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Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study

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PMID: 20965447 DOI: 10.1016/j.brs.2010.07.003

Abstract

Background: Although transcranial magnetic stimulation (TMS) can be an effective acute antidepressant treatment, few studies systematically examine persistence of benefit.

Objective: We assessed the durability of antidepressant effect after acute response to TMS in patients with major depressive disorder (MDD) using protocol-specified maintenance antidepressant monotherapy.

Methods: Three hundred one patients were randomly assigned to active or sham TMS in a 6-week, controlled trial. Nonresponders could enroll in a second, 6-week, open-label study. Patients who met criteria for partial response (i.e., >25% decrease from the baseline HAM-D 17) during either the sham-controlled or open-label study (n = 142) were tapered off TMS over 3 weeks, while simultaneously starting maintenance antidepressant monotherapy. Patients were then followed for 24 weeks in a naturalistic follow-up study examining the long-term durability of TMS. During this durability study, TMS was readministered if patients met prespecified criteria for symptom worsening (i.e., a change of at least one point on the CGI-S scale for 2 consecutive weeks). Relapse was the primary outcome measure.

Results: Ten of 99 (10%; Kaplan-Meier survival estimate = 12.9%) patients relapsed. Thirty-eight (38.4%) patients met criteria for symptom worsening and 32/38 (84.2%) re-achieved symptomatic benefit with adjunctive TMS. Safety and tolerability were similar to acute TMS monotherapy.

Conclusions: These initial data suggest that the therapeutic effects of TMS are durable and that TMS may be successfully used as an intermittent rescue strategy to preclude impending relapse.

Trial registration: ClinicalTrials.gov NCT00104611.

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