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TMS for Resistant Depression: Long-term Results Are In

Caroline Cassels

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SAN FRANCISCO — Transcranial magnetic stimulation (TMS) appears to offer long-term efficacy in patients with treatment-resistant major depressive disorder (TR-MDD), new research shows.

Presented here at the American Psychiatric Association's 2013 Annual Meeting, the multicenter, longitudinal, naturalistic, observational study showed that acute TMS induced "statistically and clinically meaningful response and remission" in patients with TR-MDD during the acute phase, and that the results were maintained at 52 weeks.

"This is the first study to examine 12-month outcomes of TMS in a large dataset in a real-life setting. We have data on 257 patients that got all the way through the long-term follow-up, and we found that 68% improved and 45% had complete remission at 1 year follow-up," study investigator Linda L. Carpenter, MD, assistant professor, Department of Psychiatry and Human Behavior, Brown University School of Medicine, and chief, Mood Disorders Program, Butler Hospital, in Providence, Rhode Island, told *Medscape Medical News*.

"I think this will really be impressive for confirming the long-term durability of this effect to potential payers. This is exciting times for psychiatrists and patients, who have a new treatment option to pursue," she added.

Previous research has shown that TMS is a safe and effective acute treatment option for patients with TR-MDD. However, the long-term efficacy and durability of the treatment in this patient population were unclear.

To assess the changes in depressive symptoms and functional capacity across the duration of acute and long-term follow-up of TMS treatment, the investigators studied 307 depressed patients who were part of a prospective multicenter observational clinical trial examining the utilization and outcomes of the NeuroStar TMS Therapy System (Neuronetics Inc, Malvern, Pennsylvania).

Study participants had a primary diagnosis of unipolar, nonpsychotic major depressive disorder and had failed to receive benefit from prior antidepressant treatment. The mean age of the participants was 48.6 ± 14.2 years, and 66.8% were women.

The study's primary outcomes included Clinical Global Impressions–Severity of Illness Scale (CGI-S), Patient Health Questionnaire (PHQ-9), and the Self-Rated Inventory for Depression Symptomatology (IDS-SR).

All patients initially received the standard stimulation protocol (120% of motor threshold, 10-Hz cycles of 4 seconds of active stimulation followed by 26 seconds of no stimulation for a total of 3000 pulses per treatment session), but this could change to meet patient needs. Treatment was received daily for a period of 4 to 6 weeks.

Real-world Study

Of the total study population, 264 patients (62%) from 42 clinical practices achieved symptomatic improvement, and 41% reported complete remission with acute treatment.

Of these individuals, 257 entered a 12-month long-term follow-up phase of the study, in which they were tapered off of the acute treatment regimen and were observed for 52 weeks.

Outcome measures were obtained at 3, 6, 9, and 12 months. Concurrent medication use and TMS reintroduction for recurrent symptoms were recorded and summarized during the long-term follow-up.

At 12 months, 68% of patients achieved symptomatic improvement, and 45% reported complete remission. Maintenance of benefit was observed under a pragmatic regimen of continuation antidepressant medication and access to TMS reintroduction for symptom recurrence.

The researchers report that compared with baseline, there was a statistically significant reduction in mean (standard deviation [SD]) CGI-S, PHQ-9, and IDS-SR total scores at the end of acute treatment (5.1 [0.9] vs 3.2 [1.5]; 18.3 [5.2] vs 9.6 [7.0]; and 45.7 [11.0] vs 27.4 [15.8]; all $P < .0001$), which was sustained throughout the 52-week follow-up period (3.0 [1.5], 9.4 [7.2], and 27.3 [16.1], respectively; all $P < .0001$).

"The durability of NeuroStar TMS Therapy demonstrated by this robust, real-world study is remarkable, as it's not typical to see long-term benefit in patients who have treatment-resistant forms of depression," study investigator Philip Janicak, MD, professor of psychiatry, Rush University Medical College, and medical director of the Rush Psychiatric Clinical Research Center, in Chicago, said in a statement.

"Great News"

Asked by *Medscape Medical News* for independent comment on the study, Mark George, MD, professor of psychiatry, radiology, and neurosciences and director of the Medical University of South Carolina Center for Advanced Imaging Research as well as the Brain Stimulation Laboratory in Charleston, said that the study is good news for clinicians and patients alike.

Dr. George's group was the first to publish a [study](#) on TMS and depression in 1994, and he has been actively investigating the technology since that time.

He also led a large National Institutes of Health [study](#), published in 2010, showing that repetitive daily TMS produced statistically significant and clinically meaningful antidepressant effects compared with sham treatment in patients with TR-MDD.

"This is a very important and exciting study. Several prior studies have shown that prefrontal rTMS works to treat depression acutely. Until this study, we have had only limited information about how well these patients do a year after completing a course of TMS. Long-term data following remission produced by medications or electroconvulsive therapy [ECT] in these treatment-resistant patients have been disappointing, with only about 13% being still remitted a year later.

"For example, over half of patients who remit with ECT are ill again 6 months later. Thus, having 45% in remission a full year later is very, very encouraging that rTMS is perhaps changing the underlying pathological circuitry associated with depression and producing a more stable remission than the other treatments.

"This is great news for our field and for the millions of patients who suffer from depression and do not respond well to medications," Dr. George added.

Dr. Janicak reports that he has received grant/research support from Janssen-Ortho Pharmaceutica Inc, Neuronectics Inc, Otsuka Pharmaceuticals, and Sunovion Pharmaceutical Inc. Dr. Carpenter reports that she is a consultant for Abbott Laboratories, Johnson & Johnson, and Lundbeck and that she has received grant/research support from NeoSync, Medtronic Inc, Neuronetics, and the National Institute of Mental Health. Dr. Dunner has disclosed no relevant financial relationships. The remaining authors are employees of Neuronetics Inc. Dr. George reports no relevant financial relationships, he reports that he does not take money from TMS manufacturers for speaking or consulting, and he reports that he does not own equity in any device or drug company.

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