"Can We Deliver TMS to Patients With Implanted Devices?"

A Practical Summary of the Recent Safety Recommendations

To the Editor: One of the most frequent questions directed to our Medical Affairs division is, "Is it safe to deliver TMS (transcranial magnetic stimulation) to individuals with an implanted device?" This is a reasonable question, and one that has been revisited by expert groups of key opinion leaders as the field of TMS has evolved. While the original safety recommendations were extremely cautious, these guidelines have now been revised, as there are more data to inform decision making. The details can be found in the article by Rossi and colleagues[1] (the basis of this article began with a Consensus Statement from the IFCN Workshop on "Present, Future of TMS: Safety, Ethical Guidelines," Siena, October 17–20, 2018, updating through April 2020), but in summary the committee concluded that "TMS can be safely applied in patients with implanted stimulators in the central or peripheral nervous system….Care should be taken to minimize the currents induced in any connections to external stimulators or amplifiers"[1(p281)] and that "Caution should be taken to avoid accidental firing of the TMS coil near electronic implants."[1(p281)] Unfortunately, the United States Food and Drug Administration (FDA) has not updated their guidelines. Consequently, the Instructions for Use (IFU) documents associated with many TMS devices have also not been updated to the currently accepted guidelines by the Key Opinion Leaders in the field.[1] The lack of consistency among these 3 pieces of documentation leads to confusion. The goal of this letter is to provide a simple overview for providers and regulatory officials.

What Are the Theoretical Concerns of Conducting TMS With an Implanted or Non-Removable Device Present?

The theoretical concerns of conducting TMS with an implanted or non-removable device present are heating of the implanted device if it is made of highly conductive material, mechanical movement of an unanchored implanted device if it is made from a highly ferromagnetic material, demagnetization of implanted permanent magnets, and induction of a current in the wires or electrodes of the implanted device. Strong electromagnetic induction mainly occurs when the implanted device's wires are oriented in the same direction as elements of the TMS coil. In such a case, the current may even damage the implanted device. Risk of induced current in electrodes' wires is significantly reduced if the electrodes' wires are arranged to be close or twisted together, with each turn circling in opposite direction (eg, one turn clockwise and the next turn counterclockwise), without looping either between wires or of the whole wire bundle.[2] We learned a lot about the safety of stimulation with combined devices from the field of magnetic resonance imaging (MRI). Clinical MRI's field is 1.5–3 Tesla, while the strongest TMS-induced magnetic fields are about 2 Tesla, and on the brain surface 1.5–2 cm from the coil less than 0.5 Tesla.[3] The strength of the field decays as one moves farther from the coil. Moreover, while MRI induces a strong static magnetic field, the TMS field is brief (< 1 millisecond); hence, its effect on ferromagnetic materials is generally weaker.

Practical Considerations

As a rule of thumb, anything MRI safe or conditional is TMS safe. Some practical examples are tattoos and jewelry, which, even if they have ferromagnetic material, do not heat up or move in an obvious manner. Mechanical movement of an implanted device is not a problem,[4] nor is heating of non-ferromagnetic material. Very conservative guidance is to avoid placing ferromagnetic material within 10 cm of the coil since the electromagnetic forces at 10 cm are effectively null.[5] Even closer than 10 cm, anything anchored such as a screw or plate, or held like a phone, will not move under the influence of TMS. Hearing aids should be removed during TMS for hearing protection, and their durability under the coil may be manufacturer dependent.

Many patients have had courses of repetitive TMS with figure-8 and H-coils with implanted vagal[6,7] and hypoglossal nerve stimulators without any damage to the stimulators. We do not have data on occipital nerve stimulators. Cochlear implants have specific MRI guidance, and some newer devices are MRI conditional.[8] No damage to cochlear implants was found even at an extremely high TMS magnetic field of 2.2 Tesla.[9] The safety of repetitive TMS (rTMS) in patients with cochlear implants that do not have MRI guidance must be determined. The same rule applies to ventriculoperitoneal shunts, since the older programable cerebrospinal fluid (CSF) shunts are affected by higher strength MRIs but will not be affected by TMS and will not need reprogramming after a treatment course.[10,11] TMS in patients with deep brain stimulators should be done only if there are justifiable scientific or medical reasons. In such cases, electrodes' leads loops should be avoided or wound with each turn circling in opposite direction, and the TMS coil should be operated away from the leads. Occasionally, patients say they have implants in the skull, but they do not know if the material is ferromagnetic or not (like titanium). They may not recall the facility where the surgery took place, and the surgeon may no longer be in practice. For such cases, it is useful to have a handheld ferromagnetic detector. This is much cheaper than whole body ferromagnetic detectors used in MRI clinics,[12] and the area where the coil is going to be placed can be scanned to alleviate patient concerns.

Moving Forward

Our hope is that the FDA guidelines will soon be adjusted and manufacturer IFU documents will all be revised to reflect the status of our knowledge in this field. Consistency not only improves compliance, but it also reduces confusion among providers and patients. It promotes rigorous and responsible use of these devices and will ensure that patients are receiving evidence-based care. In the meantime, we hope this is a valuable summary of the current recommendations and that it may be useful for emerging practitioners, trainees, and other individuals that may be new to the TMS field. In summary, we advise providers to consider the risks and benefits of TMS treatment in patients and consider the recent consensus guidelines and literature reports instead of universally excluding patients on the basis of outdated conservative manufacturer guidance documents.

REFERENCES

1. Rossi S, Antal A, Bestmann S, et al. Safety and recommendations for TMS use in healthy subjects and patient populations, with updates on training, ethical and regulatory issues: Expert Guidelines. *Clin Neurophysiol*. 2021;132(1):269–306.
2. Repetitive Transcranial Magnetic Stimulation (rTMS) Systems—Class II Special Controls Guidance for Industry and FDA Staff | FDA n.d. FDA website. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/repetitive-transcranial-magnetic-stimulation-rtms-systems-class-ii-special-controls-guidance. July 26, 2011. Accessed January 19, 2023.

3. Dodick DW, Schembri CT, Helmuth M, et al. Transcranial magnetic stimulation for migraine: a safety review. *Headache*. 2010;50(7):1153–1163.
4. Peterchev AV, Wagner TA, Miranda PC, et al. Fundamentals of transcranial electric and magnetic stimulation dose: definition, selection, and reporting practices. *Brain Stimul*. 2012;5(4):435–453.
5. Phielipp NM, Saha U, Sankar T, et al. Safety of repetitive transcranial magnetic stimulation in patients with implanted cortical electrodes. An ex-vivo study and report of a case. *Clin Neurophysiol*. 2017;128(6):1109–1115.
6. George MS, Caulfield KA, O'Leary K, et al. Synchronized cervical VNS with accelerated theta burst TMS for treatment resistant depression. *Brain Stimul*. 2020;13(5):1449–1450.
7. Philip NS, Carpenter SL, Carpenter LL. Safe use of repetitive transcranial magnetic stimulation in patients with implanted vagus nerve stimulators. *Brain Stimul*. 2014;7(4):608–612.
8. MRI safety and Cochlear Implants—Nucleus, Osia and Baha n.d. Cochlear website. https://www.cochlear.com/us/en/home/ongoing-care-and-support/device-help-and-support/mri-and-medical-considerations. November 1, 2011. Accessed January 19, 2023.
9. Mandalà M, Baldi TL, Neri F, et al. Feasibility of TMS in patients with new generation cochlear implants. *Clin Neurophysiol*. 2021;132(3):723–729.
10. Lavinio A, Harding S, Van Der Boogaard F, et al. Magnetic field interactions in adjustable hydrocephalus shunts. *J Neurosurg Pediatr*. 2008;2(3):222–228.
11. Fransen P, Dooms G, Thauvoy C. Safety of the adjustable pressure ventricular valve in magnetic resonance imaging: problems and solutions. *Neuroradiology*. 1992;34(6):508–509.
12. Kanal E, Barkovich AJ, Bell C, et al; Expert Panel on MR Safety. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging*. 2013;37(3):501–530.

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Article Information

Published Online: July 12, 2023. https://doi.org/10.4088/JCP.23l14857

To Cite: Tendler A, Roth Y, Hanlon CA. "Can we deliver TMS to patients with implanted devices?": a practical summary of the recent safety recommendations. *J Clin Psychiatry.* 2023;84(4):23l14857.

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Relevant Financial Relationships: All the authors are currently engaged in medical and scientific affairs of a multinational TMS manufacturer. **Dr Tendler** has a financial interest in BrainsWay, Liva Nova, Biohaven, α Tau Medical, the Clinical TMS Society, and a commercial psychiatric clinical and research center. **Dr Roth** and **Dr Hanlon** have a financial interest in BrainsWay.

Funding/Support: BrainsWay (TASE, NASDAQ) provided a consultant fee to Dr Tendler as medical director and salary support to Dr Roth as chief scientist and to Dr Hanlon as vice president of medical affairs and innovation. No funding or involvement was provided for this project, and the sponsor had no knowledge of this project.

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