

This letter pertains to the January 27th meeting about the Repetitive Transcranial Magnetic Stimulation device.

January 14, 2007

Dear Neurological Devices Panel,

I am a psychiatrist who works for a large HMO in California. I am in no way affiliated with any of the companies that make the TMS devices. I am simply a clinician who has been closely watching the TMS story unfold. I would very much like to provide you with my perspective as you begin your review.

A little over half of the 75 patients I see in my office each week have a form of major depressive disorder. We provide them with brief therapy and usually evaluate them for medication management. Most of these people are in the lower-middle socio-economic classes. They are typically employed in factory, construction, clerical or teaching jobs and have families who depend on them. Needless to say, an episode of major depression is not only emotionally painful to them, but their families and relationships are often deeply affected as well. Work performance is also at risk—often we “write them off” work for a few weeks while we await the therapeutic effect of medications and therapy.

I do my best to elicit a thorough medical and psychiatric history in order to select the medications that are most likely to be effective for each patient. However, more times than I like, a patient comes back 6 weeks later, no better, or with intolerable side effects. The recent large study on antidepressant effectiveness, (STAR*D, portions published in *N Engl J Med* 2006;354:1231-1242) gave remission rates of about 30% for Celexa. Non-responders or those intolerant to Celexa were switched to one of a few different antidepressants. For this group remission rates were between 18% and 25%. Unfortunately, these numbers don't provide the large measure of hope that our depressed patients and their families need so badly.

When patients repeatedly fail several medication trials we do have the option of ECT. Of course, ECT is quite effective and that is gratifying, however, there are a number of drawbacks to this treatment. 1. Stigma—sometimes we can overcome this with education, sometimes not. 2. Need for general anesthesia—makes the treatment expensive and introduces risk, 3. Inconvenience—patients are not allowed to drive during a course of treatment which typically lasts 2-3 weeks and they usually cannot work as well, 4. Cognitive impairment---I once had a patient who forgot that he was a smoker during his ECT course and was cured of both his smoking habit and his depression! However, most people are unhappy with losing chunks of their memory prior to and during their ECT course.

I've read quite a bit about Repetitive Transcranial Magnetic Stimulation and I have had discussions with people involved in TMS research. I've observed it being performed and tried operating a device myself. What I've learned is exciting to me because it seems to be effective and safe, is not invasive, does not produce cognitive side effects and can be

done out-patient without the need for anesthesia. I know earlier studies had mixed results, but it seems to me that now that progress has been made in determining the best anatomical sites and treatment parameters, the studies have become more favorable. For example, a recent study compared ECT and rTMS and found them comparable for non-psychotic refractory depression (International J of Neuropsychopharmacology, 2006).

Thank you very much for the opportunity to contribute my thoughts to you. I hope I have communicated the need for additional tools, such as rTMS, for the treatment of this debilitating illness.

Sincerely,

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Diplomate, American Board of Psychiatry and Neurology