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A two-site pilot randomized 3 day trial of high dose left prefrontal repetitive transcranial magnetic stimulation (rTMS) for suicidal inpatients.

George MS[1], Raman R[2], Benedek DM[3], Pelic CG[4], Grammer GG[3], Stokes KT[2], Schmidt M[4], Spiegel C[3], Dealmeida N[3], Beaver KL[4], Borckardt JJ[4], Sun X[2], Jain S[2], Stein MB[2].

Author information

Abstract

BACKGROUND: Suicide attempts and completed suicides are common, yet there are no proven acute medication or device treatments for treating a suicidal crisis. Repeated daily left prefrontal repetitive transcranial magnetic stimulation (rTMS) for 4-6 weeks is a new FDA-approved treatment for acute depression. Some open-label rTMS studies have found rapid reductions in suicidality.

DESIGN: This study tests whether a high dose of rTMS to suicidal inpatients is feasible and safe, and also whether this higher dosing might rapidly improve suicidal thinking. This prospective, 2-site, randomized, active sham-controlled (1:1 randomization) design incorporated 9 sessions of rTMS over 3 days as adjunctive to usual inpatient suicidality treatment. The setting was two inpatient military hospital wards (one VA, the other DOD).

PATIENTS: Research staff screened approximately 377 inpatients, yielding 41 adults admitted for suicidal crisis. Because of the funding source, all patients also had either post-traumatic stress disorder, mild traumatic brain injury, or both.

TMS METHODS: Repetitive TMS (rTMS) was delivered to the left prefrontal cortex with a figure-eight solid core coil at 120% motor threshold, 10 Hertz (Hz), 5 second (s) train duration, 10 s intertrain interval for 30 minutes (6000 pulses) 3 times daily for 3 days (total 9 sessions; 54,000 stimuli). Sham rTMS used a similar coil that contained a metal insert blocking the magnetic field and utilized electrodes on the scalp, which delivered a matched somatosensory sensation.

MAIN OUTCOME MEASURE: Primary outcomes were the daily change in severity of suicidal thinking as measured by the Beck Scale of Suicidal Ideation (SSI) administered at baseline and then daily, as well as subjective visual analog scale measures before and after each TMS session. Mixed model repeated measures (MMRM) analysis was performed on modified intent to treat (mITT) and completer populations.

RESULTS: This intense schedule of rTMS with suicidal inpatients was feasible and safe. Minimal side effects occurred, none differing by arm, and the 3-day retention rate was 88%. No one died of suicide within the 6 month followup. From the mITT analyses, SSI scores declined rapidly over the 3 days for both groups (sham change -15.3 points, active change -15.4 points), with a trend for more rapid

decline on the first day with active rTMS (sham change -6.4 points, active -10.7 points, P = 0.12). This decline was more pronounced in the completers subgroup [sham change -5.9 (95% CI: -10.1, -1.7), active -13 points (95% CI: -18.7, -7.4); P = 0.054]. Subjective ratings of 'being bothered by thoughts of suicide' declined non-significantly more with active rTMS than with sham at the end of 9 sessions of treatment in the mITT analysis [sham change -31.9 (95% CI: -41.7, -22.0), active change -42.5 (95% CI: -53.8, -31.2); P = 0.17]. There was a significant decrease in the completers sample [sham change -24.9 (95% CI: -34.4, -15.3), active change -43.8 (95% CI: -57.2, -30.3); P = 0.028].

CONCLUSIONS: Delivering high doses of left prefrontal rTMS over three days (54,000 stimuli) to suicidal inpatients is possible and safe, with few side effects and no worsening of suicidal thinking. The suggestions of a rapid anti-suicide effect (day 1 SSI data, Visual Analogue Scale data over the 3 days) need to be tested for replication in a larger sample.

TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT01212848, TMS for suicidal ideation.

KEYWORDS: Magnetic; Prefrontal; Suicide; TMS; Transcranial

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