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THE EFFICACY AND SAFETY OF SURFACE AUDITORY BRAINSTEM PROSTHESIS

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The surface auditory brainstem implant (ABI) is undergoing worldwide clinical trials to rehabilitate patients who cannot benefit from cochlear implants. Clinical results showed that neurofibromatosis-II patients implanted with the Multichannel ABI could achieve a beneficial hearing sensation, including open-set speech recognition. Data on the safety of the surface ABIs are limited. The only safety study concerned with their long-term implantation in patients was an analysis on the tissue sheath of an implant removed from a patient.

To examine the safety of the surface ABI the cat cochlear nuclei were implanted and stimulated chronically with bipolar surface electrodes using charge-balanced biphasic current pulses at rates of 250 pulses/sec. The stimulation was continuous 16 hours/day up to 12 weeks. The electrically evoked auditory brainstem response (EABR) was used to monitor neuronal excitability of the cochlear nuclei following the chronic electrical stimulation. The body weight, respiration and body temperature of the cats were monitored throughout the experiment. The amplitudes and latencies of the EABR waves were measured fortnightly and compared among the before, during and after the chronic electrical stimulation. The activation of the central auditory pathway by the prosthesis was demonstrated with the 2-deoxyglucose (2-DG) technique. Histological examination was performed on all cochlear nuclei. The volumes of cochlear nuclei and neuron soma areas and densities were analyzed with 3-dimensional reconstruction techniques.

The results showed that the respiration, body weight and body temperature of the cats remained within normal limits during the chronic stimulation. During the stimulation, no change was found in the EABR waveform, but a decreased threshold and wider dynamic range were observed after the stimulation. There was no significant change in the amplitudes and latencies of the EABR waves after stimulation. A broad 2-DG labeling was found in the auditory system from ipsilateral cochlear nucleus to bilaterally in inferior colliculus. Passive ABI implantation was associated with significant decreases in the CN volumes and soma areas. Electrical stimulation prevented the decreases in CN volumes and soma areas, but did result in a decrease of the neuron density in the posteroventral cochlear nucleus (PVCN).

The present findings suggest that electrical stimulation through the ABI activated the auditory brainstem; chronic bipolar electrical stimulation with surface electrodes at rates of 250 pulses/sec is safe for neuronal excitability of the cochlear nucleus in the cat.

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