

pulses of high frequency 10 Hz/s, 120% MT over the left dorsolateral prefrontal cortex (DLPFC).

Results: At base line, all subjects did not differ in ISI, depression severity, or comorbidity. However, there was a clinically significant increase in ISI during treatment for one month into TMS treatment for all participants. Furthermore, all subjects had ISI decline after completing TMS course regardless of their response to TMS. 3/5 patients who clinically responded to TMS (based on PHQ-9 & HAMD assessments) had 71% improvement in ISI score after completing TMS vs 25% improvement in ISI for 2/5 subjects who did not respond to TMS.

Conclusion: This small sample of patients showed patients with increasing insomnia during TMS. The mechanism isn't clear. Future research is needed to analyze larger sample populations and look for trends with sleep associated with TMS.

ELDERLY TMS RESPONSE AND DURATION: A 6 MONTH STUDY

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Background: This study used 15 patients having an age > 65 years and compared them to an equal number <65 years old randomly selected out of a group of 50 patients receiving TMS. They were followed over a 6 month period. The average age of the elderly patients was 70.

Design/Methods: Using the *Brainsway* dTMS system the patients received on average 30.5 treatments over the left DLPFC up to 120%MT, while following the Patient Health Questionnaire-9 (PHQ-9), the Beck Depression Inventory (BDI), the Insomnia Severity Index (ISI), and the Pittsburgh Sleep Quality Index (PSQI) at start of treatment, end of treatment, 3 and 6 months following the completion of treatment.

Results: Analyzing paired t-tests from start to end of treatment, the elderly had improvement on the PHQ-9 ($p < .001$) and BDI ($p < .001$) scales, but not on either sleep scale (ISI $p = .54$ PSQI $p = .23$). Those <65 had statistically significant decreases on all scales (PHQ-9 $p < .001$, BDI $p < .001$, ISI $p = .005$, PSQI $p = .004$). In the elderly, the mean initial PHQ-9 score was 15.2 which decreased to 9.33 by the end of treatment, then was 10.7 at 3 months and 10.88 at 6 months. The initial mean BDI score was 28.2 which decreased to 13.87 by the end of treatment then 18 at 3 months, and 17.5 at 6 months. Three of the 15 elderly had booster sessions, averaging an addition of 14.6 treatments.

Conclusions: This study documented improvement using TMS on mood (but not insomnia) scales in the elderly, with some increase in symptoms over a 6 month period.

Conflict of Interest

**No support was given for this study. The authors have no conflict of interest to report

GENDER RELATED TMS RESPONSE IN DEPRESSION AND INSOMNIA

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Background: This study analyzed 50 TMS patients (36 females and 14 males) using the Wilcoxon signed-rank test on all patients, and then an equal number of males versus females using Paired sample t-tests.

Design/Methods: Patients were followed using the Patient Health Questionnaire-9 (PHQ-9), the Beck Depression Inventory (BDI), the Insomnia Severity Index (ISI), and the Pittsburgh Sleep Quality Index (PSQI) while using the *Brainsway* dTMS system for an average of 30 treatments over the left DLPFC at 120%MT.

Results: Statistically significant improvements were noted on all 4 scales in the sample of 50 with the Wilcoxon test (PHQ-9 = $p < .001$, BDI = $p < .001$, ISI = $p < .001$, PSQI = $p < .001$). In the subsample of women ($n = 14$) the mean improved on the PHQ-9 from 14.71 to 8.86 ($p = .005$), the BDI from 29.5 to 13.21 ($p < .001$), the ISI of 13.57 to 11.07 ($p = .20$), and the PSQI of 12 to 9.93 ($p = .06$). Male data ($n = 14$) demonstrated PHQ-9 improvements from 14.29 to 5.86 ($p < .001$), BDI of 26.14 to 11.79 ($p < .001$), ISI of 12.07 to 7.57 ($p = .03$), and PSQI from 10.36 to 7.93 ($p = .02$). Females had a mean age of 55.25, an increased number of treatments (31), and increased initial severity of PHQ-9 and BDI scores. Males had a mean age of 43.6 and an average of 27 treatments. In comparison, female patients had greater improvement in the BDI scales with males having a greater response in the PHQ-9, ISI, and PSQI.

Conclusions: This study revealed gender related differences, with females having increased severity, number of treatments, and response on the BDI. Males performed better on the PHQ-9 and both sleep scales.

Conflict of Interest

**No support was given for this study. The authors have no conflict of interest to report.

AUDIO-GUIDED MINDFULNESS MEDITATION DURING TMS SESSIONS FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER (MDD): A FEASIBILITY PILOT STUDY

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Background: Mindfulness-Based Cognitive Therapy (MBCT) has been shown to enhance long-term treatment outcomes for MDD, and engagement of specific brain activities during brain stimulation may produce synergistic effects. Audio-guided meditation exercises are a component of MBCT that might be combined with standard TMS therapy sessions. We developed and pilot-tested a modified MBCT protocol for MDD patients undergoing a standard course of TMS.

Methods: Four MBCT audiotapes were selected with differing durations and types of mental focus. Patients listened to the audiotapes through headphones during daily TMS sessions for 5 consecutive weeks. The primary goal was to evaluate feasibility/acceptability of the intervention. Changes in self-rated measures of symptom severity, stress, life satisfaction and mindfulness were also assessed.

Results: 52 consecutively treated patients at 2 sites were invited. Of the 29 consented, 17 completed the study and 12 terminated early. Reasons included negative reactions associated with combined approach ($n = 7$), lack of interest in track content ($n = 2$), difficulty with hearing ($n = 1$), early TMS termination ($n = 1$), and concerns for falling asleep ($n = 1$). TMS percussive sensations and clicking sounds hindered patients' ability to fully concentrate or clearly hear the audiotape narrator's voice. Some became overwhelmed or felt increased pressure, anxiety, or aggravation trying to do meditation exercises while receiving TMS.

Conclusion: There is a growing interest in combining TMS with other concurrent interventions to optimize outcomes. Our results highlight numerous feasibility issues with meditation via guided audiotapes during daily TMS. Revised protocols and randomized trials are needed to further develop this intervention.

ABSTRACT OUTCOMES OF KETAMINE IV TREATMENTS FOR TMS THERAPY POOR RESPONDERS

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Background: We began treating patients with TMS therapy in 2015 and integrated Ketamine IV (K-IV) in 2016. Of on-going discussion within our clinic and in the intervention psychiatry community, is where do each of

these modalities fit in the treatment of MDD. We report on one approach of crossing poor responders of TMS to Ketamine IV.

Methods: From 2016 to early 2020 we treated nine patients with suboptimal results with a full course (36) TMS therapy treatments. Five of the nine patients had less than a 25% response rate, and four had a greater than 50% response rate, with none reaching remission. Each patient was tracked using the PHQ-9 instrument during TMS and K-IV. The nine patients entered a course of K-IV treatments, with the average number of treatments being 5.75.

Results: After K-IV treatments, 4 of the nine patients had a significant response with a score of 10, 7, and 6. Each of these patients had no response to the previous TMS course. The remaining five patients who crossed over to K-IV had no improvement. No adverse events were reported.

Conclusions: We saw four of the nine patients that had failed to gain improvement from TMS therapy gain significant improvement with 6 K-IV treatments. Although this is a small sample size, we are optimistic about continuing to offer Ketamine IV for those with TRD who are not gaining symptoms improvement with a full course of TMS. Consider that over 1/3 of those crossed to K-IV are achieving significant improvement responses who had previously failed to benefit from multiple courses of medication and a full course of TMS therapy.

Discussion: Choosing between TMS therapy and K-IV for those with treatment-resistant depression is less optimal than desired. Primary criteria include patient distance to the office, financial / insurance solvency, and a history of substance abuse. A portion of the population in Billings, Montana, consists of a rural community. For those struggling with TRD and at a considerable distance from the office (over 100 miles is not unusual) Ketamine IV maybe a better solution for it requires only six office visits compared to over 30 for TMS treatments. Another challenge in selecting the right treatment is the out-of-pocket expense for Ketamine IV, which is not covered by insurance. This cost is typically no less than double the price of a patient deductible who has TMS therapy covered by their insurance. Lastly, we see those who have a history of substance abuse to be contraindicated for Ketamine IV and primary candidates for TMS therapy. In addition to the small sample size, we do find from many who are treated with Ketamine IV a response several weeks beyond the final treatment. Future analysis needs to include better post treatment follow-up. Future research should also include an arm for patients not benefiting from Ketamine IV as the first interventional treatment to cross-over to TMS therapy.

GENDER DIFFERENCES IN TRANSCRANIAL MAGNETIC STIMULATION TREATMENT OUTCOMES FOR MAJOR DEPRESSIVE DISORDER: A SINGLE INSTITUTION EXPERIENCE

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Background: Transcranial Magnetic Stimulation is an FDA-approved treatment option for patients with treatment refractory major depressive disorder and obsessive compulsive disorder. Previous studies have suggested that there are significant differences in treatment outcomes for MDD based on gender¹. The objective of this study was to determine if this difference was reproduced in the patient population of a new TMS clinic.

Methods: A retrospective analysis of recent cases of patients ages 28 to 72 who underwent treatment with TMS for refractory major depressive disorder in 2019. The Beck's Depression Inventory-II (BDI-II) was used to gauge symptom severity at the initiation and completion of treatment, and the differences between the BDI-II for each patient was used to calculate the change in BDI-II as the primary outcome measure. The BDI-II changes divided by patient sex, and the averages of each group were analyzed using the two-sample T-test. A secondary analysis was performed after separating the female cohort into premenopausal up to age 50 and postmenopausal groups.

Results: Of the 22 individuals in the study, 16 were female and 6 were male. The statistical analysis of treatment outcomes revealed no significant differences in BDI-II changes between females versus male patients, even when separating the female cohort into premenopausal (n=3) and postmenopausal groups (n=13); $p > 0.05$, two-tailed test.

Conclusions: Conclusions are limited due to sample size.

REAL-WORLD EFFICACY OF DEEP TMS FOR OBSESSIVE-COMPULSIVE DISORDER: INTERIM POST-MARKETING ANALYSIS OF 192 PATIENTS FROM TWENTY-TWO SITES

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Background: Deep transcranial magnetic stimulation (dTMS) with the H7-coil was FDA cleared for obsessive-compulsive disorder (OCD) in August 2018 based on multicenter sham-controlled studies but the efficacy in real world practices is not known.

Methods: All dTMS clinics were asked to supply their data on details of treatment details and outcome measures. The primary outcome measure was response, defined by at least a 30% reduction in the Yale Brown Obsessive Compulsive Scale (YBOCS) score from baseline to endpoint. Secondary outcome measures included first response, defined as the first time the YBOCS score has met response criteria, and sustained response, defined as when two consecutive YBOCS scores met response criteria. Analyses included response rate at endpoint, after 29 dTMS sessions, number of sessions and days required to reach first and sustained response.

Results: 22/175(13%) clinical sites with H7-coils provided data on details of treatment and outcome (YBOCS) measures from a total of 192 patients. One-hundred-eighty patients who had at least one post-baseline YBOCS measure were included in the analyses. Endpoint first and sustained response rates were 73.2% and 62.2%, respectively. The response rate was 58% after 29 dTMS sessions. First response was achieved in average after 18 sessions (SD=9.4) or 28 days (SD=22.4). Sustained response was achieved after 19 sessions (SD=9.6) or 30 days (SD=24.5). Average YBOCS scores demonstrated continuous reduction with increasing numbers of dTMS sessions.

Conclusions: Most OCD patients benefit from dTMS, and improvement usually starts within 20 sessions. Extending the treatment course beyond 29 sessions results in continued reduction of OCD symptoms, raising the prospect of value for extended treatment protocols in non-responders.

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INCIDENCE OF SIDE EFFECTS IN PATIENTS RECEIVING REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (RTMS)

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