Results of a prospective surgical audit of bilateral paediatric cochlear implantation in the UK

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Background: Following the approval of bilateral paediatric cochlear implantation in 2009, the prospective multi-centre UK National Paediatric Cochlear Implant Audit was established to collect a large dataset of paediatric implantations. The aim of the surgical part of the audit, reported here, was to collect data on surgical practice, outcomes and complications.
Methods: Data from 14 surgical centres was collected prospectively, including simultaneous and sequential bilateral as well as unilateral implantations. Data collected included age at implantation, aetiology of deafness, implant type, duration of surgery, the use of electrophysiological testing, and the use of pre- and post-operative imaging. Details of major and immediate minor complications were also recorded.
Results: 1397 CI procedures in 961 CI recipients were included; 436 bilateral simultaneous, 394 bilateral sequential, 131 unilateral. The overall major complication rate was 1.6% (0.9% excluding device failure) and was similar following bilateral CI compared to sequential and unilateral CI.
Conclusion: This prospective multi-centre audit provides evidence that bilateral paediatric CI is a safe procedure in the UK, thus endorsing its role as a major therapeutic intervention in childhood deafness.

Keywords: Cochlear Implant, Pediatric, Audit, Complications

Introduction

Cochlear implantation (CI) is a well-accepted treatment for children with severe-to-profound hearing loss, leading in a high proportion of cases to an improved linguistic, academic and social performance (Bond *et al.*, 2009). Owing to improved access to CI and the introduction of universal neonatal screening, the number of paediatric cochlear implant recipients has increased greatly in recent years and the age at implantation has been significantly reduced. There has been increasing interest in the additional benefits of bilateral CI compared to unilateral, and bilateral simultaneous CI has emerged as the preferred standard for the treatment of the profoundly deaf child in developed countries (Ramsden *et al.*, 2012; Peters *et al.*, 2010). In 2009, the National Institute for Health and Clinical Excellence (NICE) issued guidance on CI in children in England and Wales, approving simultaneous bilateral CI (NICE, 2009); sequential CI was approved for children who had undergone unilateral CI prior to the guidance, if in the opinion of the CI team, there was a likelihood of gaining sufficient additional benefit. Following the NICE guidance, a British national multi-centre prospective CI study was established, primarily to confirm the safety and effectiveness of the procedure as carried out in centres across the United Kingdom. This study reports on the surgical aspects and complications of bilateral CI (both simultaneous and sequential) following the introduction of this service in the National Health Service in the UK.

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Methods

Data collection took place in the 2 years between January 2010 and December 2011. Fourteen British CI centres participated. Surgeons prospectively completed a standardized audit proforma for all children (from birth to 18 years old) undergoing CI. This included simultaneous bilateral and sequential bilateral implantation, with data collected on a group of unilateral implantations for comparative purposes. Institutional approval for the audit was obtained at each participating site. Data collected included demographic details, aetiology of deafness, use of pre- and

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post-operative imaging, type of device used, duration of surgical procedure, use of intra-operative electrophysiological testing, and length of hospital stay. Post-operative complications were also recorded. The audit was supported by a grant from the Healthcare Quality Improvement Partnership (HQIP).

Results

In total, 961 CI recipients (1397 implant procedures) were entered into the audit. Male-to-female ratio was 474:462 (data missing $n = 25$). There were 436 bilateral simultaneous, 394 bilateral sequential, and 131 unilateral CI procedures. Age data were available for 915 children, with a mean age (years:months) at implantation of 6:1 (median 4:9, range 4 months to 18 years). Mean age at implantation for children with congenital deafness undergoing bilateral simultaneous implantation ($n = 345$) was 3:1 (median 2:2, range 4 months to 17:8). Aetiology of deafness was recorded in 940 (98%) cases. Congenital deafness accounted for 85% of the cases ($n = 799$), with most of these ($n = 639$, 80%) being of unknown aetiology. Use of pre-operative imaging was recorded in 925 (96.3%) cases. Both magnetic resonance imaging (MRI) and computerized tomographic (CT) scans were performed in 511 (55.2%) of children. MRI and CT alone were performed in 280 (30.2%) and 134 (14.5%) cases, respectively. Duration of surgery was defined as the time between the patient entering the anaesthetic room and the patient leaving the operating theatre, and was recorded in 631 of 961 (66%) cases. The mean duration of surgery (hours:minutes) for bilateral simultaneous CI ($n = 284$) was 4:32 (median 4:15, range 1:40 to 8:45). Mean duration for sequential CI ($n = 262$) was 2:25 (median 2:15, range 1:00 to 7:25) and for unilateral CI ($n = 85$) was 2:44 (median 2:30, range 1:25 to 9:45). Use of intra-operative testing was documented in 910 of 961 cases (95%). Telemetry was used to measure the electrically evoked compound action potential (ECAP) from the auditory nerve in 626 (69%) patients. Use of post-operative imaging was documented in 854 (89%) cases. The majority (603 of 854; 71%), had a post-operative plain film to check for a satisfactory position of the implant electrode. Data for length of stay in hospital was recorded in 795 (83%) cases. Fifty patients (6.3%) underwent surgery as a day case procedure, defined as admission to and discharge from hospital on the same day. The majority were admitted to hospital for a single overnight stay (n = 642, 80.8%).

Surgical complications

Following descriptions by Bhatia *et al.* (2004), and Hansen *et al.* (2010), a major complication was defined as 'an adverse event occurring during or after surgery that necessitated a further major surgical intervention, admission to Intensive Therapy Unit (ITU), exposure to invasive intervention or a permanent disability such as persistent facial weakness' (Bhatia *et al.*, 2004; Hansen *et al.*, 2010). Device failure was included as a major complication whether or not re-implantation was performed. Major complications were classified as immediate (intra-operative or first week following surgery) or delayed (occurring within the period of the audit). Owing to the length of the audit period, follow-up ranged from 3 to 24 months (mean 12.5 months). A minor complication was defined as 'an adverse event managed by medical measures or by a minor surgical procedure (e.g. aspiration of a haematoma)'. Only immediate (defined as above) minor complications were recorded. Overall, there were 15 major complications, giving an overall major complication rate of 1.6%. This included four immediate major complications (two (0.2%) CSF leaks requiring lumbar drainage, one haemorrhage requiring blood transfusion, one immediate return to theatre to reposition the electrode array). There were 11 delayed major complications (six (0.6%) device failures, two (0.2%) wound infections requiring explanation, one (0.1%) case of meningitis, and two cases requiring return to theatre: one for drainage of infection and one for a recurring collection of air under the scalp flap). There were no permanent facial nerve palsies, and no deaths. Sixty-two (6.5%) immediate minor complications were reported. These included 12 cases of imbalance leading to prolonged hospital stay (other imbalance was not considered to be a complication) and two cases of temporary partial (House-Brackmann Grade 3) facial nerve weakness.

Conclusion

In this study, the results of the surgical aspects of a prospective multi-centre national paediatric bilateral CI surgical audit are presented, representing one of the largest series to date. Although the follow-up was short, the overall major complication rate was 1.6% (0.9% excluding device failures); similar to that reported in other series. There were no deaths or permanent facial nerve palsies in this series. There was no evidence of an increased risk of complications following bilateral CI compared to sequential and unilateral CI. This study provides evidence that bilateral paediatric CI, whether simultaneous or sequential, is a safe procedure in cochlear implant centres in the UK, thus endorsing its role as a major therapeutic intervention in childhood deafness.

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