Transcranial Magnetic Stimulation

ORG: B-801-T (BHG)
Link to Codes

MCG Health
Behavioral Health Care
24th Edition

Clinical Indications for Procedure

- Transcranial magnetic stimulation (TMS) may be indicated when **ALL** of the following are present(1)(2):
  - Age 18 years or older(21)
  - Major depressive disorder (severe) and **1 or more** of the following[A][B](1)(2)(3)(28)(29):
    - Need for acute treatment, as indicated by **1 or more** of the following:
      - Inadequate response to pharmacotherapy despite **ALL** of the following(42):
        - Adequate duration and dosage
        - Documented adherence
        - Trials from 2 or more classes of medications
      - Inability to tolerate pharmacotherapy as evidenced by 4 trials of agents with documented side effects (37)
    - Continuation of acute treatment, as indicated by **ALL** of the following[C]:
      - Recurrence of symptoms
      - Previous positive response to acute treatment[D]
  - No acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform, or schizoaffective disorder)
  - No cochlear implant, deep brain stimulator, or vagus nerve stimulator
  - No epilepsy or history of seizure or presence of other neurologic disease that may lower seizure threshold (eg, cerebrovascular accident, severe head trauma, increased intracranial pressure)
  - No metallic hardware or implanted magnetic-sensitive medical device (eg, implanted cardioverter-defibrillator, pacemaker, metal aneurysm clips or coils) at a distance within the electromagnetic field of the discharging coil (eg, less than or equal to 30 cm to the discharging coil)

Alternatives to Procedure

- Alternatives include:
  - For major depressive disorder:
    - Antidepressant medication
    - Psychotherapy
    - Antidepressant/psychotherapy combination treatment
    - Electroconvulsive therapy. See Electroconvulsive Therapy (ECT) BHG for further information.

Evidence Summary

Background

Transcranial magnetic stimulation (TMS) uses a brief and intense magnetic field within a coil resting on the scalp to painlessly penetrate human tissue and induce cortical neural activation or inhibition, and is proposed for use in a variety of psychiatric disorders.(1) **(EG 2)** Repetitive TMS (rTMS) involves the stimulation of the cortex by a series of magnetic pulses at frequencies between 1 to 20 Hz.(1)(3) **(EG 2)** Deep transcranial magnetic stimulation (dTMS) allows for direct stimulation of deeper subcortical structures than does rTMS.(4)(5) **(EG 2)** Unlike electroconvulsive therapy (ECT), TMS does not require anesthesia and it has not been associated with adverse memory effects such as may be seen with ECT.(1)(3) **(EG 2)** For patients with metallic hardware in close contact to the discharging coil (eg, cochlear implants), rTMS is contraindicated.(6) **(EG 2)** For patients with an implanted magnetic-sensitive device (eg, implanted cardiac defibrillator), the implanted device must be located outside the electromagnetic field generated by the rTMS coil.(6)(7) **(EG 2)**

Criteria

For major depressive disorder (severe) and need for acute treatment, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A systematic review with network meta-analysis of repetitive transcranial magnetic stimulation (rTMS) for major depressive episodes (81 studies, 4233 patients) found support (vs sham) for low-frequency (LF), high-frequency (HF), and bilateral rTMS.(30) **(EG 1)** Another systematic review and meta-analysis (61 randomized placebo-controlled (eg, sham stimulation) trials, 3682 patients) of the use of rTMS in patients with drug-resistant major depression found evidence supporting antidepressant efficacy for HF rTMS of the left dorsolateral prefrontal cortex (DLPFC).(1) **(EG 1)** A systematic review and meta-analysis of 18 randomized sham-controlled trials examining rTMS for treatment-resistant depression (2 or more prior antidepressant failures) found rTMS to be beneficial vs sham for all outcomes; specifically for clinically relevant decreases in depression severity, response rates, and remission rates.(3) **(EG 1)** A systematic review and meta-analysis of rTMS of the DLPFC (80% of studies examined HF rTMS of the left DLPFC) in the treatment of depression (54 randomized, sham-controlled studies, 2242 patients) found evidence for the antidepressant properties of this modality, including in patients not classified as treatment-resistant (6 studies).(28) **(EG 1)** A systematic review and meta-analysis of HF rTMS (left DLPFC) as an augmenting strategy for patients receiving antidepressant medication (6 randomized sham-controlled trials, 392 patients) reported that rTMS led to a higher treatment response rate at a mean of 2.7 weeks after treatment initiation, and higher response and remission rates at a mean of 6.8 weeks of treatment.(29) **(EG 1)** Systematic reviews and meta-analyses of randomized trials comparing rTMS and ECT have found both to be effective in treating depression, but ECT appears to be superior to (albeit less well tolerated than) rTMS in patients with more severe symptoms, as well as in patients with psychotic depression.(31)(32)(33)(34)(35) **(EG 1)** A naturalistic observational study of 257 patients with resistant major depressive disorder who completed a course of acute TMS treatment showed that a statistically significant reduction in various scales measuring severity of illness was sustained throughout follow-up at 52 weeks; patients were continued on antidepressant medication as needed, and 36% of patients required reintroduction of TMS for symptom recurrence.(36) **(EG 2)** A trial of 212 patients with drug-resistant major depressive disorder were randomized to sham or active TMS during the acute 4-week treatment phase, followed by a continuation phase of 2 treatments a week for an additional 12 weeks; at the end of the continuation phase, there was a significant difference in response rates between active (44%) and sham (26%) groups, but not in remission rates.(37) **(EG 1)** For major depressive disorder that is in relapse or remission, guidelines have indicated that there is minimal evidence to support a role for TMS for maintenance treatment or relapse prevention.(38)(39)(40) **(EG 2)** A systematic review and meta-analysis of the use of deep transcranial magnetic stimulation (dTMS) in the treatment of major depression identified 9 open-label studies and concluded that there was a large antidepressant effect after 20 acute high-frequency sessions of dTMS, as compared to baseline, in mostly unipolar and treatment-resistant patients. Further studies of the concurrent use of antidepressants may be needed.(41) **(EG 1)** For major depressive disorder in adolescent patients, while a systematic review of the role of TMS in adolescents with treatment-resistant depression (7 studies, 56 total participants, trial sizes ranging from 1 to 25 participants) found some preliminary support for this indication, the generalizability of this evidence is limited due to the small number of studies to date, small study sizes, and heterogeneity of study design.(21) **(EG 1)** A specialty society consensus review states that TMS should be considered for patients who present with drug-resistant major depressive disorder, or those for whom intolerance to medications precludes their use. In addition, TMS is recommended for patients who previously benefitted from an acute treatment course and are experiencing a recurrence of illness.(22) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For Alzheimer disease, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis identified 48 studies that investigated the use of repetitive transcranial magnetic stimulation (rTMS) placebo in the treatment of Alzheimer disease; no recommendations could be made due to the absence of replicated placebo-controlled studies from independent research groups.(1) **(EG 1)**

For anxiety disorders, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of randomized

placebo-controlled trials examining the use of repetitive transcranial magnetic stimulation (rTMS) in anxiety disorders found relatively few studies, and those that were identified were notable for small sample sizes and conflicting results; the authors were unable to draw conclusions as to efficacy for panic or generalized anxiety disorder (6 studies).(1) **(EG 1)**

For bipolar depression, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A randomized trial of 50 patients with treatment-resistant bipolar disorder compared 4 weeks of deep transcranial magnetic stimulation (dTMS) with sham procedure and found, at the end of treatment, that dTMS was associated with more improvement in Hamilton Depression Rating Scale with 17 items (HDRS-17) scores as compared with sham; after an additional 4 weeks of follow-up (during which neither group received therapy) no difference was seen between the groups. The authors noted that the small number of included patients and short follow-up time limited the results, and further trials were recommended.(8) **(EG 1)** An evidence-based guideline on the therapeutic use of TMS did not support it having a role in treatment of any type of bipolar disorder.(1) **(EG 2)** Although a naturalistic study of repetitive transcranial magnetic stimulation (rTMS) in the treatment of bipolar depression (240 patients) suggested a possible benefit for patients who cannot respond to, or cannot be treated with, antidepressant medication, this study did not include a sham-control, and so placebo response rates could not be assessed.(9) **(EG 2)**

For obsessive-compulsive disorders, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review identified 19 studies of repetitive transcranial magnetic stimulation (rTMS) and 1 study of deep transcranial magnetic stimulation (dTMS) related to the treatment of obsessive-compulsive disorder. The authors concluded that rTMS shows encouraging but mixed results (when stimulating different brain areas, including the dorsolateral prefrontal cortex, supplementary motor area, orbitofrontal cortex, and anterior cingulate cortex), making it a potential add-on treatment strategy but requiring refinement; additional research is needed to determine how to optimize use of rTMS and dTMS to achieve clinically relevant results.(4) **(EG 2)** A systematic review states that different brain stimulation techniques may represent promising add-on techniques for treatment of refractory obsessive-compulsive disorder, but studies have reported inconsistent results; additional research on TMS is needed to establish a standardized methodology and clarify its role.(10) **(EG 1)** A randomized controlled trial of 99 patients with obsessive-compulsive disorder showed that there was a significantly greater reduction in symptom severity in response to treatment with high-frequency dTMS targeting the medial prefrontal cortex and anterior cingulate cortex (as measured by the Yale-Brown-Obsessive-Compulsive Scale) as compared with sham treatment.(11) **(EG 1)**

For peripartum depression, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review identified a randomized controlled trial, 3 uncontrolled trials, 3 case series, and 5 case studies (with a total of 87 patients) that studied the use of repetitive transcranial magnetic stimulation (rTMS) for treatment of peripartum depression. The randomized controlled trial reported efficacy of rTMS with an effect size of 0.87, while the uncontrolled studies reported rates of clinical response from 41% to 71%. While rTMS may be effective for the treatment of peripartum depression, additional studies are needed.(12) **(EG 1)**

For posttraumatic stress disorder (PTSD), evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Recommendations in evidence-based guidelines for the use of transcranial magnetic stimulation (TMS) for PTSD are mixed.(13) **(EG 2)** A guideline on the management of PTSD indicates that TMS should not be considered first-line therapy, but suggests that it may be considered as an alternative treatment for patients with treatment-resistant disease or who have a severe and chronic condition that has not been relieved with first-line treatments.(14) **(EG 2)** Other guidelines on the use of TMS to treat PTSD do not support its role in PTSD management, describing the evidence base for this indication as Level C (ie, further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate).(1) **(EG 2)** A systematic review of the use of TMS in the treatment of PTSD (3 trials were included in the meta-analysis) reported some symptomatic benefit; however, the review did not detail inclusion/exclusion criteria, the process of study selection, or test for publication bias, thus limiting the clinical applicability of these findings.(15) **(EG 1)** A randomized trial of 103 combat veteran patients with PTSD compared 12 weekly sessions of cognitive processing therapy combined with either repetitive transcranial magnetic stimulation (rTMS) or sham procedure and found, during therapy and at 1-month, 3-month, and 6-month follow-up, that rTMS was associated with improved Clinician Administered PTSD Scale (CAPS) scores. However, the authors noted that the inclusion of only combat-experienced patients limited the generalizability of the results, and further studies were recommended.(16) **(EG 1)**

For schizophrenia, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 14 randomized placebo-controlled trials (393 patients) examining the effect of low-frequency repetitive transcranial magnetic stimulation (rTMS) of the left temporal parietal cortex (TPC) on auditory hallucinations described numerous limitations in the evidence base, including small trial sample sizes, wide heterogeneity among included patients, and conflicting overall results across studies. This same analysis reported similar results from 11 randomized controlled trials (315 patients) looking at

treatment with rTMS for the negative symptoms of schizophrenia.(1) **(EG 1)** A systematic review and meta-analysis of TMS in the treatment of schizophrenia (41 studies, 1473 participants) found no difference in favor of TMS vs sham in terms of global state or positive symptoms (the evidence from these trials was described as very low quality).(17) **(EG 1)** Guidelines for the treatment of schizophrenia indicate that there is insufficient evidence to recommend rTMS for the treatment of depressive symptoms in patients with schizophrenia.(18) **(EG 2)**

For substance abuse and addiction, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review on the use of deep transcranial magnetic stimulation (dTMS) for the treatment of substance use disorders identified 9 studies of patients with alcohol, nicotine, or cocaine use disorders. While decreases in cravings and consumption were observed, large randomized controlled trials are needed to determine the efficacy and optimal stimulation parameters of dTMS.(19) **(EG 1)** A systematic review and meta-analysis identified 10 randomized placebo-controlled trials (265 patients) on the use of repetitive transcranial magnetic stimulation (rTMS) for treatment of substance abuse, including nicotine and alcohol; however, the trials were too heterogeneous and the results too contradictory to draw conclusions as to efficacy.(1) **(EG 1)**

For Tourette syndrome, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 8 studies (113 patients) evaluating the efficacy of repetitive transcranial magnetic stimulation (rTMS) for Tourette syndrome found significant improvement in tics and obsessive-compulsive symptoms from baseline in patients treated with rTMS. However, no differences in outcomes were seen when rTMS was compared with sham treatments; the authors recommended further prospective studies.(20) **(EG 1)**

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Footnotes

[A] There has been variability in the number of pulses delivered per session and total session number associated with clinical response, but there is evidence to suggest that a minimum of 1000 pulses per session, delivered over at least 10 sessions, is associated with the highest response rates.(1) A typical course of TMS consists of treatment 5 days a week for up to 6 weeks (up to 30 sessions); it is tapered off over 3 weeks (3 treatments in week 1, 2 treatments the next week, and 1 treatment in the last week).(2)(22) [A in Context Link 1]

[B] The diagnosis and severity of depressive disorders may be confirmed and documented by the use of standardized rating scales that reliably measure depressive symptoms in adults, including the Beck Depression Inventory (BDI), the Hamilton Depression Rating Scale (HDRS), the Patient Health Questionnaire-9 (PHQ-9) in the primary care setting, the Montgomery-Asberg Depression Rating Scale (MADRAS), and the Geriatric Depression Scale (GDS) for older adults.(23)(24)(25) As an example, the PHQ-9 asks the patient to describe the frequency of 9 symptoms over the past 2 weeks on a scale of 0 to 3 (0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day), and depression severity is scored as follows: 0 to 4 none, 5 to 9 mild, 10 to 14 moderate, 15 to 19 moderately severe, and 20 to 27 severe.(26) In addition to screening, rating scales are often administered throughout treatment to measure changes in symptoms. An approximate 50% decrease in scores on the BDI, HDRS, PHQ-9, and/or MADRAS has been found to be clinically significant.(24)(27) [B in Context Link 1]

[C] An index or acute course of treatment is the initial series of treatment given to relieve acute symptoms of the illness. Continuation TMS is a course that begins after the index course, lasts up to 6 months, and is designed to prevent relapse of the episode (return of the symptoms to full syndromal criteria before the end of the natural duration of the illness). Maintenance treatment is a course that begins after the end of continuation treatment and is intended to prevent recurrence of an episode (ie, a new episode).(22) [C in Context Link 1]

[D] A positive response is usually defined as a reduction of at least 50% in a depression severity rating scale, as compared with baseline.(37)(39) [D in Context Link 1]

Codes

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