Cochlear implant should not be absolute contraindication for electroconvulsive therapy and transcranial magnetic stimulation

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Dear Editor

Cochlear implants (CI) provide deaf or severely hearing-impaired people with speech perception. A microphone and sound processor behind the ear capture sound and transmit it, via a radio-frequency link and magnets, to an implant below the scalp. The implant delivers the transformed acoustic signal as electric pulses onto the auditory nerve fibres through intracochlear electrodes [1]. Importantly, hearing loss increases the risk of dementia, depression, psychosis, and schizophrenia.

Electroconvulsive therapy is a highly effective treatment for severe and psychotic depression and other psychiatric conditions, and ECT is often the last resort in medically treatment-resistant patients. ECT relies on the induction of seizures by electrical stimulation (Fig. 1). Transcranial magnetic stimulation (TMS), on the other hand, uses electromagnetic induction fields in different brain regions to treat neurological and psychiatric disorders [2]. Both methods space a range of doses that determines the strength of the current or the electromagnetic field generated in the body. The dose is defined by parameters that affect the spatial distribution (including properties of the stimulating electrodes or coil) and temporal characteristics (including parameters of the current or voltage waveform of the stimulating electrodes or coil) of the electromagnetic field [3].

The number of CI-users is increasing [1], and so is the number of CI-users that may need psychiatric treatment with ECT or TMS. However, ECT and TMS are not advised by CI manufacturers and contraindicated in ECT and TMS guidelines [2,4]. Thus, CI-patients are prevented from an effective and, in some cases, life-saving treatment [5,6].

Potential problems with electrical or magnetic stimulation in CI patients have been argued to include heating of the device and heat-induced injury to adjacent tissue, induction of current, damage to the implant, and magnetic displacement [2].

Here, we review the sparse literature on the use of ECT and TMS in CI-users and argue that a CI should not be an absolute contraindication for ECT or TMS treatment.

CIs and ECT

There are no absolute contraindications for ECT treatment, but in practice, a CI is considered one [4]. The literature on ECT and CI safety is limited to a study on cadaver heads and two case reports.

Ten CIs (Nucleus CI512/N5) were implanted in fresh human cadaveric heads and administered 12 ECT sessions with maximum full pulse-width energy (576mC, 800mA, 1.0ms pulse width, 60Hz, 6s duration). Half received ECT contralateral to the CI and the other half ipsilateral. Impedance measurements before, in between, and after ECT showed no damage to the electrodes. There was no statistically significant difference in impedance values between ipsilateral and contralateral ECT. Further testing by the manufacturer did not show any electrical damage [4].

A 17-year-old male CI-user (Nucleus 22) received two *en-bloc* contralateral ECT treatments (48mC, 800mA, 9.9J, 1ms pulse width, 40Hz, 0.75s) on vital indication due to manic delirium; later subjective and objective assessment of the CI showed no dysfunction [5]. The CI was replaced four months later due to pain at the site of the external processor, and examination of the CI revealed it was not a fault related to the ECT [4].

A 78-year-old female CI-user (Nucleus CI24RE) received on vital indication 13 contralateral ECT treatments (up to 1004mC, 900mA) due to severe psychotic depression and refusal of medicine, food, and fluids. The treatments had no complications, and no CI damage was observed in the following control [6]. The studies used treatments with 80–100% of the maximal stimulus (1008mC) [4–6].

Deep brain stimulators (DBS) are similar to CIs, and manufacturers similarly warn against ECT, because the safety has not been studied. There are several published cases of uneventful ECT in the presence of DBS.

CIs and TMS

A single study from 1997 tested TMS in CI-patients (nine Nucleus 22, one Clarion) [7]. They used a circular 5cm 3T coil placed 1cm above the temporal bone, external auditory canal, and mastoid. 10–50% stimulus strength elicited audible clicks for the patient; and tactile thumping sensations, and 30–70% elicited facial twitches at; no damage was reported. The CIs were not documented or marketed as MRI safe.

Since there is no other safety data on TMS in subjects with CIs and similarly cardiac pacemakers, both implants are still

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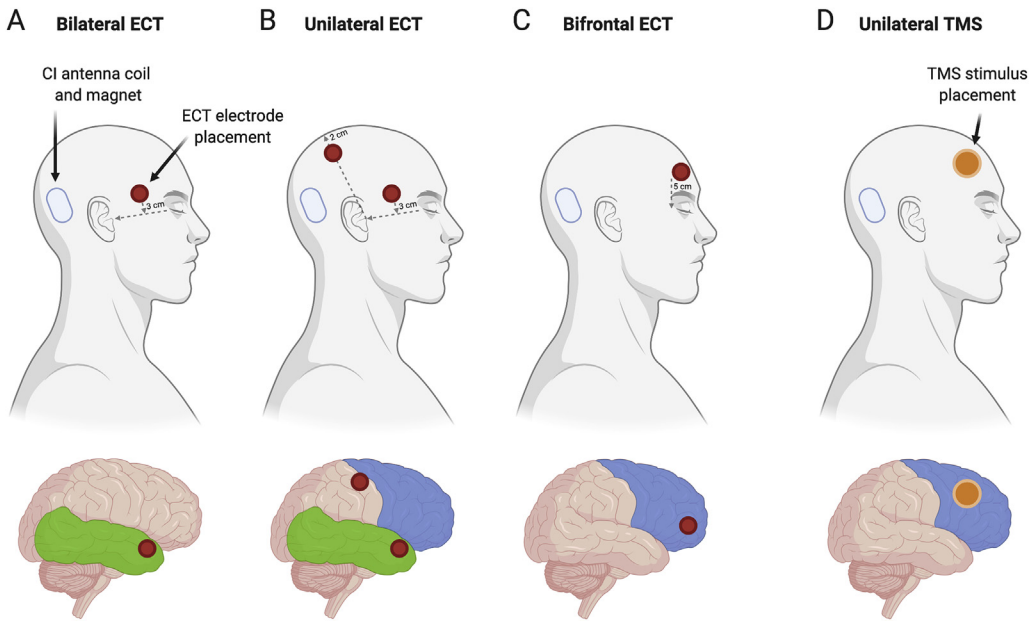

Fig. 1. The proximity of ECT and TMS stimulus and CI device. A) Bilateral ECT is traditional with placement on both temples. B) While right unilateral placement on the right temple and 2 cm right from the vertex is increasingly used, studies suggest that administering the stimulus to the nondominant hemisphere causes fewer cognitive side-effects [10]. C) Bifrontal electrodes are in a small study as efficacious as bitemporal placement and with less cognitive impairment [10]. D) Current TMS for depression unilaterally targets the dorsolateral prefrontal cortex (dlPFC) while newer studies are investigating the medial prefrontal cortex (not shown). Original protocols targeted the left dlPFC, but targeting the right-side causes fewer cognitive side-effects and is equally as efficacious [11]. Patients can have a single or bilateral CIs. ECT can be administered bifrontal and contralateral to a single CI to limit proximity; TMS contralaterally. Bifrontal ECT and right-sided TMS are therefore best for bilateral CI. Created with BioRender.com.

considered a contraindication and exclude patients from treatment. However, ex and in vivo studies show that as long as the "internal pulse generator" system is not in close proximity to the TMS coil, TMS seems safe for patients with implanted stimulators [2]. Nonetheless, the exact distance of "close proximity" has yet to be determined.

In contrast to ECT, is TMS a more diverse and evolving technology with different coil shapes and sizes, e.g. the F8-coil for repetitive TMS and the H1-coil for deep TMS in a handheld or helmet (i.e. Brainsway) design, different treatment protocols with various stimulus locations, target depth, pulses, intensities, frequencies and strengths [8]. Consideration of CI related issues should be specific to device design (e.g. coils) and protocol (e.g. investigational stimulation locations and waveforms).

Discussion

In our review, no damage to the patient or the CI was observed in the 135 ECT treatments on 12 CIs (three models, one manufacturer). Likewise, TMS administered in very close proximity to the CI in 10 patients at high stimulus strengths produced no damage to the patient nor the CI.

Minimising the potential risk of damage to the CI by minimising proximity to the ECT stimulation site and TMS magnetic field is advisable. Patients can have a single or bilateral CIs. The greatest distance between the CI and the ECT-electrodes is provided by contralateral or bifrontal ECT (Fig. 1).

Magnets in new CIs are considered MRI-safe up to 3T because they can adjust to variations in the magnetic field and/or be temporarily removed by a small incision; the wiring is similarly deemed safe from induced currents.

TMS for depression is given unilaterally to the prefrontal cortex (Fig. 1). The peak field strength with each TMS pulse is approximately 0.5T. Modelling of maximum spatial field gradient at the dlPFC would be 8T/m and <1T/m at the site of an ipsi- or contralateral CI; well below the 20T/m safety limits of newer CIs [9]. 15 min of continuous 3T MRI-scanning of a newer CI (Ultra 3D, Advanced Bionics) produced a safe increase of <3 °C. New MRI-safe CIs could, therefore, be considered correspondingly TMS safe, but further research is needed to benefit this patient group.

Future CIs include both optimisations of existing design and fully-implantable CIs. In fully-implantable CIs, the external processor is implanted with a microphone in the middle ear and a battery on the chest. The two former components are similar to already used in middle ear implants which are MRI-safe for up to 3T. And the battery is used in pacemakers, which are compatible with ECT, TMS and MRI. Future CIs should, in our opinion, thus be as safe/problematic for MRI, TMS and ECTs as the newest CIs used today. However, this needs to be confirmed.

While CI manufacturers have not tested ECT and TMS compatibility with CIs and advise against it, the case reports and tests demonstrate that ECT and TMS can be administered without harm to the patients or the CI. As with any procedure, harm is a risk and must be outweighed by benefits, but a CI should not be an absolute contraindication for life-saving or beneficial treatment with ECT or TMS.

Declaration of competing interest

All authors declare that they have no financial interests or any other conflict of interest with other people or organisations that could inappropriately influence this work.

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