaced endotracheal tube can result in bradycardia, and if severe may lead to a cardiac arrest (Bhananker et al., 2007; Johr et al., 2008). The decreased functional residual capacity and higher oxygen consumption of infants puts them at increased risk for hypoxia and cardiac stress during periods of apnea (Flick et al., 2019). Blood loss during surgery or inappropriate fluid therapy may further exacerbate this problem (Anagiotos & Beutner, 2013). The small circulating blood volume (approximately 80 ml/kg in children younger than 1 year) can lead to hypovolemic shock with as little as a 10% loss of volume (Anagiotos & Beutner, 2013; Johr et al., 2008; Maertzdorf et al., 1991; Roland et al., 2009). This underscores the importance of maintaining hemostasis and minimizing blood loss, such as from the scalp incision or oozing bone marrow. These cardiopulmonary risks are highest in infants 1 to 3 months of age; even so, infants up to 1 year of age are at heightened risk compared with older

pediatric patients (Flick et al., 2019). In the present study, the average blood loss was 1.7 ml/kg, and the average loss in circulating volume per case was 2%. All patients, except one, had less than 10% loss in circulating blood volume. The one patient with 16% loss of circulating blood volume had a congenital ear anomaly; although no hemodynamic instability was noted, it is important that patients with ear malformation, especially those with venous lakes within the mastoid, warrant even greater caution when considering surgery.

Anesthetic risk for pediatric patients undergoing CI surgery is considered low, even for infants younger than 1 year of age (Yeh et al., 2011). Yeh et al. reported that all adverse events were managed without difficulty and without long-term sequelae, similar to the current series. Hoff et al. stratified patients by their American Society of Anesthesiologists class which is a system for assessing the fitness of patients before surgery. The authors found no major anesthetic complications, albeit a limitation of this study is that most patients were American Society of Anesthesiologists Class I or II (Hoff et al., 2019). Patients with asthma or central nervous system abnormalities were the most likely to require admission post-implantation and therefore patients with these comorbidities required extra consideration (Patel et al., 2018). In the present series, patient comorbidities were not associated with extended length of stay. Of the six patients that deviated from the discharge protocol at their center and required longer observation, four had postoperative vomiting. All these patients had undergone bilateral simultaneous CI, which may suggest that a bilateral vestibular disturbance is responsible for the symptoms as opposed to an anesthetic effect. Regardless of the cause, all patients found resolution of their vomiting within a few days postoperatively and resumed their normal activities.

Patients younger and older than 9 months tolerated general anesthesia without complication. The youngest two patients to be implanted (due to bacterial meningitis) were 3 and 4 months old, respectively. Despite lower body weights (6.1 kg and 7.2, respectively) compared with the other children, they both had uneventful surgeries. Minimal blood loss (less than 2% of their approximate circulating volume) was reported in this series, and no patients required a blood transfusion to maintain hemodynamic stability. However, all patients were managed by a pediatric anesthesiologist, which likely contributed to reducing the perioperative risk and achieving the excellent safety record observed. Keenan et al. found that bradycardia is more common in infants younger than 1 year of age compared with those 1 to 4 years of age and that bradycardia can lead to significant morbidity. However, bradycardia was less than half as likely when anesthesia was delivered by a board-certified pediatric anesthesiologist (Keenan et al., 1992). Other series focused on the anesthetic safety of CI surgery in infants have corroborated these findings (Hoff et al., 2019; O'Connell et al., 2016; Yeh et al., 2011). Having an experienced pediatric anesthesiology team is advised for all cases of CI surgery in children younger than 1 year.

Limitations

Several study limitations deserve mention. This is a retrospective review conducted across multiple sites. As such, the data available were dependent on what was present in the electronic medical record and are subject to input and selection bias as well as potential inaccuracies. For example, the amount of blood loss was recorded from the operative note, which traditionally is a subjective measurement. In cases of surgical site or device infections in the setting of bilateral simultaneous CI, we were unable to determine if the infection occurred on the first or second side because of inconsistencies in reporting this data.

In addition, a control group of pediatric CI patients older than 1 year of age was not included for study, and thus present data were compared with published data from other cohorts of pediatric CI recipients. Lastly, the follow-up time in this cohort is limited to 6 months. While this is longer than the 30-day follow-up reported in studies employing the ACS-NSQIP database, the authors recognize that complications may continue to arise years after CI surgery, and therefore, this study fails to capture these events.

Conclusion

Cochlear implantation in patients younger than 1 year of age is safe when performed by an experienced CI surgeon and with an experienced team including a pediatric anesthesiologist. There were no major anesthetic complications in this cohort. The rate of adverse surgical complications for infants who proceeded with CI surgery younger than 1 year in the present study was comparable to historical data reported for CI surgeries completed in children older than 1 year of age. A pediatric anesthesiology team and careful patient selection is critical to mitigate risks and ensure a safe and successful CI surgery. Results of this retrospective multicenter study support reducing the indication for a Cochlear Nucleus Implant System to younger than 1 year of age.

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