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Sham Transcranial Magnetic Stimulation Using Electrical Stimulation of the Scalp

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Abstract

Background—Most methods of sham, repetitive transcranial magnetic stimulation (rTMS) fail to replicate the look, sound, and feel of active stimulation in the absence of a significant magnetic field.

Objective/hypothesis—To develop and validate a new method of sham rTMS appropriate for a double-blind, placebo-controlled study with subject crossover.

Methods—The look and sound of active rTMS was replicated using a matched, air-cooled sham TMS coil. Scalp muscle stimulation associated with rTMS was replicated using large rubber electrodes placed over selected muscles. The intensity and pulse width of electrical stimulation necessary to match 1-Hz rTMS was developed in one sample of normal subjects. The sham technique was validated in back-to-back comparisons with active rTMS in new samples of normal subjects who were either naïve or experienced with rTMS.

Results—Subjects naïve to TMS could not tell which type of stimulation was active or sham or which was electrical or magnetic. Naïve subjects *incorrectly* picked sham stimulation as active, when forced to choose, because electrical stimulation felt more focused than magnetic stimulation. Subjects experienced with TMS could correctly identify sham and active stimulation. Experimenters could detect subtle differences between conditions.

Conclusions—This method of sham rTMS closely mimics the look, sound, and feel of active stimulation at 1Hz without creating a significant magnetic field. It is valid for use with naïve subjects and in crossover studies. It can accommodate differences in scalp muscle recruitment at different sites of stimulation, and it could potentially be used with higher frequency stimulation.

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Keywords

TMS; rTMS; sham

Introduction

Transcranial magnetic stimulation (TMS) is used experimentally to treat a range of clinical disorders that may involve altered states of cortical excitability, such as depression, anxiety, and tinnitus (1-3), but the lack of a convincing placebo or sham stimulation condition compromises judgments about the efficacy of TMS. Electrical current is discharged through a stimulation coil during active TMS to create a brief, focused magnetic field over the scalp. Magnetic fields pass almost unimpeded through the scalp and skull, where they induce electrical currents in brain tissue that stimulate neurons within 2 cm of the coil (4). Magnetic pulses delivered repetitively (rTMS) and at low frequencies tend to inhibit neural activity (5) whereas high-frequency stimulation tends to facilitate neural activity (6,7). The difficulty with creating a valid sham condition concerns replication of the sensory side effects of TMS in the absence of a magnetic field. Side effects include rhythmic stimulation of scalp muscles close to the coil and clicking sounds produced when electrical current is discharged through the coil. Air-cooled coils, used to resist overheating during rTMS, may also produce a loud vacuum noise.

Tilting the coil 45 to 90 degrees from the scalp to direct the magnetic field away from the brain is the most commonly used method of sham stimulation in controlled trials of rTMS as a treatment modality (8). Clicking sounds are still detectable and some muscle twitching is preserved; however, neurons may still be activated by the magnetic field and both subjects and experimenters know the coil is in a different position from the active condition. Sound conduction through bone is also lost by the coil tilt method. Several of these problems can be avoided using commercially available sham coils, which markedly attenuate the magnetic field and produce clicking sounds and vacuum noises, but these coils do not stimulate scalp muscles.

Three studies have used electrical stimulation during sham rTMS to induce scalp muscle twitching. The first study (9) attached electrodes to the surface of the coil that delivered a train of weak electrical impulses (15–25 mA; duration 0.1 ms) to the scalp to replicate muscle twitching associated with high frequency rTMS over the frontal cortex (50 × 2-sec trains of 40–20 Hz stimuli at 80% MT). The second study (10) applied surface cup electrodes directly to the scalp and delivered stimulation at .2 Hz and twice the intensity needed to surpass the sensory threshold. Electrical stimulation was timed to coincide with low-frequency pulses from a sham coil held over the motor cortex. A second, active coil was located near the subject's head to produce clicking sounds. The third study (11) developed a device for high- and low-frequency sham stimulation consisting of two electrodes fixed to a 3-cm shim attached to the back of an active coil. Electrodes located on the surface of the shim are exposed to the hair and scalp to induce muscle twitching, but no special preparation of electrodes was reported. The shim creates separation between the coil and scalp to attenuate the magnetic field by about 75%. The attenuation is not as great as a sham coil, which achieves about 95% reduction, but it is enough to prevent recordable motor and sensory responses evoked by active stimulation. Subjects naïve to TMS were more likely than non-naïve subjects to pick electrical stimulation as active rTMS.

Electrical scalp stimulation is a significant improvement over the coil tilt method and a significant addition to the sham coil method, but electrodes attached under the coil cannot be adjusted either to make good contact with the scalp or to stimulate selected muscle groups. Positioning electrodes is important because scalp muscle recruitment can vary considerably

depending on the brain region targeted for TMS. The use of multiple coils and devices during sham stimulation also prevents a true double-blind experiment because the sham method is obvious to experimenters. It is impractical, if not impossible, to blind the investigator actually administering rTMS; however, a method of simulating rTMS that would effectively blind other study personnel who are present during rTMS would be of great value for clinical trials.

We report the development and validation of a sham rTMS method that uses a flexible placement of two large rubber electrodes over selected scalp muscles in combination with an air-cooled sham coil. The method was developed for a double-blind study, with subject crossover, of rTMS over the auditory cortex to treat tinnitus. Sham stimulation had to mimic jaw movements and sounds associated with active rTMS over the auditory cortex because both factors can influence tinnitus perception (12). Subject crossover was desirable because tinnitus is subjective, and a crossover component allows subjects to serve as their own control. The sham technique was validated using normal subjects as an initial step.

Methods

Subjects

Twenty-four subjects, 12 female and 12 male with a mean age of 32.2 years (SD = 9.7 years), were recruited for two phases of the study. New subjects were recruited for each phase. Each subject was determined to not have any contraindications to TMS (13). Subjects gave written informed consent prior to participation. The study was approved by the local Institutional Review Board (IRB) for Research Involving the Use of Human Subjects.

Apparatus

Active rTMS was delivered using a Magstim Super Rapid system with an air-cooled, 70-mm, figure-of-eight stimulating coil (Magstim Company, Whitland, Wales, UK). Sham rTMS was delivered using a matching air-cooled coil produced by Magstim that delivers only 5% of the stimulator output. A clicking sound is produced mechanically by the sham coil with each TMS pulse. The stimulator was set to 40% of the maximum stimulator output (MSO) during sham stimulation. Clicking sounds at this MSO are indistinguishable from those produced by the active coil, even at higher settings. The sound level of the sham coil at 40% of MSO was 87 dB. The sound level of the active coil at 49, 65, and 80% of MSO (the lowest, average, and highest settings) was 86 dB. The magnetic field beneath the sham coil was calculated to be equal to 2% of MSO during sham stimulation (5% of 40% = 2%). Vacuum noises during active and sham stimulation were produced by the same apparatus in both conditions and measured to be 80 dB.

Electrical stimulation was delivered to scalp muscles using a DS3 Isolated Stimulator (Digitimer Ltd., Welwyn Garden City, Hertfordshire, U.K.) and two rectangular, carbon-impregnated rubber electrodes (4 × 5 cm). A dial on the face of the DS3 isolated stimulator was used by subjects to adjust the level of the electrical current in the first phase of the study. The DS3 pulse stimulator was triggered by the TMS controller base unit via its TTL trigger output so that each electrical pulse coincided exactly with each sound produced by the sham stimulation coil. An F-EZM5 (Grass Technologies, West Warwick, RI) electrode impedance meter was used to determine the impedance between the two stimulating electrodes.

Procedures

The intensity and quality of electrical stimulation necessary to mimic the feel of active, 1-Hz rTMS was determined in the first phase of the study. The validity of the sham technique was examined in the second phase. The center of the TMS coil was always placed 1 cm above the

top of the subject's ear as this location lies over the auditory cortex, which is the area targeted for treatment in tinnitus studies (2,3).

Phase 1: Stimulation Intensity curve development—Four male and 6 female subjects, mean age 36 years, were tested. One electrode was placed approximately 3 cm anterior to the top of the ear, and one was placed approximately 2 cm behind the top of the ear (Figure 1). Placement was adjusted slightly to accommodate differences in head size and muscle location. Electrode placement targeted the anterior superior and posterior inferior margins of the temporalis muscle. Conductive gel was applied to electrodes to decrease inter-electrode impedance (measured to be less than 25 K Ω in all subjects). The TMS motor threshold (MT) was determined for each subject as the lowest intensity of the MSO necessary to elicit a visible contraction of the thumb or fingers of the hand contralateral to single TMS pulses delivered over the motor cortex in at least 3 of 6 trials.

Subjects received 20 active rTMS pulses at 1 Hz and at 100 and 110% of the MT. Subjects were instructed to increase the intensity of 1-Hz electrical muscle stimulation using the dial on the face of the DS3 isolated stimulator. Starting at 0 mA, subjects increased the dial setting until they thought electrical stimulation best matched magnetic stimulation, which immediately preceded the electrical stimulation. Subjects were encouraged to increase and decrease intensity until the best match was obtained. Two intensity curves were produced: one for a pulse width of 500 μ sec and one for a pulse width of 800 μ sec. The order of two rTMS intensities and two pulse widths was counterbalanced within and across subjects. Subjects rated how well electrical and magnetic stimulation matched using a scale of 10 to 99 (10=not similar, 99=identical). Subjects were also asked to describe differences in sensation if present.

Phase 2: Sham methodology validation—Four male and 6 female subjects, mean age 33 years, who were naïve to TMS, and 3 male and 2 female subjects, mean age 25 years, who had experienced TMS, participated in the sham validation phase.

Electrodes were applied with conductive gel, electrical impedances were recorded, and the MT was established for each subject. Both the subject and the experimenter (M.M.) left the room to blind them to condition before the technician (K.C.C.) set up active and sham coils (Figure 1). The order of condition was counterbalanced. The technician delivered either 120 pulses of active rTMS to the subject at 1 Hz and 110% of the MT or 120 pulses of electrical stimulation, each pulse coinciding exactly with clicks from the sham coil (also set at 1 Hz). Electrical current intensity was set to match that of a given magnetic stimulation intensity based on the intensity curve developed in Phase 1. The electrical pulse width was set at 500 μ sec because subjects indicated this felt less sharp than 800 μ sec during Phase 1 testing. The subject and experimenter then left the room a second time so that the technician could set up the alternative condition. Following stimulation, the experimenter asked subjects if they could tell 1) a difference between the two conditions, 2) which was active and which was sham stimulation (subjects were instructed to guess if they could not discern a difference), and 3) which was magnetic and which was electrical stimulation (subjects were again instructed to guess if they could not discern a difference).

Results

Phase 1

Electrode impedances ranged from 6.10 to 20.3 K Ω , with a mean value of 12.7 K Ω (SE=1.1) (Table 1). The MT ranged from 49 to 80% of MSO, with a mean value of 64.8% (SE=2.3). Current intensities set to equal magnetic stimulation at 100% of MT ranged from 6.4 to 15.4 mA, with a mean value of 10.9 mA (SE=.74). The Pearson correlation for MT and current intensity was .62 ($r^2=38$), $p<.02$. Current intensities set to match 110% of MT ranged from 6.7

to 17.0 mA, with a mean value of 12.7 mA (SE=.94). The Pearson correlation between 110% MT and current intensity was .68 ($r^2=.47$), $p<.01$. The mean rating given to describe the match between electrical and magnetic stimulation was 82/100 (SE=3.2). Subjects indicated upon questioning that the 500- μ sec pulse width felt more like magnetic stimulation than the 800- μ sec pulse width because it did not feel as focused or “sharp”.

The data for electrical current and magnetic stimulation intensities were fit to linear and power functions and compared using Curve Fit in SPSS. The data for magnetic stimulation at MT fit a linear ($r^2 = .38$, $p<.04$) but not power function ($r^2=.31$, $p<.07$). The data for stimulation at 110% of MT fit both linear ($r^2 = .47$, $p<.02$) and power functions ($r^2=.41$, $p<.02$). Figure 2 shows the linear function for a pulse width of 500 μ sec for all data combined.

Phase 2

Electrode impedances ranged from 4.3 to 24.0 K Ω , with a mean of 13.0 K Ω (SE=2.4), for the naïve subjects and from 8.4 to 28.0 K Ω , with a mean of 18.6 K Ω (SE=3.4) for non naïve subjects. Values of the MSO which corresponded to 110% of MT ranged from 61.0 to 77.0 across naïve subjects, with a mean of 69.9 (SE=1.8), and from 55.0 to 86.0 across non-naïve subjects, with a mean of 70.2 (SE=5.5). Current intensities ranged from 11.0 to 15.0 mA across naïve subjects, with a mean of 12.7 mA (SE=.41), and from 10 to 15.0 mA across non-naïve subjects, with a mean of 12.4 mA (SE=1.05). None of these values were significantly different between the naïve and non-naïve subjects.

All subjects could perceive a difference between stimulation conditions in back-to-back comparisons and all subjects perceived the electrical stimulation to be more focused than magnetic stimulation. Naïve subjects, however, could not tell beyond a chance level which type of stimulation was active or sham or which was electrical or magnetic. When forced to guess, 9 of 10 naïve subjects picked electrical stimulation as the active form of stimulation ($p<.05$, Binomial Test). In contrast, 4 of the 5 non-naïve subjects could correctly identify the active and sham and the magnetic and electrical stimulation.

Discussion

A review paper of criteria for sham stimulation concluded that a method of sham rTMS should not stimulate the cortex and that neither the position, sound, nor feel of sham stimulation should be different from active stimulation (8). The method of sham stimulation used in this study accomplished most of these objectives. The sham coil reduced the magnetic field to a level of 2% of the MSO. This level of stimulation is lower than when an unshielded, active coil is used during sham stimulation. The sham device used in one study, for example (11), produced a magnetic field equal to approximately 20% of the MSO, which was not sufficient to elicit sensory or motor responses from subjects. It is very unlikely, therefore, that stimulation from the sham coil used in this study could confound an experiment by stimulating the cortex. It is also extremely unlikely that the electrical scalp stimulation could stimulate the cortex as the applied current was too weak to penetrate tissue and bone.

The position of the sham coil in the current study was identical to that of the active coil. Sounds produced by the sham coil and its air cooling vacuum system were also indistinguishable from those of the active coil; however, we did find that the sham coil does not sound identical to the active coil at *matched* stimulator output settings. The stimulator had to be set at 40% of MSO during sham stimulation in order for the clicks produced by the sham coil to sound like those of the active coil at higher settings. This adjustment does not create a problem because there is no reason to set the stimulator at identical levels during active and sham stimulation. The look and feel of the sham stimulation in our study was very similar but *not* identical to active stimulation. The appearance of the air-cooled sham coil was sufficient to blind subjects to

condition but the experimenter could detect differences between coils, such as different connection between the inductance cable and stimulator and slight variations in the coil covers, which alerted him to active and sham conditions. It would be necessary to further mask these differences to blind the experimenter to condition.

Electrical stimulation using large, rubber electrodes applied over the temporalis muscle produced rhythmic tightening of the jaw and temporalis muscles during sham rTMS, which could be felt by subjects and observed by the experimenter. Subjects noticed, however, that the electrical and magnetic stimulation felt different. The difference was sufficient to bias subjects toward picking electrical stimulation as active when forced to make a choice even though naïve subjects could not identify active and sham conditions. Naïve subjects said they picked electrical stimulation as active because it felt more focused than magnetic stimulation. Non-naïve subjects, however, recognized the broader impact of magnetic stimulation and reliably distinguished between the two conditions.

This method of sham stimulation is valid for use with naïve subjects and it is appropriate for a parallel study design and with subject crossover. One limitation of the study is that we did not collect data for higher frequencies of stimulation. While there is no reason to assume that the method cannot be used with high frequency stimulation as in other studies (9,11), our study only establishes validity for low frequency stimulation. Another caveat is the potential for subject bias, which should be monitored because of the tendency to pick electrical stimulation as active. It might be possible to overcome this bias either by delivering electrical stimulation concurrent with active rTMS to make it feel more focused or by using an array of electrodes to make electrical stimulation feel less focused. Experimenter bias should also be monitored because subtle cues, such as a subject's reaction or comments, can alert the experimenter to condition. It is also necessary to fully mask equipment in order to blind the experimenter to the condition, which can be achieved with coil covers and shields over cable connections.

Several procedures could be used to make this method suitable for a double-blind experiment. The following procedures were used to maintain a double blind in a multi-site treatment study of depression (14). Multiple outcome measures were used to create uncertainty about which variable was the primary outcome variable and all study personnel were kept blind to the "primary" outcome variable. Subjects were instructed not to disclose details of the treatment to personnel who did not attend the treatment session but were subsequently involved with rating their symptoms. Regarding procedures and equipment: 1) an experimenter could determine the subject's motor threshold in a separate session using a coil designated specifically for this purpose; 2) a technician could then use MT information to set up either the sham or active stimulation condition according to a predetermined schedule; and 3) the experimenter and the subject enter the room, without the technician present, and use the equipment to deliver either sham or active rTMS. These procedures would keep the subject, rater, and experimenter blind to condition and all study personnel would be blind to the primary outcome measure.

In closing, we think that pairing a flexible system of electrical stimulation with an air-cooled sham coil may have several advantages over other methods of sham stimulation. First, applying electrodes directly to the scalp ensures good contact and lower electrical impedance than methods that fix electrodes to the bottom of the stimulating coil. Second, the large rubber electrodes used in this method feel less focused than cup electrodes and a flexible placement allows one to accommodate variations in head size and scalp muscle recruitment at different sites of stimulation. Third, it is easy to adjust electrical current frequencies and intensities with this method so that electrical stimulation can be adjusted to match the feel of rTMS. Finally, the sham coil used in this method is unrecognizable to subjects, it largely eliminates the possibility of active brain stimulation, and the air-cooling system on both coils eliminates the need to exchange an overheated active coil, which could disrupt the blind.

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Figure 1. Electrode placement is shown in the picture on the left. The active coil is shown in the middle picture and the sham coil is shown in the picture on the right. Differences in coil coverings between the active and sham coils were masked with Gaffer tape.

Figure 2. Stimulation Intensity Plot

Each data point is representative of the mean of three trials. The apparent relationship between TMS intensity and electrical stimulation was found to be linear over the intensity range that we explored (49% - 88% of MSO).

Table 1

Data for Each Subject

Phase 1													
Subject # (n=11)	101	102	103	104	105	106	107	108	109	110	111		
Mean Impedance (KΩ)	15.8	17.8	19.0	12.9	9.5	20.3	6.1	6.8	8.1	8.0	15.5		
MT (%)	80	64	66	64	49	56	68	67	69	65	65		
Mean Current (mA)	15.4	12.0	9.4	12.6	10.0	6.4	11.9	13.5	8.7	9.9	10.4		
110% MT (%)	88	71	73	71	54	62	75	73	76	71	72		
Mean Current (mA)	17.0	15.3	9.6	12.6	10.0	6.7	15.8	15.7	11.7	12.9	13.1		
Phase 2													
Naïve Subject # (n=10)	201	202	203	204	205	206	207	208	209	210			
110% MT (%)	63	75	61	65	67	77	69	75	76	71			
Sham Impedance (KΩ)	5.0	12.0	15.8	24.0	19.0	13.8	4.3	10.4					
Sham Current (mA)	11.0	13.0	11.0	12.0	12.0	15.0	12.5	14.0	14.0	12.5			
Can Detect a Difference Between Conditions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Correctly Identified Sham/Active	Yes	No	No	No	No	No	Yes	Yes	Yes	No			
Correctly Identified Electrical/Magnetic	No	No	Yes	No	No	No	No	No	No	No			
Phase 2													
Non-Naïve Subject # (n=5)	211	212	213	214	215								
110% MT (%)	62	70	55	78	86								
Sham Impedance (KΩ)	23.7	17.0	28.0	16.0	8.4								
Sham Current (mA)	10.0	13.0	10.0	14.3	15.0								
Can Detect a Difference Between Conditions	Yes	Yes	Yes	Yes	Yes								
Correctly Identified Sham/Active	No	Yes	Yes	Yes	Yes								
Correctly Identified Electrical/Magnetic	No	Yes	Yes	Yes	Yes								