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TMS Maintenance Treatment

Transcranial magnetic stimulation (TMS) is a non-invasive treatment cleared by the United States Food and Drug Administration (FDA) for adult patients with major depressive disorder. Major depressive disorder is defined as a condition in which a person experiences 2 or more weeks of at least 5 of 9 symptoms as per the DSM-V diagnostic criteria. Major depressive disorder (MDD) is considered an episodic condition, with a relapsing-remitting pattern. Between episodes, patients may have full recovery, remain symptomatic, or have chronic or persistent symptoms.

TMS has usually been regarded as a treatment for an active acute major depressive episode and repeat courses of TMS for subsequent episodes. However, some patients experience very frequent MDD episodes and do not benefit from pharmacotherapy. For these patients, maintenance treatments are reasonable and warranted, similar to maintenance ECT. TMS is a treatment, not a cure, and treatments often need to be repeated and ongoing for chronic illnesses.

A relapse or recurrence is defined by a return of symptoms to a degree that interferes with day-to-day functioning and last at least 2 weeks. Although the treatment goal therapies for depression is for patients to reach full remission, this is not achieved in all patients and sometimes only response 50% reduction of symptoms is achieved. Furthermore, even remission does not have infinite durability. Depression is a relapsing-remitting illness, and the expectation is that relapse is very likely to occur at some point in the future. A 2018 study by Senova et al. followed patients for 1 year. Of patients who initially responded to TMS, 66% sustained their response at 3 months, 59% sustained their response at 6 months, and 46% sustained their response at 12 months.[2]

A medically reasonable schedule for maintenance TMS should be considered as the minimum frequency of TMS that prevents the patient from having a recurrence. There is a growing collection of studies that provide evidence for TMS maintenance treatment to prevent recurring symptoms. Studies in 2013 and 2018 showed that a maintenance protocol of 5 sessions over the course of 3 days each month helps to prevent relapse.[3-4] Similarly, Wang's 2017 study showed that 5-10 sessions delivered over the course of 3 days each month is also effective.[5]

In conclusion, the best clinical management of patients with MDD who had a positive response to intensive TMS, but who have symptom recurrence after intensive TMS is stopped, is to use maintenance TMS to prevent relapse. Just as in ECT, this should clearly be the standard of care.

Additional TMS used as maintenance treatment can prevent full depressive relapse in TMS-responsive patients. However, insurance company policies often deny or delay access to TMS treatment after the initial acute course. This means a patient must become increasingly symptomatic and fully relapse before receiving the treatment that is known to be effective for them. Too prevent patients from experiencing unnecessary suffering, we implore you to reconsider these harmful policies.

References

1. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. Nov 2006;163(11):1905-17. doi:10.1176/ajp.2006.163.11.1905

2. Senova S, Cotovio G, Pascual-Leone A, Oliveira-Maia AJ. Durability of antidepressant response to repetitive transcranial magnetic stimulation: Systematic review and meta-analysis. *Brain Stimul*. 2019 Jan - Feb 2019;12(1):119-128. doi:10.1016/j.brs.2018.10.001

3. Fitzgerald PB, Grace N, Hoy KE, Bailey M, Daskalakis ZJ. An open label trial of clustered maintenance rTMS for patients with refractory depression. *Brain Stimul*. May 2013;6(3):292-7. doi:10.1016/j.brs.2012.05.003

4. Pridmore S, Erger S, Rybak M, Kelly E, May T. Early relapse (ER) transcranial magnetic stimulation (TMS) in treatment resistant major depression. *Brain Stimul*. 2018 Sep - Oct 2018;11(5):1098-1102. doi:10.1016/j.brs.2018.05.013

5. Wang HN, Wang XX, Zhang RG, et al. Clustered repetitive transcranial magnetic stimulation for the prevention of depressive relapse/recurrence: a randomized controlled trial. *Transl Psychiatry*. 12 2017;7(12):1292. doi:10.1038/s41398-017-0001-x