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The Effectiveness of Bilateral Cochlear Implants for Severe-to-Profound Deafness in Adults: A Systematic Review

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Objective: Assessment of the clinical effectiveness of bilateral cochlear implantation compared with unilateral cochlear implantation or bimodal stimulation, in adults with severe-to-profound hearing loss. In 2007, the National Institute for Health and Clinical Excellence (NICE) in the U.K. conducted a systematic review on cochlear implantation. This study forms an update of the adult part of the NICE review.
Data Sources: The electronic databases MEDLINE and Embase were searched for English language studies published between October 2006 and March 2011.
Study Selection: Studies were included that compared bilateral cochlear implantation with unilateral cochlear implantation and/or with bimodal stimulation, in adults with severe-to-profound sensorineural hearing loss. Speech perception in quiet and in noise, sound localization and lateralization, speech production, health-related quality of life, and functional outcomes were analyzed.
Data Extraction: Data extraction forms were used to describe study characteristics and the level of evidence.
Data Synthesis: The effect size was calculated to compare different outcome measures.
Conclusion: Pooling of data was not possible because of the heterogeneity of the studies. As in the NICE review, the level of evidence of the included studies was low, although some of the additional studies showed less risk of bias. All studies showed a significant bilateral benefit in localization over unilateral cochlear implantation. Bilateral cochlear implants were beneficial for speech perception in noise under certain conditions and several self-reported measures. Most speech perception in quiet outcomes did not show a bilateral benefit. The current review provides additional evidence in favor of bilateral cochlear implantation, even in complex listening situations. **Key Words:** Adults—Bilateral cochlear implants—Bimodal stimulation—Cochlear implantation—Severe-to-profound deafness—Systematic review—Unilateral cochlear implants.

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During the last decades, cochlear implants (CIs) have become standard treatment for both children and adults with severe to profound bilateral hearing loss. In the Netherlands, it is standard clinical practice to provide a CI unilaterally (UCI). However, the human auditory system is specialized in processing sound perceived by 2 ears, as summarized by Akeroyd (1).

Listeners with normal hearing have an increased loudness perception when listening with 2 ears compared with one because of binaural summation (between 3 and 10 dB depending on the level). Interaural level and time differences provide the listener with information about the location of the source. Binaural squelch occurs when the signal is out of phase across the ears and the noise is in phase (or vice versa), leading to a benefit of up to 6 dB

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for speech perception. Binaural redundancy results in benefit of 1 or 2 dB when identical combinations of signal and noise are presented at each ear (2).

The binaural mechanisms described above give rise to the question about the effect of bilateral cochlear implantation (BiCI) compared with UCI. Our hypothesis is that the natural situation of hearing with 2 ears will be approached better when both ears receive auditory input, which can be achieved by implanting 2 CIs.

In 2007, the National Institute for Health and Clinical Excellence (NICE) in the UK conducted a systematic review on the clinical and cost-effectiveness of unilateral and bilateral cochlear implantation in children and adults (3). The authors searched for evidence in 2007 and reported some positive trends towards benefits for BiCIs, but they could not support this with sound statistical evidence.

Since 2007, more evidence was published on the effect of BiCIs in adults. Therefore, we updated the NICE review. Our objective was to assess the clinical effectiveness of bilateral cochlear implantation compared with unilateral cochlear implantation alone or with a contralateral hearing aid (CIHA). The results of our review regarding children were reported in 2010 (4). Here, we report our results for adults with severe-to-profound hearing loss and how they compare with the results of the NICE review.

MATERIALS AND METHODS

Search Methods

We adapted the original search strategy of the NICE (3). We searched in the electronic databases MEDLINE and Embase for eligible studies, published between October 2006 and March 2011. The main search terms were *cochlear implant* and *hearing loss*.

Criteria for Inclusion of Studies

We searched for randomized controlled trials (RCTs) and systematic reviews that included RCTs, as well as nonrandomized studies, cross-sectional studies, and studies where subjects acted as their own controls. Only studies involving prelingually and postlingually deafened adults (aged 18 years and older) with severe-to-profound hearing loss (≥70 dBHL) were considered. Studies had to address unilateral, bimodal, or bilateral stimulation with the use of multi-channel CIs using whole-speech processing strategies. We compared BiCI with either UCI or CIHA. Outcome measures included speech perception in quiet and in noise, sound localization and lateralization, speech production, health-related quality of life and functional outcomes.

Study Selection

The first 2 authors made independent study selections: first by reading the title and abstract and then by retrieving the full articles and making the final selection based on the criteria described. Disagreements were resolved by discussion.

Data Extraction

We collected data from the included studies using standardized data extraction forms (5). When results could only be extracted from figures, we increased the accuracy by enlarging the figures to approximately 400%.

Methodologic Quality

The first 2 authors made independent assessments of the methodologic quality of the included studies. We applied the same criteria as the NICE (3) combined with the criteria formulated by the Cochrane Collaboration (5). Methodologic comments were subdivided into 5 types of bias: selection bias, performance bias, detection bias, bias because of incomplete outcome data, and reporting bias. Disagreements were resolved by discussion.

Analysis

To increase readability and to enable comparisons of the selected studies, results from the studies were standardized for each outcome measure. This was performed by calculating the effect size (ES) according to (5) and (6):

$$\mathrm{ES} = (\mu_2 - \mu_1)/\sigma_{\mathrm{pooled}}$$

in which μ_2 is the mean of the outcome measure in the bilateral condition, μ_1 is the mean of the outcome measure in the unilateral or bimodal condition and σ_{pooled} is the pooled standard deviation of both conditions. In the analyses, all data were treated as unpaired. To standardize the ESs, the values were multiplied by -1 when a positive effect corresponded with a negative value (e.g., a decrease in error). In this way, positive ES values represented a beneficial effect of BiCI compared with the alternative treatment. Whenever possible, we performed a meta-analysis by the use of the inverse variance method (5).

Level of Evidence

To assess the level of evidence (LoE), we used the scoring method proposed by Cox (7) and Harbour and Miller (8). This method rates the strength of the study design with a number that ranges from 1 to 5 (see Supplemental Digital Content Table 1A, http://links.lww.com/MAO/A131). To make the rating more sensitive for the difference between within-subject and between-subject designs, we subdivided category 4 into 4a and 4b (Table 1A, http://links.lww.com/MAO/A131).

To rate the quality of the studies within each level of design strength, a rating was given to qualify the risk of bias (see Supplemental Digital Content Table 1B, http://links.lww.com/MAO/A131). The risk of bias can range between ++ (very low risk) and – (high risk). We assigned an additional value (+/−) because of the expected small variation in the risk of bias between the studies. The quality of the study design together with the risk of bias forms the LoE.

RESULTS

Study Selection

A flow chart of the study selection process is shown in Figure 1. We included 14 studies (9–22). Two BiCI studies were excluded because no new data were presented (23) and because data were nonextractable because of missing standard deviations or raw data (24). The NICE reviewed 5 studies including adults (25–29). Therefore, the total number of included studies was 19.

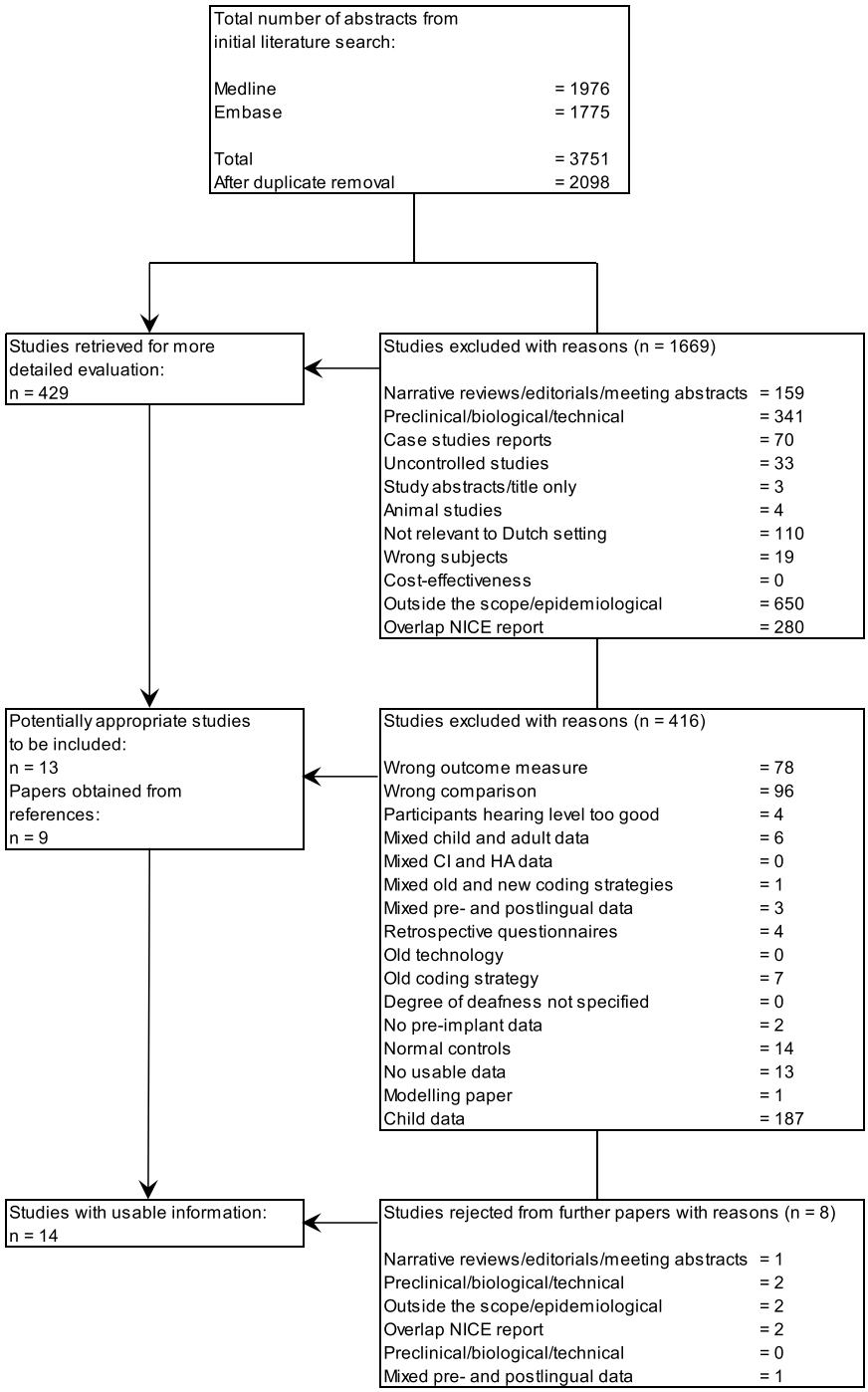

FIG. 1. Flow chart of the study selection of the search.

Study Characteristics

Table 2 (see Supplemental Digital Content Table 2, http://links.lww.com/MAO/A131) summarizes the characteristics of the studies. In all studies, BiCI was compared with UCI, and 3 studies were also compared BiCI with CIHA (11,12,20). These latter 3 were all published after the NICE review. Seven studies discussed simultaneous bilateral implantation (9,10,16,19,21,22,29), whereas 5 studies reported on sequential implantation (17,22,25–27). Eight studies mixed the results of simultaneous and sequential implantation (11–15,18,20,28).

Methodologic Quality

One RCT was included (25) with a medium risk of bias (+/−), and 5 cross-sectional studies (9,11,12,19,20) with an LoE 4a. In the remaining studies, the subjects acted as

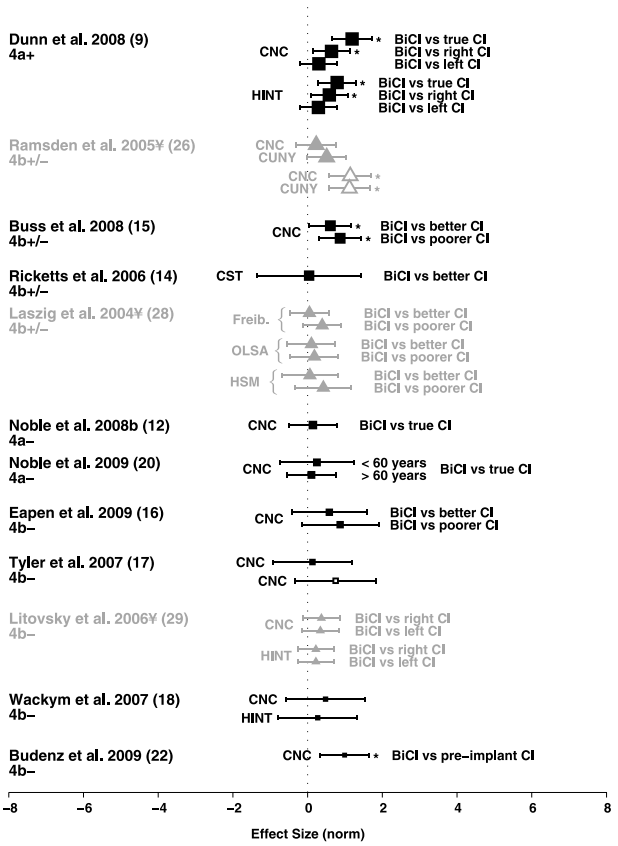

FIG. 2. Speech perception in quiet (BiCI versus UCI). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

their own control (LoE 4b). One of the 5 cross-sectional studies (9) had a low risk of bias (+), whereas the risk of bias of the other studies was either medium (+/−) or high (−). Table 2 (http://links.lww.com/MAO/A131) shows the most important reasons for bias under the heading "comment."

Study Results

Meta-analyses could not be performed due to the heterogeneity of the studies. The results are therefore presented qualitatively.

Bilateral Versus Unilateral Implantation

Speech Perception in Quiet

Twelve studies reported on speech perception in quiet (9,12,14–18,20,22,26,28,29) and are described in Table 3, (see Supplemental Digital Content Table 3, http://links.lww.com/MAO/A131). and Figure 2. All studies reported %-correct scores that were obtained using monosyllabic words or sentences. The studies included by the NICE (26,28,29) did not show a bilateral advantage when performing a within-subject comparison. Only Ramsden et al. (26) reported on a significant bilateral benefit when comparing bilateral stimulation with only the second CI switched on but not with the first CI. In contrast, some of the additional studies showed a bilateral benefit when performing a between-subject comparison (9) as well as a within-subject comparison (9,15,22). Moreover, the study by Dunn et al. (9) had a lower risk of bias compared with the studies included in the NICE review.

Speech Perception in Noise

Table 4, (see Supplemental Digital Content Table 4, http://links.lww.com/MAO/A131) and Figure 3 show the results on speech perception in noise (14,17–19,26,28,29). The studies included by the NICE only showed a bilateral

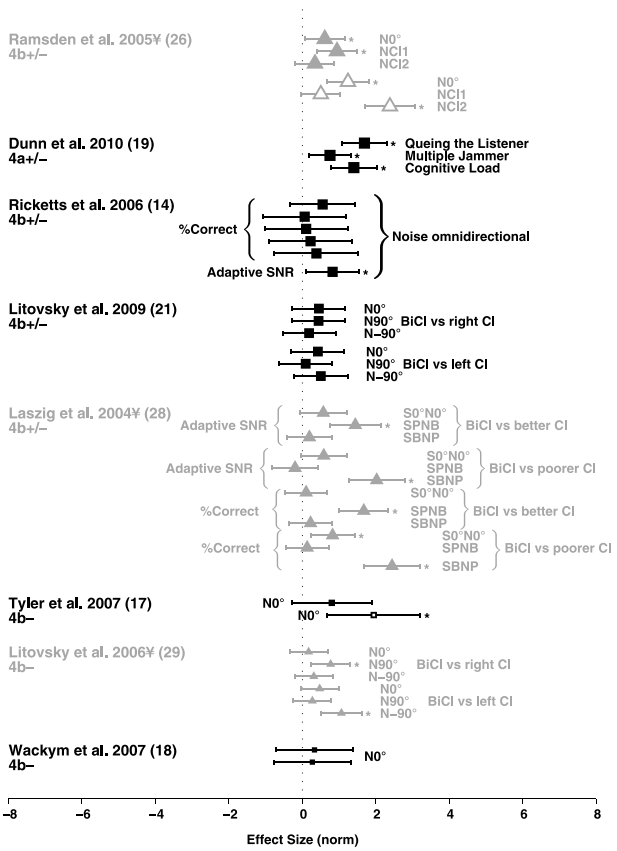

FIG. 3. Speech perception in noise (BiCI versus UCI). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

advantage when noise was presented from the unilaterally aided side when speech and noise were spatially separated (28,29) or when presenting speech and noise from the front and comparing either the first or second implanted CI with bilateral stimulation (26). The former test setup was also used by Litovsky et al. (21) in 2009 and resulted in similar outcomes, although without significant bilateral benefits. In addition to the NICE review, 2 studies showed results on speech in noise tests with multiple noise sources (14,19). Dunn et al. (19) found a significant benefit for BiCI users in comparison with UCI users when testing localization and speech perception simultaneously. Ricketts et al. (14) reported on 5 test conditions with a fixed SNR and 1 condition with an adaptive SNR. Only in the latter condition a significant bilateral advantage was found.

Functional

Localization is the only functional outcome that was reported [Table 5, (see Supplemental Digital Content Table 5, http://links.lww.com/MAO/A131) and Fig. 4]. In agreement with the studies NICE included (27,28), all additional studies showed a bilateral advantage for localization when performing a within-subject comparison (13,21,10) as well as a between-subject comparison (9,12,20). Tyler et al. (17) tested too few subjects to calculate the ES.

Self-Reported Measures

The 5 studies (11,12,20,25,28) that investigated self reported measures used various disease specific and overall quality of life (QoL) questionnaires. The results are displayed in Table 6(see Supplemental Digital Content Table 6, http://links.lww.com/MAO/A131) and Figure 5.

The study by Summerfield et al. (25), which was already included in the NICE review, is the only study with a Level of Evidence of 2. For the current review, we obtained additional data from the authors to calculate the ESs for the between-subject comparisons, whereas only the within-subject comparisons were analyzed in the NICE review. Although small, the most important difference between the 2 comparisons is that a significant bilateral benefit on the speech subscale of the Speech, Spatial and Qualities of Hearing Scale (SSQ) was found when performing a between-subject comparison.

In agreement with the studies reported by the NICE, the study by Noble et al. (12) showed a bilateral benefit on the quality and spatial domains of the SSQ. The studies by Noble et al. (11,12,20) also included the Hearing Handicap Questionnaire (HHQ) and the Hearing Handicap Inventory for the Elderly (HHIE). In 2009 (20), 2 age groups were analyzed separately. In the 2008 studies (11,12), the largest bilateral benefit was found on the spatial subscale of the SSQ. On the HHQ and HHIE, the main advantages regarding BiCI were found on the hearing difficulty and social restriction subscales.

Bilateral Implantation Versus Bimodal Stimulation

The NICE did not report on studies in which BiCI was compared with CIHA. Noble et al. (12,20) compared speech perception in quiet between BiCI and bimodal stimulation but found no significant differences [Table 7 (see Supplemental Digital Content Table 7, http://links.lww.com/MAO/A131) and Fig. 6]. When performing the same comparison for localization capabilities, the bilaterally implanted subjects scored better, with the older subjects performing better than the younger group [Table 8 (see Supplemental Digital Content Table 8, http://links.lww.com/MAO/A131) and Fig. 7]. The 3 studies performed by Noble et al. (11,12,20) compare BiCI with CIHA regarding self-reported measures

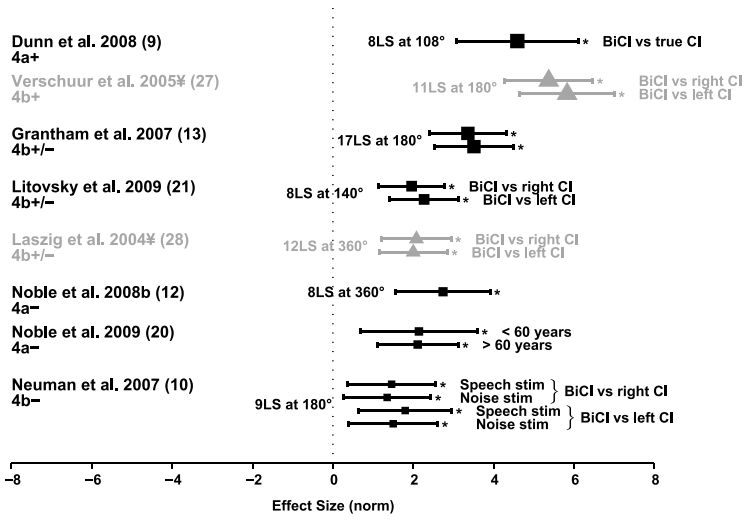

FIG. 4. Localization (BiCI versus UCI). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

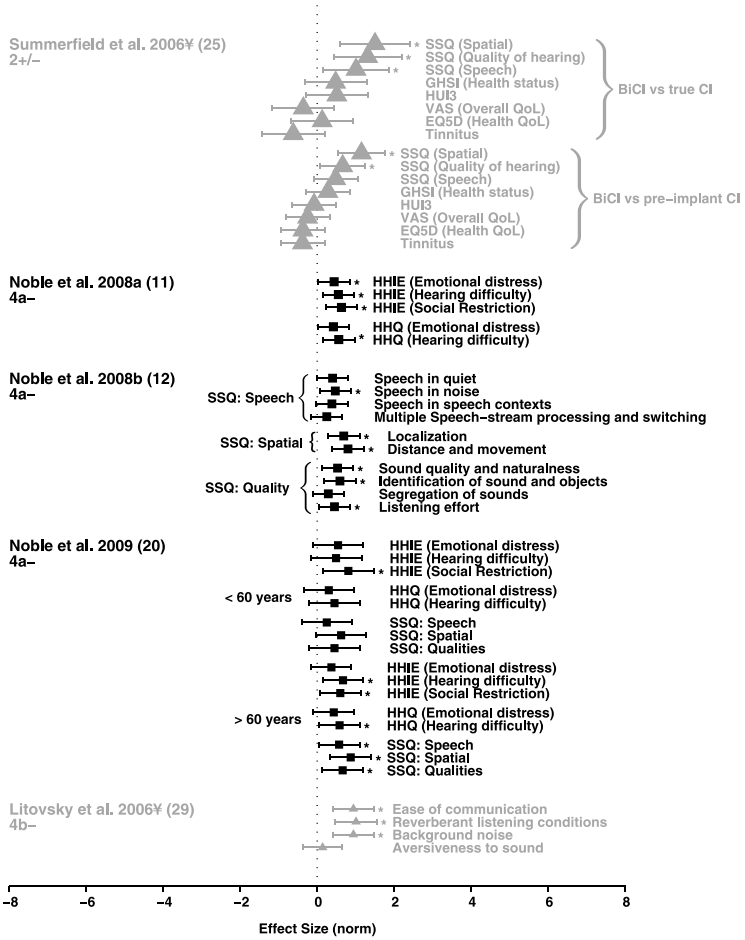

FIG. 5. Self-reported measures (BiCI versus UCI). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

[Table 9 (see Supplemental Digital Content Table 9, http://links.lww.com/MAO/A131) and Figure 8]. The SSQ showed a bilateral benefit in most situations, and on all subscales of the HHIE and the HHQ, better scores were obtained in the bilateral situation, except for the older subjects in the 2009 study (20), where no significant bilateral benefit on any of the SSQ subscales was found.

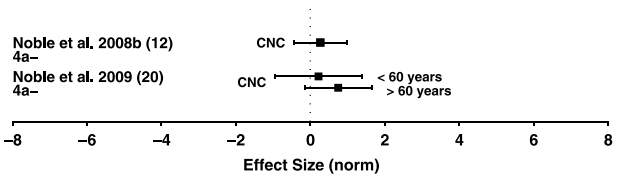

FIG. 6. Speech perception in quiet (BiCI versus CIHA). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

DISCUSSION

This systematic review of the clinical effectiveness of BiCIs compared with UCI and CIHA, forms an update of the assessments by the NICE in 2007 (3). We found another 14 relevant studies and also included the 5 studies reviewed by the NICE. Most studies had a low level of evidence with a low, medium, or high risk of bias. This was in accordance with the findings of the NICE. The NICE review did not include studies in which a comparison was done between BiCIs and CIHA. The current review does report on this comparison.

Owing to the heterogeneity of the studies regarding test setup, population, and outcome measures, we did not perform any meta-analyses. We presented the results

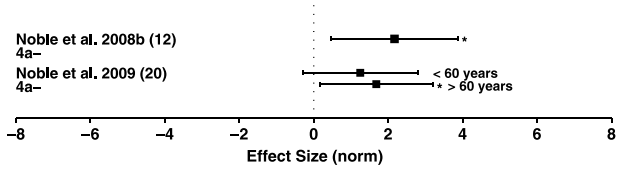

FIG. 7. Localization (BiCI versus CIHA). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

descriptively and visualized these by forest plots. The statistically significant effects of BiCI reported in the original studies were not always confirmed by our transformations of mean difference into the ES. We expect that treating paired data as unpaired may have led to more conservative estimates.

In this review, we analyzed the following outcome measures: speech perception in quiet, speech perception in noise, functional outcomes, and self reported measures. When available, BiCI was compared with both UCI and CIHA. This section discusses the results of the recent studies and how they compare to the NICE review. For speech perception in quiet, 1 study with a low risk of bias was added (9) that showed a bilateral benefit. In addition, the current review includes 2 studies (19,20) that investigated speech perception in noise in complex listening situations and demonstrated a bilateral benefit. Additional studies regarding localization showed a consistent bilateral benefit. This benefit is present but not always significant when it concerns self-reported measures. These results largely confirm the findings by the NICE. Lastly, several studies by Noble and colleagues (11,12,20), which were published after the NICE review compared bimodal stimulation with bilateral implantation.

Regarding speech perception in quiet, a significant bilateral advantage was found in 1 of the 3 cases where a between subject design was used (9). This study regarded simultaneously implanted subjects, matched for age at implantation and duration of deafness. The bilateral advantage was found when performing a between subject comparison and when comparing bilateral stimulation to stimulation with the right CI only within the subjects. This study, which was not included in the NICE review, was the only study with a low risk of bias. In general, no consistent bilateral benefit was found for speech perception in quiet.

For speech perception in noise, several studies showed a significant bilateral benefit when the noise was presented from the unilaterally aided side (26,28,29). These results underline an important benefit for BiCI users: they can switch to the CI with the better SNR in everyday listening situations, whereas UCI users cannot. Litovsky et al. (21) used the same setup in 2009 as they did in 2006 (29) but did not find a significant bilateral benefit in the more recent study. Thirty-seven subjects were included in the older study versus 17 subjects in 2009, which may account for the observed difference. As an

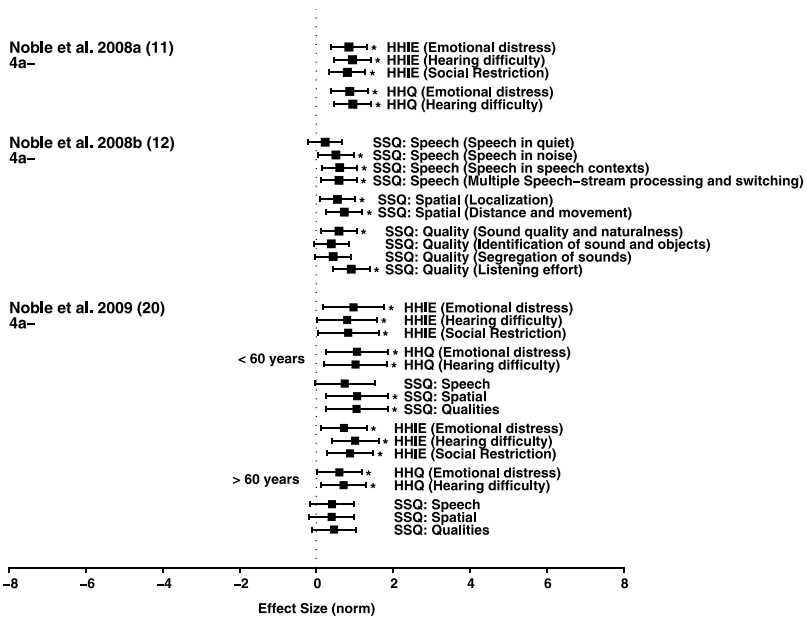

FIG. 8. Self-reported measures (BiCI versus CIHA). *Black squares* represent the ES of our included studies, *gray triangles* represent the ES of the studies by included by NICE. The comparison BiCI versus CI2 is indicated by *open markers*. Other comparisons are indicated by *filled markers*. A higher LoE is represented by a *larger marker*. *Bars* indicate the 95% confidence interval. *Asterisks* indicate that an ES is significantly different from zero. In longitudinal studies, only the outcomes at the final interval are depicted. For calculation of the ES, data were treated as unpaired.

addition to the NICE review, the studies of Dunn et al. (19) and Ricketts et al. (14) were included in the current review. Whereas all other studies used a relatively simple loudspeaker setup (front, left and/or right), they used an array of loudspeakers to create a more realistic listening situation. Moreover, Dunn et al. used a design in which both speech perception in noise and localization were tested. They found convincing bilateral advantages for all 3 tests. Ricketts et al. only found a slight bilateral benefit when an adaptive procedure was used to estimate the SNR at 50% speech perception.

A difference in performance with the first or second implanted CI was seen for speech perception in noise by Ramsden et al. (26) and Tyler et al. (17). The latter is an additional study, whereas the first was included by the NICE. The bilateral benefit was largest when comparing BiCI with the second CI alone. This difference was also visible for speech perception in quiet but not significant in the study by Tyler et al. The observed difference might be the result of more experience with the first CI or the fact that these subjects had never functioned with the second CI alone as opposed to their unilateral experience before the second surgery (26).

With regard to localization, this review demonstrates a significant bilateral benefit for all studies [Table 6 (http://links.lww.com/MAO/A131) and Fig. 4]. In the NICE review, this bilateral benefit was demonstrated in the studies of Verschuur et al. (27) and Laszig et al. (28). The additional 6 studies in the current review all show a similar bilateral benefit and thus result in more solid evidence.

Concerning the self-reported measures, the study of Summerfield et al. (25) shows a trend toward a bilateral disadvantage for the generic QoL measures when performing a pre-/post-comparison. Summerfield et al. state that this negative trend is a consequence of the increased tinnitus after bilateral cochlear implantation. Additional data provided by the authors also made it possible to calculate the effect sizes for the between subject comparison. The observed trend is similar, although the confidence intervals are larger, possibly because of the smaller group sizes for the between subject comparison. With regard to the SSQ, the speech subscale now shows a significant bilateral advantage. A bilateral benefit was also found on the other 2 subscales of the SSQ: spatial and qualities of hearing. Noble et al. (12) reported on the same questionnaire, and significant bilateral advantages were found on the same subscales as those in Summerfield et al. (Fig. 5). The same trend is reflected in their study in 2009 (20), especially regarding the older group. However, the observed ESs are smaller, possibly because of the smaller group size. Noble et al. (11) reported on 2 hearing handicap scales in 2008 and found small but significant bilateral advantages for all but 1 subscale.

For the comparison between BiCI and CIHA, 3 studies were included, which were all published after the NICE report (Fig. 8). Noble et al. (11,12,20) reported on bimodal stimulation and found the following: 1) no significant differences for speech perception in quiet, 2) a bilateral advantage in localization performance, and 3) positive effects for a number of self-reported measures (especially the listening effort and spatial subscales of the SSQ). Note that the groups were small for speech perception in quiet and localization outcomes. Noble et al. (20) also looked into the effect of age. As opposed to the younger subjects and the total group, the older subjects (>60 yr) did not show a significant bilateral benefit over CIHA on any of the SSQ subscales.

A limitation of the present study was the low LoE of the included studies. The study by Summerfield et al. (25) was the only study with a LoE of 2, which was already available when the NICE performed their review, although in the current review, additional data from this study are presented. The level of evidence of the remaining studies was low. In this field of research, high levels of evidence are hard to obtain. Besides this, especially because of the low number of patients available, it is difficult to perform a study with a low risk of bias by including a homogeneous study group with a matched reference group. However, within the level of evidence obtained, most outcomes point toward a benefit of BiCI.

Furthermore, a general design weakness of most studies is the within-subject comparison in which subjects performed all tests with either 1 or 2 CIs switched on. The UCI use does not reflect the everyday listening conditions of the BiCI user, possibly leading to worse unilateral performance, resulting in an overestimation of the bilateral advantage. This is a consequence of the aforementioned difficulty in obtaining a homogeneous and matched reference group. This design weakness was present in the majority of the studies included in the NICE review and in the current review.

A logical next step based on this review is to conduct a study with a higher level of evidence to assess the effect of bilateral cochlear implantation with a higher degree of certainty. There is a need for such studies regarding the comparison between BiCI and UCI but also between BiCI and CIHA. Of the latter, too little data are available to make valid assumptions. This specific comparison, however, is of clinical importance because adults who use 1 CI and have some residual hearing in the contralateral ear, will often wear a hearing aid on this ear. At this moment, it is uncertain whether a second CI is beneficial in these cases. Lastly, the only randomized controlled trial included in the current review regards self-reported measures. There is also need for studies of a high level of evidence that investigate the effect of speech perception and localization.

In conclusion, the studies included in this systematic review do not provide the highest LoE. This finding is similar to that of the NICE review. However, a benefit of bilateral cochlear implantation is demonstrated systematically, especially concerning localization tasks and, to a lesser extent, speech perception in noise and self reported measures. The additional studies in this review confirm these benefits and also show a benefit of speech understanding in noise in more complex listening situations. Less benefit of bilateral implantation was found for speech

perception in quiet, although some of the additional studies do point towards an advantage. For the comparison between BiCI and CIHA, no evidence was available up until now. Although the evidence is still scarce, a bilateral advantage was seen for localization and the self-reported measures. To summarize, bilateral cochlear implantation in adults seems to be beneficial, although there is still need for studies with higher levels of evidence.

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