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Repetitive transcranial magnetic stimulation: Hearing safety considerations

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Background
The guidelines for use of repetitive transcranial magnetic stimulation (rTMS) advise frequent updating of rTMS safety guidelines and recommendations. Although rTMS can produce sound of more than 120 dB C, which is sufficient to induce hearing loss, the effect of rTMS noise on the hearing of both patients and rTMS practitioners is understudied.

Objective
This study investigated the effects of rTMS noise on subjects' hearing using otoacoustic emissions evoked by clicks (transiently evoked otoacoustic emissions, TEOAEs), which is an objective and sensitive method of cochlear exploration.

Methods
Hearing thresholds and TEOAEs were recorded in 24 normal-hearing healthy subjects before and after a real or sham rTMS session (a single 20-minute session applied to the superior temporal gyrus with 1200 pulses at 100% of the individual motor threshold).

Results
No significant difference in hearing thresholds was observed between subjects exposed to real or sham rTMS. However, the difference in TEOAE amplitude between pre- and post-rTMS sessions increased significantly with rTMS noise for those subjects the least protected by earplugs, showing a post-rTMS slight decrease of TEOAE amplitude for high rTMS intensities and hence minor hearing function alteration. However, this correlation was no longer found 1 hour after the rTMS session.

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Conclusions
These findings suggest that, even when rTMS is used within normal safety limits and with good hearing protection, rTMS noise can transiently disturb hearing mechanisms in normal-hearing healthy subjects. This transient effect of rTMS on hearing may be an important consideration for Institutional Review Boards when rTMS is used at higher stimulation intensities.

Keywords repetitive transcranial magnetic stimulation; otoacoustic emissions; hearing; safety; side effect

Repetitive transcranial magnetic stimulation (rTMS) is a noninvasive and effective method of direct human brain stimulation[1] that is widely used in neurology, cognitive neuroscience,[2,3] tinnitus therapy,[4,5] and for various psychiatric disorders (e.g., depression,[6,7] anxiety disorders,[8] and auditory hallucinations in schizophrenia[9]). The body of evidence regarding the clinical efficacy of rTMS is growing, including long-term maintenance therapy with multiple rTMS sessions over long periods. Hence, there is a need for frequently updating TMS safety guidelines and recommendations for clinical implementation.[10] However, the effect of sound produced by rTMS on hearing in both patients and rTMS practitioners has been neglected. Indeed, in the first version (2001) of a questionnaire aimed at screening patients before rTMS,[11] no hearing-related item was present, whereas the new 2010 questionnaire[12] identifies hearing deficits and tinnitus as risk factors for rTMS. Indeed, rTMS can produce sound greater than 120 dB p.e. SPL,[13] a level above that known to produce hearing loss.[14] The sound produced by rTMS originates from rapid mechanical deformation of the stimulating coil and consists of a loud click, with the greatest energy at high frequencies (from 2 to 7 kHz),[15] where the human ear is most vulnerable. In addition, human ears show a wide variability of susceptibility to noise,[16] from an absence of symptoms or a temporary hearing threshold shift with intermittent tinnitus to hearing damage with permanent tinnitus, all for the same noise energy.

The amplitude of rTMS noise is directly linked to the coil design and the absolute stimulation intensity, which is tailored to each subject's resting motor threshold (MT). Hence, the amount of noise received by subjects depends on their MT, which varies widely across a population, and also depends on the testing method used and on individual characteristics.[17] Although patients' hearing protection is systematically recommended in the rTMS safety guidelines,[1] most studies dealing with rTMS do not specify whether or which type of hearing protection was used. Furthermore, in practice, subjects sometimes decline hearing protection in the form of earplugs, usually citing discomfort[18] and the desire to communicate with the researcher or rTMS practitioner. Moreover, earplugs are not systematically provided in every laboratory[19] and patients are not usually trained to fit an earplug, leading to lower protection.[20] Indeed, earplug efficacy varies greatly from subject to subject,[21] depending on the type used and the quality of the fit.[20]

Hearing alterations have been identified in audiometric studies as a possible effect of rTMS noise,[1] and a few cases have been reported.[22-24] However, only pure-tone audiometry was used in these studies. Although pure-tone audiometry is the universally accepted method for diagnosing sensorineural hearing loss, it is a subjective method and not as sensitive to noise-induced cochlear alterations as transiently evoked otoacoustic emissions (TEOAEs).[25] TEOAEs are minute sounds recorded within the outer ear canal in response to a click stimulus. They reflect cochlear function[26] and enable early identification of small cochlear alterations caused by noise exposure.[27]

Objective

The aim of this study was to evaluate the potential modifications of hearing thresholds and TEOAE amplitudes in response to rTMS noise in normal-hearing subjects fitted with earplugs. Both hearing thresholds and TEOAEs were recorded before and after a single 20-minute rTMS session, targeted on the left (12 subjects) and right (12 subjects) superior temporal gyrus, corresponding to the primary auditory cortex, hence with the coil close to the pinna.

Methods

Patient selection

The study was given ethical approval by the local ethics committee (ref 08-021), and written informed consent was obtained from all study participants before examination. Twenty-four healthy adults (12 females, 12 males; mean age: 23.8 years) took part in this study and were split into two groups matched for sex and age, receiving either active or sham rTMS (active group: mean age = 24.3 years (20-33 years), 16 subjects; sham group: mean age = 22.8 years (19-29 years), 8 subjects). None of the volunteers suffered from any diseases. In particular, the neurologic and otologic examinations (including hearing thresholds $<$ 15 dB hearing level [HL], tympanometry and otoscopy) were