Measurement of Comfort Levels by Means of Electrical Stapedial Reflex in Children

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Background: Patient success and satisfaction with a cochlear implant largely depend on the adequacy of the speech-processing program. The program is generated by means of behaviorally determined threshold and comfort levels for each electrode. As the minimum age for implantation continues to decrease, behavioral methods of measuring comfort levels have become more problematic, and so the need for objective ways to program speech processors has become more important.

Objectives: To evaluate the use of electrically evoked stapedial reflexes (ESRs) to measure comfort levels for children and compare these results with behavioral measurements, and to report the results of a questionnaire assessing the acceptability and general performance of program before and after adjustment of comfort levels measured with ESRs.

Design and Setting: Before-after trial in the cochlear implant unit of a tertiary hospital.

Patients and Methods: Programming with the ESR technique was successfully completed in 20 of a consecutive sample of 26 children undergoing programming of their cochlear implants.

Outcome Measures: Programming units as measured by the 2 programming techniques and numerical score of questionnaire.

Results: Comfort levels with the ESR method were found to be consistently lower than those obtained with behavioral techniques. Children using programs set with ESRs wore their implants longer and had fewer episodes of discomfort to environmental sounds.

Conclusion: Comfort level estimation by means of ESRs is reliable and objective and hence a valuable programming tool in the pediatric population.

PATIENTS AND METHODS

PATIENTS

The study included all children who were scheduled for programming in August and September 1999. Verbal consent was obtained from all parents. A total of 26 children were tested. The mean age was 4.9 years (range, 2-9 years), and the male-female ratio was 15:11. The mean length of implant use was 18.5 months (range, 2-36 months). Twenty children were using the Nucleus 24 cochlear implant with the Sprint processor (Cochlear Ltd, Sydney, Australia) and 6 were using the Nucleus 22 with the Spectra processor (Cochlear Ltd). All children were using the Spectral Peak speech processing strategy (Cochlear Ltd).

PROCEDURE

A middle ear analyzer (GSI 33, version 2.0, model 1733; Grayson Stadler, Milford, Ohio) was used to perform tympanometry and record the ESRs. All children underwent tympanometry before ESR testing. The Nucleus 22 speech processors were connected to the Nucleus diagnostic programming system, while the Nucleus 24 processors were connected to the clinical programming system. The recording system of the middle ear analyzer is very sensitive to movement. To minimize artifacts caused by movement, passive cooperation was obtained from the children. They were seated in front of a color television and provided with an age-appropriate video to watch, or they were allowed to read. Parents were encouraged to bring a selection of their child’s favorite cartoons or movies to the clinic.

After impedance checks and behavioral T-level measurements, each child had a short break and his or her processor was reactivated with their current map. Parents were encouraged during this interval to take the child for a short walk. We believe that this reduces the large contrast between listening at threshold levels and listening at suprathreshold measurements.

The electrically evoked stapedial reflex (ESR) by means of electrical stimulation in cochlear implant recipients has been established since 1986. Shallop and Ash6 showed that ESR correlated with the most comfortable level rather than the uncomfortable level in an adult population, and Spivak et al7 showed ESR to be safely below the threshold for discomfort. Hodges et al8 demonstrated that maps generated by means of ESR to measure C levels resulted in speech-perception performance that matched that of behaviorally derived maps in an adult test group. Therefore, using ESR as an objective predictor of C levels is potentially a very useful tool in the pediatric population.

The recording of ESR was attempted in the ear contralateral to that implanted. An appropriate probe tip was inserted in the ear; occasionally, smearing the cuff with petroleum jelly provided a more stable and consistent seal. The probe case was retained on the strap and placed over the child’s or parent’s shoulder.

Once a normal tympanogram was obtained, the middle ear analyzer was set to the “special (reflex decay)” mode and the system was pressurized. Stimulation was derived via the appropriate interface by means of standard biphasic pulses and presented through the child’s own speech processor at the standard rate of 250 pulses per second. A change in acoustic admittance for the 226-Hz probe’s tone resulting from the stapedial reflex contraction was presented as a downward deflection of the prestimulus baseline.

Stimulation began at 20 programming units below the previously behaviorally measured C level. The number of presentations ranged from 1 to 3. For the Nucleus 24 users, this was controlled by the keyboard command for WinDPS (Windows Diagnostic Programming System) (version R16.02 [build 445], service release 2; Cochlear Ltd). For Nucleus 22 users, control was through the diagnostic programming system (version 6-10F; Cochlear Ltd). If a clear reflex was present, the stimulus level was decreased by 5 units. If no reflex was evident, stimulation was increased by 2 units until a reflex was present or there were behavioral signs of the signal producing loudness discomfort. The ESR threshold was taken as the lowest stimulus level that produced a deflection in baseline recording, synchronous with the stimulus presentation.

The C level was set at 2 programming units below the level at which the ESR threshold was identified. All available electrodes were tested.

STATISTICAL ANALYSIS

Statistical analysis used the paired means t test with the use of Minitab for Windows, version 12.22 (Minitab Inc, State College, Pa).
The aims of this study were to compare the results of behaviorally vs objectively recorded measurements of C levels with the use of ESR and to establish whether there were any changes in the child’s behavior or response to sound when a program with C levels set by ESR was used.

RESULTS

The ESR technique could not be performed in 6 patients (23%). Middle ear effusion was present in the contralateral ear in 2 of these children. Three children reported loudness discomfort before reaching ESR threshold; all 3 of these had a history of previous middle ear disease. Sufficient cooperation was not obtained in 1 child on 2 separate occasions to allow the procedure to be performed. The 20 remaining children successfully completed ESR measurement. A total of 391 individual measurements were made. Nine electrodes were not tested because of nonauditory stimulation.

BEHAVIORALLY VS OBJECTIVELY RECORDED MEASUREMENTS OF C LEVELS BY ESR

The T levels were remeasured by behavioral methods to ensure that they remained consistent with the T levels obtained in the previous programming session. There was no statistical difference between the T level measurements obtained during the 2 programming sessions (Figure 1).

The 2 methods of measuring the C level were compared and the average measurement for each electrode of the 20 children was calculated (Figure 2).

The C level obtained with ESRs was found to be consistently lower across all electrodes. Figure 3 shows the difference in C levels (behavioral–ESR); a positive value indicates that the behavioral C level was higher than ESR C level, whereas a negative value indicates that the ESR C level was higher. The minimum and maximum levels represent the range. The difference in C levels with the 2 measurements was found to be statistically significant across all electrodes. Of the 391 measurements made, 380 were positive values and only 11 were negative values.

OUTCOME OF NEW PROGRAM WITH ESR C LEVEL

Parents were asked to complete a questionnaire relating to the new programming technique compared with that used on all the previous visits, ie, the behavioral method. Answers were completed in the form of a numerical analog scale ranging from 0 to 4, where 0 represented “never” and 4 represented “always.” Parents were required to rate the original program set based on behavioral methods and the new program set based on ESR. The questions consisted of 2 subgroups: the first group of questions (Figure 4) asked whether the child ever showed discomfort to a range of 8 different environmental sounds. The next 12 questions (Figure 5) pertained to the child’s willingness to wear the implant and are outlined in the Table. Across all the questions, the program based on ESR was rated better than behavioral programming, and the differences for 10 of the questions were statistically significant (Figures 4 and 5).
Testing of ESRs is a clinically feasible procedure in patients with no middle ear effusion and was successfully used in creating the map for the speech processor. From the clinician’s perspective, it is an effective procedure that is easier to perform than behavioral tasks. It is both safe and reliable, and one can be confident that the sound is audible but not uncomfortable. From the patient’s perspective, the new program results in fewer situations that cause discomfort; therefore, patients are likely to wear the implant more. Since this study, measuring ESR has replaced behavioral techniques in programming the speech processor in our department and has become routine procedure. We believe that it is a superior technique and should replace traditional, subjective techniques when cochlear implants are programmed in the pediatric population.

CONCLUSIONS

Testing of ESR is not universally performed in programming cochlear implants. It is objective and relatively straightforward to carry out. Therefore, if it were to be accepted as a feasible method of programming, use of the ESR should improve the ease of programming and, more important, the quality of the speech-processing map. If measurement of ESR is to replace traditional behavioral methods for setting C levels, certain criteria need to be met: (1) ESR maps must not result in unacceptable levels of discomfort, (2) ESR maps must result in the same or superior implant use, and (3) sound quality should be similar or better than that produced by traditional behavioral techniques.

The T levels were assessed to ensure that the 2 programming sessions were comparable despite being performed on different days. When C levels obtained with ESR were compared with those obtained with behavioral methods, the ESR levels were found to be consistently below behavioral levels. As a result, we can be certain that the children are not being overstimulated through the use of the ESR technique. Only 11 measurements across all electrodes in all 20 patients were above those established by behavioral techniques. In 1 patient there was a difference of as much as 80 programming units, and this child was taking his implant off regularly despite the fact that previously repeated measurements obtained with behavioral techniques had shown consistent C levels. Our findings are similar to those found in previous studies, although our results were more consistent and had less variation.

As the new C levels were all set at a lower level, we were concerned that the child’s ability to use the implant may be compromised. The questionnaire that was filled out by the parents demonstrated that the majority of children found the new map superior to the original one, in particular, in situations that would imply that the child was being overstimulated with the C levels obtained by behavioral techniques. The degree of difference in the 2 programs was surprising and was statistically significant in 50% of questions. Although this was not a randomized controlled trial, the parents were unanimous in their belief that programming with ESR results in improved usage and less discomfort than traditional techniques.

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