Access to aidable residual hearing in adult candidates for cochlear implantation in the UK

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Abstract

Guidance from the National Institute for Health and Care Excellence (NICE) permits candidates to receive a cochlear implant provided they only hear sounds louder than 90 dB HL at 2 and 4 kHz. In some patients, their level of residual hearing may be sufficient to warrant the use of a hearing aid in their non-implanted ear. A survey of unilaterally-implanted adults indicated that those implanted since the publication of NICE guidance were almost seven times more likely to use a hearing aid than those implanted prior to this. If contralateral hearing aid use provides additional benefits over implant use alone, it may be appropriate to consider the capacity to use residual hearing following implantation when determining candidacy.

Keywords: cochlear implants, bimodal aiding, cochlear implant candidacy, bimodal candidate, contralateral hearing aid, residual hearing.

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Introduction

Traditionally, cochlear implants (CIs) for adults in the UK were typically restricted to those with profound deafness, or little or no access to useful residual hearing (UKCISG 2004). They were therefore unlikely to benefit from the use of an acoustic hearing aid (HA) in their non-implanted ear following implantation. By the early 2000s, studies were emerging that demonstrated the capacity of cochlear implantation to provide benefit in patients with greater levels of residual hearing (Cullen et al., 2004; Dowell et al., 2004). Hearing preservation techniques were also being proposed to maximise the retention of residual hearing in the implanted ear (Lenarz et al., 2009). The publication of guidance from the National Institute for Health and Care Excellence (NICE 2009) formally expanded candidacy criteria in the UK to include adults with severe-to-profound hearing loss with some measurable residual hearing (up to 90 dB HL at 2 & 4 kHz) and open-set speech discrimination (less than 50% key words correct when presented in quiet).

Notably, NICE guidance places no restriction on low frequency hearing other than its capacity to support speech perception. Therefore, CI recipients in the UK may still have access to potentially useful and aidable low frequency hearing despite the restriction that NICE guidance places on their pre-operative speech perception abilities. Zhang *et al* (2010) demonstrated that low frequency information can still contribute to speech understanding when combined with a CI even if it is not sufficient to support open-set speech perception by itself. However, it is likely that obtaining benefit from the level of residual acoustic hearing available to UK candidates would require the use of a HA. It is possible, therefore, that NICE

guidance may have increased the proportion of implant recipients who use a contralateral acoustic HA with their CI; i.e. who listen 'bimodally'.

The most recent large outcomes study in the UK was conducted before the publication of NICE guidance (UKCISG 2004). It is therefore unclear whether the combined effects of the guidance, the emerging evidence of the benefits of residual hearing, and the development of hearing preservation techniques in the late 2000s led to an increase in access to residual hearing among candidates and consequently to an increase in the use of contralateral acoustic HAs in the UK. A survey of adult unilateral CI users was conducted to establish whether those implanted since the publication of NICE guidance are more likely to use a HA in their non-implanted ear compared to those implanted in or prior to 2009.

Methods

A total of 623 surveys were sent to unilateral CI recipients at the Nottingham Adult Implant Programme and to 404 recipients at the Midlands Hearing Implant Programme. The inclusion criteria were: (1) 18 years or older; (2) unilateral CI recipient; (3) implanted in the UK. Eligible participants were given the option to return a paper survey or complete it online using Survey Monkey. The study was given a favourable opinion by the Health & Social Care Research Ethics Committee B (REC reference 15/NI/0054).

Respondents were asked to indicate their age, which ear was implanted, the year of implant surgery (or the first surgery if they had been subsequently re-implanted), whether they were implanted in the UK, which was their better-hearing ear before surgery, and whether they currently use a HA in their non-implanted ear. Responses about which ear was implanted and which was perceived to be the better-hearing ear prior to implantation were used to classify

patients into one of three sub-groups: (1) implanted in their worse ear; (2) implanted in their better ear; and (3) ear status prior to implantation similar or unknown. The proportion of HA users was established in each sub-group and 95% confidence intervals were calculated using Wilson's procedure (Newcombe, 1998).

Respondents were divided into two categories: those who were implanted prior to the publication of NICE guidance, and those who were implanted since. Binary logistic regression established whether patients implanted since were more likely to use a HA than those implanted before NICE. The regression model controlled for the age at time of survey completion as HA usage would be expected to decline with age as any residual hearing deteriorates and those implanted before NICE were likely to have been older than those implanted since. The model also controlled for whether patients were implanted in what they considered to be their better or worse ear as those implanted in their better ear may have been less likely to wear a HA contralaterally. Missing data was found to constitute less than 5% of the data across all variables (year of implantation, HA usage, age, better ear prior to implantation) and was treated as missing at random. Rather than excluding those cases, missing data from a patient on any one variable was accounted for by estimating (imputing) the value that would have been most likely given their values on the other variables; i.e. multivariate imputation. Fifty imputations by chained equations were conducted using the 'mice' package in the R statistical programming environment (van Buuren and Groothuis-Oudshoorn, 2011). The overall regression model comparing HA usage rates before and after NICE was run both with and without imputation to confirm that the pattern of effects was not driven by the use of this procedure.

Results

In total, 314 paper responses and 44 online responses were received representing a response rate of 35%. One respondent was excluded on the basis of age (under 18 years) and four on the basis of their country of implantation (outside the UK). Table 1 contains a summary of the remaining 353 responses. Forty-three percent of respondents received their implant in the six years since NICE guidance, 23% in the preceding six years between 2004 and 2009, with the remainder having been implanted in the 19 years between 1985 and 2003. Almost one third of all respondents reported using a contralateral HA and nearly 60% recalled having a better-hearing ear prior to implantation.

Table 1 here

Figure 1 shows the proportion of reported contralateral HA users separately for those implanted before and after the publication of NICE guidance. Across the whole sample, HA use was found to increase by 34.3% from a pre-NICE score of 13.3% to a post-NICE score of 47.6% ($\chi^2(1)=45.1$, $p<.001$). A significant increase in HA use was apparent in all three sub-groups with the largest increase observed among those who reported being implanted in their worse ear (40.3% increase to 56.7% from 16.4%, $\chi^2(1)=38.4$, $p<.001$).

Figure 1 here

To assess whether HA use increased gradually over time or abruptly following the publication of NICE guidance, the proportion of reported contralateral HA users was calculated for all those who were implanted within consecutive 3-year periods between 2004 and 2015 (Figure 2). A similar proportion of contralateral HA users was observed amongst those implanted in 2004-6 (22.2%) and 2007-9 (18.5%; $\chi^2(1)=0.01$, p=.54). The proportion of HA users then increased significantly amongst those implanted in 2010-12 (37.7%; $\chi^2(1)=4.3$, p<.05), and increased further in the most recent period from 2013-15 (54.5%; $\chi^2(1)=3.4$, p<.05).

Figure 2 here

The logistic regression model indicated that reported HA use was almost three times more likely among those who indicated that they were implanted in their worse ear compared to those implanted in their better ear (OR=2.9, 95% confidence interval 1.5 to 5.6). No significant influence of age was observed ($\chi^2(4)=4.8$, p=.31). After controlling for these factors, the regression model indicated that patients implanted in the six years since the publication of NICE guidance were almost seven times more likely to use a HA than those implanted anytime between 1985 and 2009 (OR=6.7, 95% confidence interval 3.6 to 12.3) and almost four times more likely than those implanted in the six years immediately preceding the publication of the guidance (2004 to 2009, OR=3.69, 95% confidence interval 1.82 to 7.47).

Discussion

It is possible that the reported HA use rates of around 30% across all respondents and 48% across those implanted since NICE may be over-estimates. Some HA non-users may have decided that the survey was not applicable to them even though the survey was sent to CI recipients regardless of whether they used a HA or not and the supporting information clearly stated that we also wished to hear from those who do not use a HA. Additionally, the number of respondents implanted since NICE guidance was almost as numerous as those implanted before (43% and 51% respectively with 6% missing data) despite only six years having elapsed since its publication. Therefore, the survey respondents may have been self-selecting on the basis of HA use. Nevertheless, the results would seem to suggest that HA use has increased substantially since NICE guidance and confirm that there may be at least 100 'bimodally-aided' listeners across just two UK implant programmes.

Although the proportion of implant recipients who reported using a contralateral HA increased significantly around the time that NICE guidance was published (Figure 2), it is unclear whether this increase can be solely attributed to the guidance alone. Research outlining the potential benefits of implanting candidates with greater levels of residual hearing (Dowell et al., 2004) and advances in hearing preservation techniques to minimise the risk of irreversible damage from implantation (Lenarz et al., 2009) were being published around the same time. However, it seems plausible that the observed effect on HA use among UK implant recipients can be attributed, at least in part, to the publication of the NICE guidance that likely led to changes in referral patterns and consequently greater levels of residual hearing in contemporary candidates for implantation.

Recent evidence suggests that some UK patients can derive benefits from the combined use of a CI and a HA (Visram et al, 2012; Green et al, 2014). However, the reasons why such a relatively large proportion of recent CI recipients continue to use a contralateral HA despite their limited access to residual hearing remain largely unclear. Only if characterised through further research would it then be possible to examine how those specific benefits could be optimised when fitting one or both devices. Should further evidence emerge that this 'bimodal' listening configuration provides additional benefits over implant use alone, it may be appropriate to consider the potential for a patient to continue to use their residual hearing following implantation when determining candidacy.

Despite the apparent increase in the number of bimodally-aided patients suggested by the current results, clinical practice does not appear to have adapted its focus away from maximising benefit from use of the CI alone. A recent survey of UK audiologists working across adult implant programmes suggested that both devices are still typically maintained by two separate service providers (Fielden and Kitterick, 2015). Thus, further research is still required to explore how the provision of services could be adapted to support and manage the effective use of both devices.

Conclusion

Since the publication of the NICE guidance in 2009, there has been a significant increase in reported contralateral HA use among adult unilateral CI users. As a result, there may now be many more CI users who benefit from simultaneous access to electric and acoustic information. It may therefore be appropriate to consider a patient's capacity to exploit their residual hearing following implantation when assessing candidacy for implantation.

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The authors declare no conflicts of interest.

References

Cullen, R. D., Higgins, C., Buss, E. et al. (2004). Cochlear implantation in patients with substantial residual hearing. Laryngoscope, 114, 2218-2223.

Dowell, R. C., Hollow, R., Winton, E. (2004). Outcomes for cochlear implant users with significant residual hearing: implications for selection criteria in children. Archives of Otolaryngology: Head and Neck Surgery, 130, 575-581.

Fielden C A and Kitterick, P T. (2015). Current clinical practice in the UK for bimodal aiding and evaluation: preliminary results. Poster presented at the British Cochlear Implant Group annual meeting, Bristol, UK

Green, T., Faulkner, A., Rosen, S. (2014). Overlapping frequency coverage and simulated spatial cue effects on bimodal (electrical and acoustical) sentence recognition in noise. Journal of the Acoustical Society of America, 135, 851.

Lenarz, T., Stover, T., Buechner, A. *et al*. (2009). Hearing conservation surgery using the Hybrid-L electrode. Results from the first clinical trial at the Medical University of Hannover. Audiology and Neurootology, 14 Suppl 1, 22-31.

Newcombe, R G. (1998). Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods. Statistics in Medicine, 17, 857-872.

NICE. (2009). Cochlear Implants for children and adults with severe to profound deafness. In National Institute for Clinical Excellence Technology Appraisal Guidance 166. UK.

UKCISG. (2004). Criteria of candidacy for unilateral cochlear implantation in postlingually deafened adults I: theory and measures of effectiveness. Ear and Hearing, 25**,** 310-35.

van Buuren, S., Groothuis-Oudshoorn, K. (2011). mice: Multivariate Imputation by Chained Equations in R. Journal of Statistical Software, 45(3), 1-67.

Visram, A. S., Azadpour, M., Kluk, K. et al. (2012). Beneficial acoustic speech cues for cochlear implant users with residual acoustic hearing. Journal of the Acoustical Society of America, 131, 4042-4050.

Zhang, T., Dorman, M. F., Spahr, A. J. (2010). Information from the voice fundamental frequency (F0) region accounts for the majority of the benefit when acoustic stimulation is added to electric stimulation. Ear and Hearing, 31, 63-69.

Legends

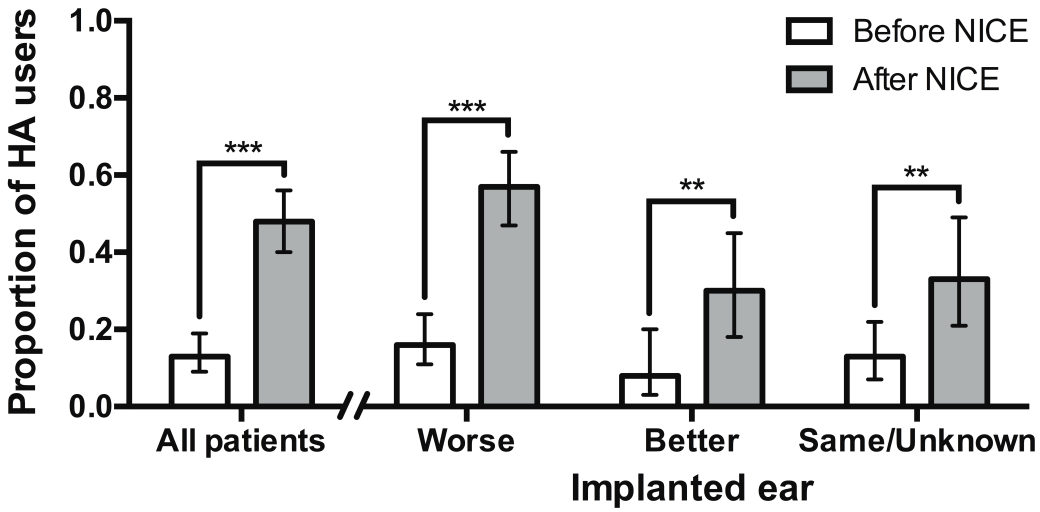
Figure 1. Proportion of reported contralateral hearing aid users across the whole sample ('All patients') and within sub-groups identified by whether they were implanted in their worse ear, their better ear, or did not report having a better ear prior to implantation ('Same/Unknown'). Error bars plot the 95% confidence intervals for the proportions. Asterisks indicate the result of comparing the proportions using Wilson's test, *** $p<.001$, ** $p<.01$.

Figure 2. Proportion of reported contralateral hearing aid users in the 6 years immediately pre- and post- NICE guidance, divided into 3-year time bins. Error bars plot the 95% confidence intervals for the proportions. Asterisks indicate the result of comparing the proportions using Wilson's test, *** $p<.001$, * $p<.05$.

Table 1. Summary statistics of the 353 respondents whose data were included in the analysis. In cases where an ear had been re-implanted, the year of the first implantation was taken as the year of surgery.

Characteristics	Category	N	%
Age at time of survey	18–32 years	62	17.56
	33–47 years	55	15.58
	48–62 years	68	19.26
	63–77 years	114	32.29
	Over 78 years	48	13.60
	Missing data	6	1.70
Implanted ear	Left	152	43.06
	Right	191	54.11
	Missing data	10	2.83
Year of surgery	1985-2003 (pre-NICE)	99	28.05
	2004-2009 (pre-NICE)	82	23.23
	2010-2015 (post-NICE)	151	42.78
	Missing data	21	5.95
Contralateral HA user	Yes	103	29.18
	No	247	69.97
	Missing data	3	0.85
Better ear prior to implantation	Implanted ear	111	31.44
	Non-implanted ear	94	26.63
	Same	98	27.76
	Unknown	36	10.20
	Missing data	14	3.97

Table 1



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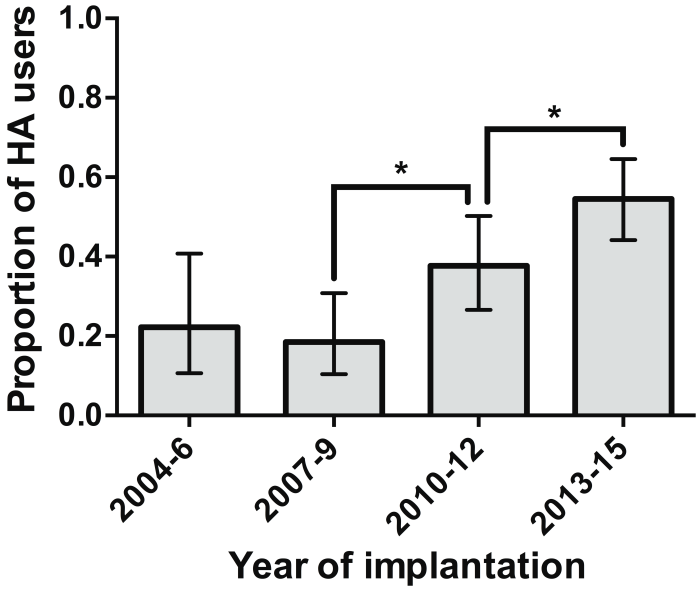

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