Pediatric Cochlear Implantation: Why Do Children Receive Implants Late?

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Objectives: Early cochlear implantation has been widely promoted for children who derive inadequate benefit from conventional acoustic amplification. Universal newborn hearing screening has led to earlier identification and intervention, including cochlear implantation in much of the world. The purpose of this study was to examine age and time to cochlear implantation and to understand the factors that affected late cochlear implantation in children who received cochlear implants.

Design: In this population-based study, data were examined for all children who underwent cochlear implant surgery in one region of Canada from 2002 to 2013. Clinical characteristics were collected prospectively as part of a larger project examining outcomes from newborn hearing screening. For this study, audiologic details including age and severity of hearing loss at diagnosis, age at cochlear implant candidacy, and age at cochlear implantation were documented. Additional detailed medical chart information was extracted to identify the factors associated with late implantation for children who received cochlear implants more than 12 months after confirmation of hearing loss.

Results: The median age of diagnosis of permanent hearing loss for 187 children was 12.6 (interquartile range: 5.5, 21.7) months, and the age of cochlear implantation over the 12-year period was highly variable with a median age of 36.2 (interquartile range: 21.4, 71.3) months. A total of 118 (63.1%) received their first implant more than 12 months after confirmation of hearing loss. Detailed analysis of clinical profiles for these 118 children revealed that late implantation could be accounted for primarily by progressive hearing loss (52.5%), complex medical conditions (16.9%), family indecision (9.3%), geographical location (5.9%), and other miscellaneous known (6.8%) and unknown factors (8.5%).

Conclusions: This study confirms that despite the trend toward earlier implantation, a substantial number of children can be expected to receive their first cochlear implant well beyond their first birthday because they do not meet audiologic criteria of severe to profound hearing loss for cochlear implantation at the time of identification of permanent hearing loss. This study underscores the importance of carefully monitoring all children with permanent hearing loss to ensure that optimal intervention including cochlear implantation occurs in a timely manner.

Key words: Age, Children, Cochlear implant, Diagnosis, Hearing loss, Newborn screening.

INTRODUCTION

Considerable attention has been accorded to the importance of early access to sound for children with hearing loss. Cochlear implantation has become a well-accepted intervention for children with severe to profound hearing loss whose parents choose spoken language development. Progress in the early identification of childhood hearing loss through widespread implementation of universal newborn hearing screening (UNHS) programs is expected to lead to benefits in early implantation and enhanced opportunities for more natural spoken language development (James & Papsin 2004; Dettman et al. 2007; Miyamoto et al. 2008). It has been well recognized that early implantation is highly desirable to maximize the child’s access to speech during periods of maximum neural plasticity that in turn should lead to more age-appropriate speech-language skills (Ching et al. 2013; Leigh et al. 2013; Tobey et al. 2013).

Research in neuroscience points to optimal periods for auditory development (Werker & Tew 2005) and consequently the importance of maximizing early auditory experience through early cochlear implantation in children with limited residual hearing (Ryugo et al. 2000; Sharma et al. 2002, 2005). Accordingly in most countries, the age of cochlear implantation has decreased to include implantation at 12 months of age or even earlier (Hammes et al. 2002; James & Papsin 2004; Tait et al. 2007; Cosetti & Roland 2010). In recent years, some investigators have advocated for implantation even before 12 months based on reports of better outcomes for very early implanted children (Dettman et al. 2007; Holman et al. 2013; Leigh et al. 2013).

Recent studies have reported that early implanted children can achieve spoken language skills comparable with their normal-hearing peers (Dettman et al. 2007; Leigh et al. 2013). A longitudinal multicenter study of 188 children in the United States reported better language skills in children implanted before 18 months of age compared with those implanted after 18 months (Niparko et al. 2010). Furthermore, the majority of early implanted children followed language growth trajectories aligned with those of their hearing peers. In recent research, age at implantation rather than age of identification of hearing loss has emerged as an important predictor of spoken language outcomes in children who use cochlear implant technology (Ching et al. 2013).

Despite the emphasis on early implantation, large studies on populations of young children with hearing loss typically report average ages of surgery in the 2- to 3-year-old range. For example, in Canada less than 50% of the 163 to 184 children implanted annually from 2000 to 2005 were younger than 3 years of age at implantation (Fitzpatrick & Brewster 2008). Given the strong support for earlier implantation, it is important to explore why substantial numbers of children still undergo late implantation in regions where cochlear implants are widely available. Previous research has suggested that children who do not meet typical audiologic criteria of severe to profound hearing loss may require more decision-making time on the part of clinicians and parents (Fitzpatrick et al. 2009; Hyde et al. 2010), but there has been little systematic research of other reasons for delays to implantation. Little is known about the factors that affect late age at implantation, and age at surgery has often been reported as an absolute value rather than in relation to duration of
Participants in the study were identified at one Canadian pediatric cochlear implant center, the Children’s Hospital of Eastern Ontario, which provides all cochlear implant surgical and audiologic follow-up services to the Eastern Ontario region, a population of approximately 1.8 million. The hospital also provides all other diagnostic and rehabilitative pediatric audiology services to the local catchment area of 1 million and is the regional diagnostic center for the UNHS program implemented in 2002. Covering a region that has 14,000 births per year, the hospital diagnoses and manages 30 to 40 new children annually with permanent hearing loss. In addition to local children identified through the UNHS program, children moving into the area, who may not have had the benefit of newborn screening, have access to the same services. At this publicly funded pediatric hospital, a comprehensive team approach to cochlear implant candidacy selection, involving medical, audiological, psychological, and family support assessments, is in place. All children receive rehabilitative services after cochlear implantation with a focus on spoken language development. Typical candidacy criteria for cochlear implantation at the time of this study included (1) age 12 months or older, (2) bilateral sensorineural severe to profound hearing loss for children older than 2 years or profound hearing loss for children younger than 2 years (better ear thresholds considered in candidacy decisions), (3) minimal progress with acoustic amplification, (4) no medical or radiologic contraindications, and (5) appropriate family expectations. Because all children in the local region are identified and followed through the hospital program, they begin the assessment process for cochlear implant candidacy when they meet audiologic criteria, that is, when the child’s overall audiologic profile and lack of auditory and speech-language development suggest that the child might derive additional benefit from cochlear implantation compared with acoustic hearing aids. The research ethics boards at the Children’s Hospital of Eastern Ontario and the University of Ottawa approved the study protocol.

MATERIALS AND METHODS

Design

Data for this study were drawn from a population-based prospective study where information was collected for all children with a permanent hearing loss in one region of Canada after the implementation of a provincial newborn hearing screening program in 2002. The data set for the current investigation included all children who received cochlear implants over a 12-year period from 2002 to 2013. Additional detailed chart reviews were carried out to extract clinical notes to determine reasons for late implantation that could not be explained by the clinical characteristics collected prospectively.

Participants

Participants in the study were identified at one Canadian pediatric cochlear implant center, the Children’s Hospital of Eastern Ontario, which provides all cochlear implant surgical and audiological follow-up services to the Eastern Ontario region, a population of approximately 1.8 million. The hospital also provides all other diagnostic and rehabilitative pediatric audiology services to the local catchment area of 1 million and is the regional diagnostic center for the UNHS program implemented in 2002. Covering a region that has 14,000 births per year, the hospital diagnoses and manages 30 to 40 new children annually with permanent hearing loss. In addition to local children identified through the UNHS program, children moving into the area, who may not have had the benefit of newborn screening, have access to the same services. At this publicly funded pediatric hospital, a comprehensive team approach to cochlear implant candidacy selection, involving medical, audiological, psychological, and family support assessments, is in place. All children receive rehabilitative services after cochlear implantation with a focus on spoken language development. Typical candidacy criteria for cochlear implantation at the time of this study included (1) age 12 months or older, (2) bilateral sensorineural severe to profound hearing loss for children older than 2 years or profound hearing loss for children younger than 2 years (better ear thresholds considered in candidacy decisions), (3) minimal progress with acoustic amplification, (4) no medical or radiologic contraindications, and (5) appropriate family expectations. Because all children in the local region are identified and followed through the hospital program, they begin the assessment process for cochlear implant candidacy when they meet audiologic criteria, that is, when the child’s overall audiologic profile and lack of auditory and speech-language development suggest that the child might derive additional benefit from cochlear implantation compared with acoustic hearing aids. The research ethics boards at the Children’s Hospital of Eastern Ontario and the University of Ottawa approved the study protocol.

Procedures

Data from clinical charts were collected prospectively for children identified with permanent hearing loss between 2002 and 2013 after implementation of the UNHS program. Clinical characteristics including etiology and risk factors, age of identification, degree and profile of hearing loss, progression of loss, other disabilities, age of and time to cochlear implantation were documented. All audiometric data were collected based on electrophysiologic test results and clinical serial audiograms obtained through conventional audiometry; in situ audiometry was not part of clinical protocol, and real ear to coupler differences were not recorded for this study. For comparison purposes in this study, the age of cochlear implantation for children identified from 1993 to 2002 before implementation of UNHS was also documented.

We initially examined the clinical characteristics of all children who had undergone cochlear implant surgery to determine time elapsed between the initial diagnosis of hearing loss and the cochlear implant surgery. We also documented age at first cochlear implant assessment and age at implantation. Subsequently, to document the factors accounting for late implantation, we conducted detailed medical chart reviews for the children with a 12-month or greater gap between hearing loss identification and cochlear implantation. A 12-month gap was selected because at the center, children were typically not implanted until approximately 12 months of age. Therefore, children diagnosed in early infancy would generally not have been eligible for surgery until 6 to 12 months after identification of their hearing loss.

Data Analysis

Statistical analyses were carried out using the Statistical Package for the Social Sciences 22.0 (IBM Corp.) Clinical characteristics were summarized using descriptive statistics (means or medians as appropriate) to determine the number of children who received cochlear implants more than 12 months after diagnosis. Median age and time to implantation before and after implementation of UNHS in 2002 were examined with the Mann-Whitney U test. Differences between clinical characteristics (e.g., sex, screening status, age at diagnosis) for children implanted within 12 months and those more than 12 months after hearing loss diagnosis were analyzed with the
Chi-square test, the Mann-Whitney U test or Kruskal-Wallis test, as appropriate. All reported p values are two-tailed, and statistical significance was accepted at p = 0.05 for all tests. Through descriptive statistics, subgroups of children with congenital/early onset (known presence of hearing loss ≤6 months of age) and severe to profound hearing loss at diagnosis were also examined. Data tables were created from detailed chart reviews to document the potential reasons for late implantation for all children not accounted for through the quantitative data. For example, clinical characteristics such as other developmental concerns and any medical chart information concerning the circumstances surrounding cochlear implantation (e.g., clinician concerns, parental hesitation, family move) were recorded in these tables.

RESULTS

Age and Time to Implantation

Figure 1 outlines the selection process for the study participants and shows both age of and time to implantation for children identified before and after 2002. Before 2002, less than 13.5% (17) of children were implanted within 12 months of confirmation of hearing loss. These 128 children had a median age of cochlear implantation of 56.1 (interquartile range [IQR]: 29.0, 108.1) months and time from diagnosis of hearing loss to implantation was 38.5 (IQR: 17.6, 85.1) months. These children had a relatively early median age of diagnosis of 11.8 (IQR: 8.0, 18.5) months; therefore, longer duration between diagnosis and cochlear implantation for this group likely reflects lower age limit candidacy criteria of 2 years during the early years of pediatric cochlear implantation, stricter audiologic criteria, and possibly more parental uncertainty.

As shown in Figure 1, since 2002, 188 children received at least one cochlear implant. Insufficient preimplant patient history information was available for one child, leaving 187 for the analysis. Children received their first cochlear implant (121 unilateral; 66 bilateral) at a significantly lower age than those implanted before 2002 (median 36.2 months; IQR: 21.4, 71.3; p = 0.014), and time to implantation was significantly shorter at a median of 18.4 (IQR: 8.9, 46.5) months than for children implanted in the early years of the program (p < 0.0001). Despite earlier age at implantation for this group, more than 12 months from diagnosis to surgery elapsed for 118 (63.1%) children with a median time of 37.3 (IQR: 21.3, 70.2) months from diagnosis to implantation.

Table 1 displays the clinical characteristics of all 187 children who received cochlear implants since 2002, with details shown separately for the 69 children implanted within 12 months of diagnosis (group 1) and the 118 children implanted more than 12 months after diagnosis (group 2). As shown in Table 1, just over one-third of these children underwent hearing screening. The large number of children not exposed to screening reflects the fact that the majority of these children were born before the implementation of universal screening (birth years ranged from 1983 to 2013) or were referred from regions without screening programs in place at the time of their birth. There was no significant difference between the number of children screened in groups 1 (34.8%) and 2 (35.6%) (p = 1.000). Although the majority of children were not screened, median age of confirmation of hearing loss was relatively young at 12.6 (IQR: 5.5, 21.7) months and the difference between the two groups was not significant (p = 0.164), suggesting that factors other than age at diagnosis likely influenced time to implantation. As detailed in Table 1, there were similar proportions of children with congenital/early onset (defined as ≤6 months), late onset, and acquired hearing disorders in each group with no statistically significant differences between groups (p = 0.371). Severity of hearing loss based on better ear three-frequency pure-tone average (PTA; 500, 1000, 2000 Hz) at confirmation of hearing loss is also shown in Table 1.

In the full cohort of 187 children, just over one-third (n = 66; 35.3%) clearly presented with profound loss (≥90 dB) at diagnosis, whereas 77 (41.2%) children presented with mild to severe loss (<90 dB HL PTA), 39 of whom had <70 dB HL PTA; 22 (11.8%) other children had a diagnosis of auditory neuropathy spectrum disorder (ANSD). Severity of hearing loss at diagnosis and changes since diagnosis could not be verified for 22 (11.8%) children who were referred for cochlear implant surgery from other regions after confirmation of severe to profound hearing loss. As shown in Table 1, differences in hearing...
loss at diagnosis between the two groups of children were statistically significant ($p < 0.001$). For example, the majority (60.9%) of group 1 children presented with $\geq 90$ dB HL PTA at diagnosis, whereas only 20.3% of group 2 children had profound loss.

Reasons for Late Implantation

As shown in Figure 2, close examination of the clinical characteristics and medical charts of group 2 revealed clear patterns related to late implantation. The primary reason for the gap from diagnosis to surgery was documented progressive hearing loss, that is, more than half of the children ($n = 62; 52.5\%$) did not meet clear audiologic criteria for candidacy at the time of hearing loss confirmation and later showed deterioration or fluctuation in hearing levels. Almost one-third ($n = 32; 27.1\%$) of the children in this category had $<70$ dB HL PTA at confirmation of hearing loss. Other major reasons for delays of more than 12 months in implantation included complex medical and/or developmental issues (16.9%), family indecision (9.3%), family’s geographical location (3.7%), and a range of other known (6.8%) and unknown reasons (8.5%). There was no indication of extensive wait times related to systemic reasons such as surgical wait lists.

Examination of Age at Implantation for Subgroups of Children

Children With Early Onset Congenital Severe to Profound Loss

Age at implantation was further examined for the children identified with permanent hearing loss of known congenital and early onset ($\leq 6$ months). An examination of the subset of 49 children implanted after 2002 with $\geq 70$ dB pure-tone average, that is severe ($n = 14$) or profound ($n = 35$) hearing loss and early onset, revealed that more than one-third (17 of 49) received implants after 2 years of age. These 49 children were
diagnosed at a median age of 5.5 (IQR: 2.6, 9.5) months and underwent surgery at a median age of 21.2 (IQR: 14.8, 39.4) months with a time lag of 11.7 (IQR: 8.8, 32.8) months. Further scrutiny of the subset of 35 children with early-onset profound hearing loss (PTA ≥ 90 dB HL), who clearly met audiologic criteria, showed a similar pattern. Despite a median age of diagnosis of 6.1 (IQR: 3.3, 9.1) months, these children were implanted at a median age of 20.6 (IQR: 14.0, 29.4) months. As children met audiologic criteria in infancy, they would typically have had timely access to cochlear implant surgery unless there were other contraindications or uncertainties. Specifically, this subset of children was determined to meet cochlear implant candidacy at a median age of 10.3 (IQR: 5.1, 21.5) months; therefore, there was a time lag to cochlear implantation of 11.2 (IQR: 8.2, 22.5) months. These findings support that reasons other than audiologic criteria also accounted for late implantation.

**Children With ANSD**  • We also specifically considered the 22 children who presented with ANSD at confirmation of hearing status. In the center where the study was conducted, cochlear implant candidacy for children with ANSD was determined applying the same procedures for children with sensorineural hearing loss. They were typically fitted with hearing aids, enrolled in a spoken rehabilitation program and carefully followed to evaluate access to hearing and progress in speech and spoken language development. They were assessed for cochlear implantation, irrespective of audiometric hearing levels if progress was not satisfactory. The median age at implantation for the full group was 29.2 (IQR: 19.0, 56.2) months, and the average time from diagnosis to surgery was 17.7 (IQR: 6.4, 44.6) months. Fifteen of these children received their implants more than 12 months after diagnosis. Reasons accounting for the longer time to implantation were similar to those for the full group and included documented changes in audiometric thresholds (n = 4), complex medical or developmental issues (6), family indecision (1), and other varied or unknown reasons (4).

**DISCUSSION**

Age at implantation continues to be considered an important determinant of outcomes in pediatric cochlear implantation (Niparko et al. 2010; Nikolopoulos 2013; Tobey et al. 2013). Population-based data can provide more accurate information about what constitutes “delayed implantation” and the factors affecting late implantation after the diagnosis of hearing loss. An important strength of this study lies in the comprehensive data collected prospectively on an entire population of children implanted in one region. Despite a median age of identification of just over 1 year of age, the median age of cochlear implant surgery in a 12 year-cohort was just over 3 years of age. Notably, 118 of 187 (63.1%) children received cochlear implants 12 months after initial diagnosis of their permanent hearing disorder.

Information about the onset of hearing loss and the progression to severe to profound hearing loss deliver a more accurate clinical profile of the pediatric cochlear implant population. In this study population, longer time to implantation was primarily due to the presence of substantial residual hearing. More than half of the children did not meet audiometric eligibility criteria at initial diagnosis but later became candidates for surgery due to deterioration in hearing thresholds. It is noteworthy that almost one-third (39 of 143) of the children with sensorineural hearing loss (whose initial degree of severity was known) had hearing loss of mild to moderately severe degree (<70 dB), placing them well outside the typical audiometric criteria for cochlear implantation. Deterioration in hearing thresholds occurred regardless of time of onset, affecting children with congenital, early-onset, and late-onset hearing loss. These findings also showed that irrespective of the degree of hearing loss, 62 (52.5%) children experienced deterioration in thresholds, including 9 children who initially presented with mild bilateral or unilateral loss at diagnosis. It is important to note, however, that all conclusions regarding deterioration in hearing reported here are based on clinical audiograms obtained in dB HL and not on real ear information. Previous research suggested that almost one-third of children with mild bilateral or unilateral loss experienced 20 dB or more deterioration in hearing (Fitzpatrick et al. 2014). The importance of careful monitoring of children with milder forms of hearing loss has been highlighted in previous reports (Hyde 2005).

In a previous study examining age at cochlear implantation, 25.6% (11 of 43) of children who received cochlear implants showed marked deterioration (≥20 dB change in pure-tone
average) in audiometric thresholds, resulting in a shift in intervention from hearing aids to cochlear implants (Fitzpatrick et al. 2011). The proportion of children who showed more than 20 dB deterioration in hearing in the present study was substantially higher and likely reflects the fact that this study, unlike the previous one, included population-based data where age of diagnosis and cochlear implant details were prospectively collected. The findings that more children experienced important deterioration in hearing are aligned with recent research on children with hearing loss across the spectrum of severity, which showed that more than half of the children from a newborn screening cohort of 330 children experienced more than 10 dB deterioration in thresholds, of whom 23% had more than 20 dB changes in hearing (Barreira-Nielsen and Fitzpatrick, Reference Note 1). In the present study, progressive loss was the main reason for the large number of children with longer time from diagnosis to surgery. There were no delays to surgery once children met audiologic criteria for cochlear implantation. This study underscores the importance of ongoing follow-up of children with permanent hearing loss of all degrees to ensure that appropriate intervention with cochlear implantation or other technology occurs in a timely manner.

Other clinical profiles that appeared to explain late implantation were the presence of one or more complex medical issues and/or additional disabilities accounting for 17% of children who experienced more than a gap of 12 months to surgery. For these children, delays may occur for health reasons or because of additional time needed for the definitive confirmation of the diagnosis. In some cases, considerable time is required to address uncertainties and concerns on the part of both parents and clinicians (Fitzpatrick et al. 2011; McCracken & Turner 2012). Known wait times for the remaining 18 (15%) children appeared to be affected by parental indecision and geographical location, that is some children were outside the typical catchment area which may have resulted in a longer time to access services. The issue of parental indecision has been highlighted by other researchers (Most & Zaidman-Zait 2003; Johnston et al. 2008) and can be more common when parents face the challenge of caring for children with additional special needs (Berrettini et al. 2008; McCracken & Turner 2012). Finally, a minority of children were implanted more than 12 months after diagnosis due to a variety of other documented reasons or for reasons that could not be determined from clinical profiles and medical chart notes.

Age of cochlear implantation has received considerable attention and is one of the most widely examined determinants of outcomes in pediatric cochlear implantation (Nikolopoulos 2013). In numerous studies, early age at implantation has positively affected outcomes in spoken language development (Svirsky et al. 2004; Nicholas & Geers 2007; Tobey et al. 2013). Analysis of this population-based data set showed that age of implantation was related to progression and degree of hearing loss. Therefore, children implanted later can be expected to have greater auditory experience with hearing aids preimplant and consequently, age at implantation may be most meaningful for children who meet implant audiologic criteria within the first few months of infancy. Several researchers have presented evidence for preimplant residual hearing as a predictive factor for spoken language outcome (Nicholas & Geers 2007; Niparko et al. 2010). Another complicating factor is that when children from multiple intervention programs are included in studies, little is known about whether early age at implantation and exposure to implants give children access to certain services and family supports that are not necessarily available to those who use conventional hearing aids in some programs. Outcome studies in children with cochlear implants are characterized by great variability in performance (Hawker et al. 2008; Tobey et al. 2013). For example, while age at implantation emerged as a signification predictor, Tobey et al. reported that some children implanted late (ages 2.5 to 5 years) followed typical learning trajectories that allowed them to achieve age-appropriate language 4 to 6 years after implantation.

This study summarizes population-level information about the profile of children who received cochlear implants since 2002. The findings offer insights into why many children continue to receive cochlear implants “late” and help explain why large numbers of children continue to receive implants well after their first birthday. Delay to follow-up for children with hearing loss in private health care can be related to socioeconomic status (Vohr et al. 2002; Armstrong et al. 2013), however, that appears less likely in a publicly funded universal access health system. There is no evidence in this research that time to implantation was associated with systemic issues such as limited resources. A limitation of this study is that age at implantation and factors affecting age were drawn from one center’s data only. This center focuses on the development of spoken language, and therefore, professionals place emphasis on ensuring that children have access to intelligible speech. It is possible that time to surgery is higher at other centers with different philosophies concerning communication development. Other factors may also affect time to implantation in other regions. Data collected for this study were restricted to audiologic and clinical characteristics, as well as cochlear implant management details. Therefore, a limitation of this study is that information related to specific hearing aid use, as well as auditory, speech, and language outcomes, were not collected. Therefore, no conclusions can be drawn about the impact of delayed cochlear implantation on children’s communication development.

Population-based studies can help shed new light on the profiles of children who receive cochlear implants and may assist in explaining differences in outcomes. Until recently in the absence of population screening, it has been difficult to accurately differentiate between children with congenital severe to profound hearing loss and children with delayed onset or progressive losses. Lacking knowledge about previous exposure to useful auditory input, the true impact of age of cochlear implantation was difficult to predict. These findings broaden understandings of the complexities related to age at cochlear implantation and point out the importance of disentangling age at implantation for children with congenital severe to profound deafness from that of children with residual hearing at diagnosis. It will be important to couple these clinical characteristics with future information on outcomes in children who are implanted late. With increasingly detailed information gleaned from studies of newborn screening cohorts, findings such as these may help explain some of the inconsistencies related to age at implantation.

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E.M.F. conceptualized and planned all aspects of the study and wrote the first manuscript draft. J.H. and J.W. collected the data and contributed to the analysis and figures. All authors discussed the findings and commented on the manuscript.

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