# TMS SAFETY

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# OVERVIEW

## TMS is generally a safe and well-tolerated procedure

- Seizures, often considered the most serious risk, are very rare!
- Side effects are generally quite manageable
- BUT investigators should be prepared to manage the common and uncommon side effects
- Safety considerations in special populations and with devices

# KEY PAPER

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Review

## Safety and recommendations for TMS use in healthy subjects and patient populations, with updates on training, ethical and regulatory issues: Expert Guidelines

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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 [1]

# NOT JUST ADVERSE EFFECTS

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# ADVERSE EFFECTS OF TMS

Potential TMS adverse effects include

- Seizures
- Syncope & presyncope
- Hearing changes (Tinnitus, hearing loss)
- Headaches; neck, scalp and dental pain
- Cognitive changes

# SEIZURES AND TMS

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## Seizures from transcranial magnetic stimulation 2012–2016: Results of a survey of active laboratories and clinics

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# SEIZURE DETAILS

**Table 2**
Characteristics of reported seizures and subjects.

| Seizure description | Frequency | Target | Diagnosis | Medications | Previous TMS |
|---|---|---|---|---|---|
| 1. "Clinical seizure" | Single/Paired-pulse | Frontal cortex | Epilepsy | Valproate, zonisamide | None |
| 2. Myoclonic | Single/paired-pulse | M1 | Myoclonus epilepsy | Antiepileptic(s) | Some (unspecified) |
| 3. Myoclonic | Single/paired-pulse | M1 | Myoclonus epilepsy | Antiepileptic(s) | Some (unspecified) |
| 4. Secondary generalized | Single-pulse | M1 | Epilepsy | Topiramate, valproate, clobazam | None |
| 5. Partial | Single-pulse | M1 | Multiple sclerosis (possible) | None | None |
| 6. Complex partial | Single-pulse | M1 | None | None | 1 session |
| 7. Partial[†] | Single-pulse | M1 | Tumor | Sertraline | 2 sessions |
| 8. Partial[*] | Single-pulse | M1 | Tumor | Levitiracetam, lamotrigine | 1 session |
| 9. Partial | Single-pulse | M1 | None | None | None |
| 10. Secondary generalized | Single-pulse | IPS | None | Oral contraceptives | None |
| 11. Generalized | Single-pulse | M1 (round coil at vertex) | Paraparesis | None | None |
| 12. Generalized[*] | Single-pulse | M1 | Epilepsy | Clobazam, pregabalin, zonisamide, levetiracetam, valproate, hydantoin | None |
| 13. Not reported | Single pulse | M1 | Stroke | Not reported | None |
| 14. Partial | Single-pulse | M1 | Arteriovenous malformation | None | None |
| 15. Myoclonic | 0.3 Hz | M1 (round coil at vertex) | Myoclonus epilepsy | Valproate, zonisamide, levetiracetam, clobazam | None |
| 16. Generalized | 1 Hz | DLPFC | Stroke | Atorvastatin, warfarin | None |
| 17. Partial[*] | 7 Hz | M1 | Epilepsy | Valproate, eslicarbazepine, lacosamide, levetiracetam | None |
| 18. Partial then generalized | 10 Hz | M1 | Stroke | Some (unspecified) | Some (Unspecified) |
| 19. Secondary generalized | 10 Hz | M1 | Stroke | Trifluoperazine | None |
| 20. Secondary generalized | 15 Hz | DLPFC | Schizophrenia | Risperidone | 4 sessions |
| 21. Secondary generalized | 18 Hz | DLPFC | Depression | None | 7 sessions |
| 22. Secondary generalized | 18 Hz | DLPFC | Depression Alcoholism | None | 12 sessions |
| 23. Generalized | 18 Hz | DLPFC | Depression/rheumatoid arthritis | Methotrexate | Unreported |
| 24. Secondary generalized | 20 Hz | DLPFC | Depression | Mirtazepine | None |
| 25. Secondary generalized | iTBS | M1 | Stroke | None | None |

# SEIZURES ARE RARE!

**Table 1**
Seizures by TMS protocol and risk category.

| | | Total | | Elevated subject risk | | | Elevated protocol risk | | | Elevated protocol & subject risk | | | No elevated risk | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TMS Protocol | Seizures | Sessions | Risk | Seizures | Sessions | Risk | Seizures | Sessions | Risk | Seizures | Sessions | Risk | Seizures | Sessions | Risk |
| Single/Paired-pulse | 13 | 112,897 | .12/1000 | 10 | 12,201 | .82/1000 | | | | | | | 3 | 100,696 | .03/1000 |
| Low-frequency (rTMS ≤ 1 Hz) | 3 | 90,631 | .03/1000 | 3 | 36,258 | .08/1000 | | | | | | | 0 | 54,373 | .00/1000 |
| High-frequency (rTMS > 1 Hz) | 4 | 82,588 | .05/1000 | 3 | 5215 | .58/1000 | 0 | 1029 | .00/1000 | 1 | 163 | 6.13/1000 | 0 | 76,181 | .00/1000 |
| Intermittent Theta Burst | 1 | 16,952 | .06/1000 | 1 | 1813 | .55/1000 | 0 | 7909 | .00/1000 | 0 | 4501 | .00/1000 | 0 | 2729 | .00/1000 |
| Continuous Theta Burst | 0 | 8568 | .00/1000 | 0 | 826 | * | 0 | 673 | * | 0 | 2075 | .00/1000 | 0 | 4994 | .00/1000 |
| H-coil high-frequency rTMS | 3 | 6924 | .43/1000 | 2 | 872 | 2.29/1000 | 0 | 2948 | .00/1000 | 0 | 10 | * | 1 | 3094 | .32/1000 |
| Totals | 24 | 318,560 | .07/1000 | 19 | 57,185 | .33/1000 | 0 | 12,559 | .00/1000 | 1 | 6749 | .15/1000 | 4 | 242,067 | .02/1000 |

Number of sessions and seizures for different TMS protocols and subject and protocol risk categories. H-coil high-frequency stimulation data are listed separately from standard high-frequency (>1 Hz) data. With the exception of standard high-frequency (>1Hz) data, other numbers include round, figure-8, "double cone," and H-Coils. Three likely spontaneous seizures (#8, #12, and #17 in Table 3) are included. Seizure #7 is not included because the number of sessions was not reported. *No seizures reported; sample size < 1000 sessions.

# SOME NOTABLE FACTS

- Majority of seizures (62%) occurred on **first exposure** to TMS
- With the exception of patients with epilepsy, **risk of seizures is very low** even in otherwise "high-risk populations"
  - 19 seizures in 57,185 sessions = 0.33/1000
  - At least 8 of these 19 seizures occurred in patients with known epilepsy
- **Seizure risk in patients with epilepsy is higher**
  - **Between 1.4% (Bae et al, 2007) and 2.9% (Pereira et al, 2016)**
- Seizure risk may be higher using H-coil device

# WHAT ABOUT WITH CLINICAL RTMS?

Brain Stimulation 14 (2021) 965–973

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Brain Stimulation

journal homepage: http://www.journals.elsevier.com/brain-stimulation


## Seizure risk with repetitive TMS: Survey results from over a half-million treatment sessions

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# SEIZURES AND CLINICAL RTMS

consistencies. In total, 18 seizures were reported in 586,656 sessions and 25,526 patients across all device manufacturers. The overall seizure rate was 0.31 (95% CI: 0.18, 0.48) per 10,000 sessions, and 0.71 (95% CI: 0.42, 1.11) per 1000 patients. The Brainsway H-coil seizure rate of 5.56 per 1000 patients (95% CI: 2.77,9.95) was significantly higher ($p < 0.001$) than the three most widely used figure- 8 coil devices' combined seizure rate of 0.14 per 1000 patients (95% CI: 0.01, 0.51).

**Table 2**
Seizure rate by device. Seizure rates were estimated per 10,000 sessions and per 1000 patients across the four most widely used manufacturers.

| | Per 10,000 Sessions | | Per 1000 Patients | |
|---|---|---|---|---|
| Manufacturer | Estimated Seizure Rate | 95% CI | Estimated Seizure Rate | 95% CI |
| All | 0.25 | (0.14, 0.42) | 0.61 | (0.33, 1.02) |
| Brainsway | 1.56 | (0.78, 2.80) | 5.56 | (2.77, 9.95) |
| Magstim | 0.00 | (0.00, 0.51) | 0.00 | (0.00, 1.75) |
| MagVenture | 0.24 | (0.03, 0.88) | 0.73 | (0.09, 2.62) |
| Neuronetics | 0.03 | (0.00, 0.17) | 0.06 | (0.00, 0.35) |

# SO WHAT CAN WE CONCLUDE?

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Editorial

## Seizures with TMS: Much ado about (almost) nothing?

See Article, pages 1409–1416



BUT you still need to be prepared!

# WHAT ABOUT OTHER ADVERSE EFFECTS?

## Syncope (Fainting) and presyncope

- True incidence is unknown, but several cases reported. Likely underreported as not as “serious” as seizure
- In study by Lerner et al, 29/174 responding facilities (17%) reported experiencing cases (often multiple) of syncope (much more than seizures)
- Risk factors can include orthostasis, prior history of syncope (including in response to blood draws), history of cardiac issues etc.
- Features suggesting syncopal origin included preceding presyncope / lightheadedness, diaphoresis, nausea; and very short post-event confusion
- Be aware of convulsive syncope as a differential for seizures!

# HEARING CHANGES

- TMS is louder than it sounds!
  - Noise level of a single pulse has been reported to be between 125-140 dB! (Koponen 2020, Kukke 2017), but hard to measure using standard sound meters because pulse is so short
  - rTMS may be 95-115 dB (Koponen 2020), well above OSHA safety limits
- Permanent hearing threshold changes reported in one participant whose ear plug slipped out of one ear (Zangen 2005)
- **Hearing protection critical** (e.g. using 32dB noise-reducing earplugs)
  - No changes in hearing sensitivity after TMS when used (Pascual-Leone 1992, O'Reardon 2007)
- **TMS technicians should wear earplugs too!**
- Individuals with cochlear implants should **NOT** undergo TMS

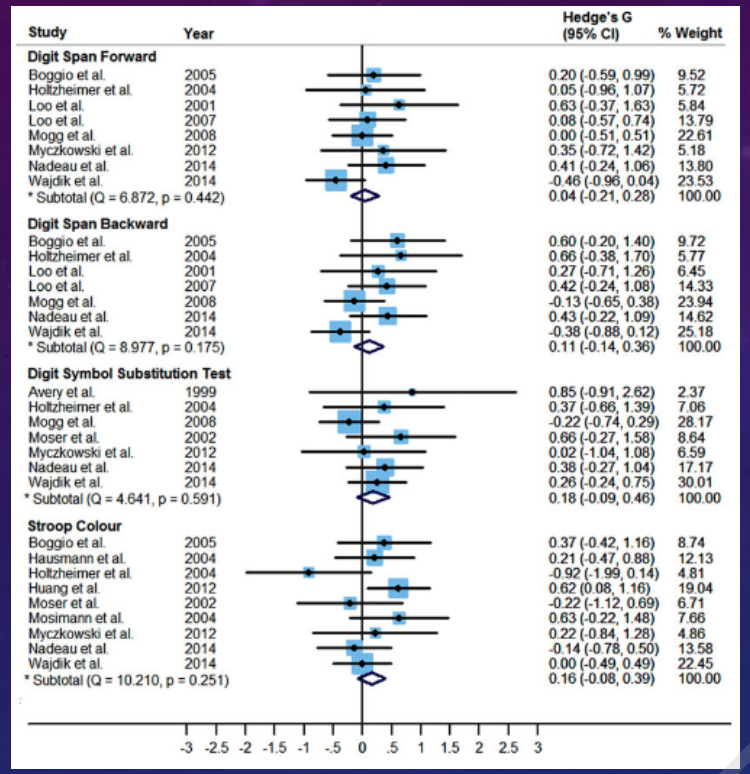
# HEADACHES AND MUSCULOSKELETAL PAIN

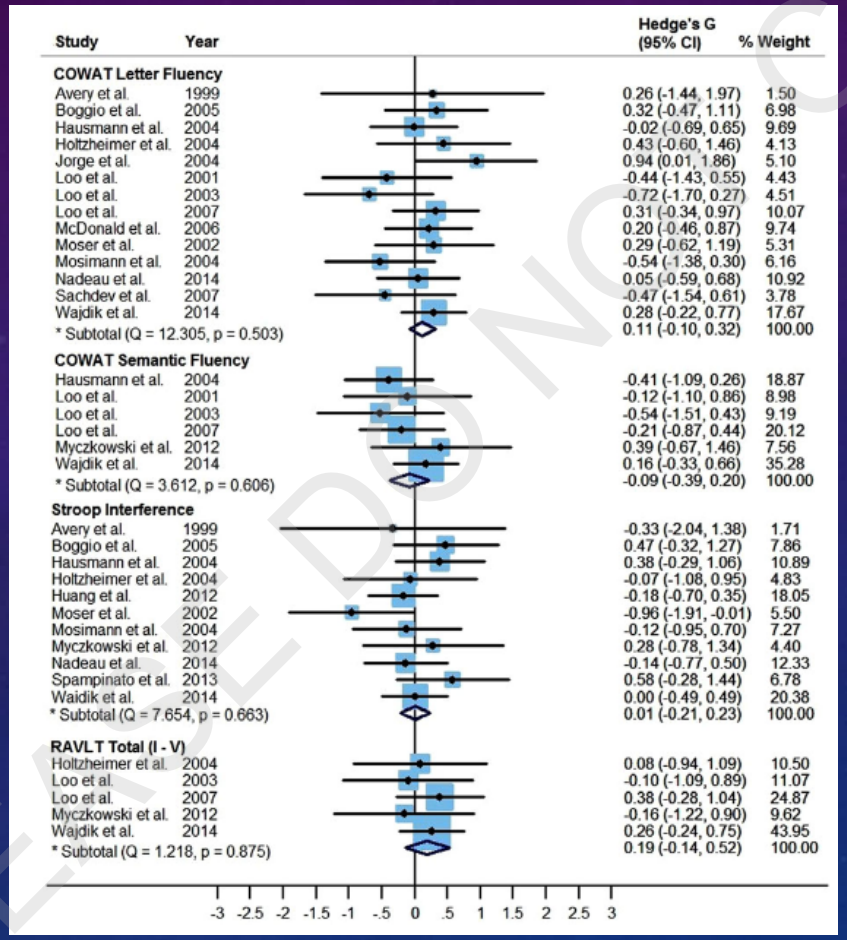
- The most common TMS side effect
  - Studies in RCTs that systematically capture side effects have reported **rates between 28% (Loo 2008) and 65% (Blumberger 2018)**, much higher than with sham stimulation (typically 10-20%)
- TMS stimulation itself can be painful, particularly to naïve patients
- Musculoskeletal and pain side effects vary greatly depending on location and orientation of stimulation (e.g. DLPFC >> M1)
  - With DLPFC, can get repetitive blinking, eye pain
  - In posterior regions, can get neck muscle and jaw activation
- Headaches typically respond well to OTC analgesics
- Local painfulness of prefrontal rTMS declines over first few days of treatment (Janicak 2008, Anderson 2009)

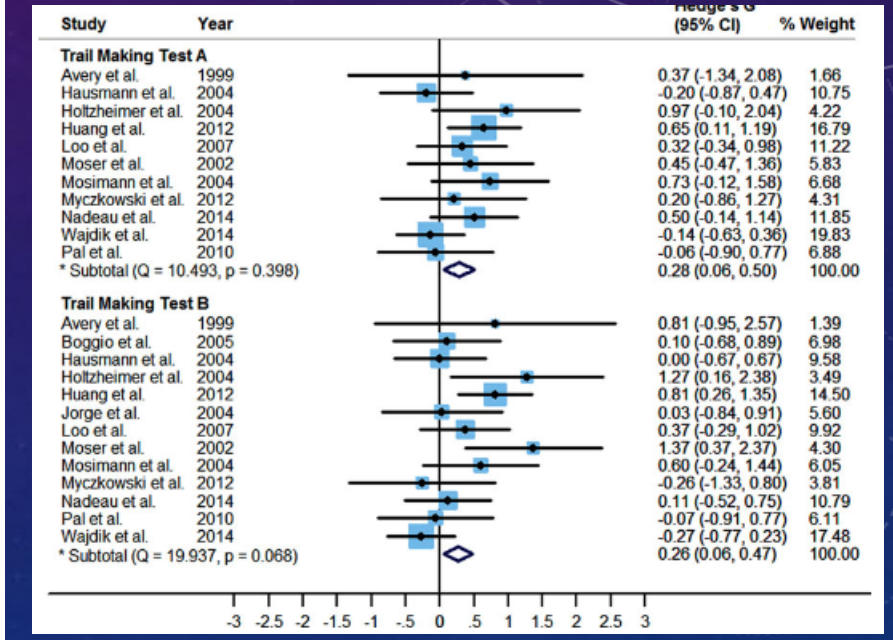
# COGNITIVE CHANGES

- In patients undergoing experimental single-session studies, transient cognitive changes lasting only a few minutes typically reported
- Following rTMS course for TRD, no clear cognitive gains or cognitive side effects in systematic reviews (McClintock 2019, Iimori 2019)
- Possible “trends toward improvement in the neurocognitive profile” in patients undergoing rTMS for TRD (Serafina 2015)
  - May have some improvement in performance with the Trail Making Test (Martin 2017)
  - Patients with baseline cognitive dysfunction may have improvements in verbal memory associated with improvements in affective symptoms (Gregory 2022)
- Some patients can report transient lightheadedness / “brain fog” immediately at the end of a session, which improves within minutes

# TASK PERFORMANCE CHANGES WITH RTMS






Serafina 2015

# PREGNANCY

- No meaningful / physiologically relevant electric field at the level of the developing fetus (Yanamalda 2017)
- TMS has been used for treatment of depression during pregnancy, with no significant side effects
- Children born to mothers treated during pregnancy with rTMS for depression did not have increased perinatal complications or cognitive/motor developmental abnormalities (Kim 2019)
- Main risk is risk of maternal seizure (which is very low)

# PEDIATRICS

- Zewdie 2020: Reviewed data from 384 children who received > 3.5 million stimulations at a single center (U of Calgary, Canada)
  - Included >500k stimulations with single- and paired-pulse TMS, and ~3 million stimulations with rTMS
  - No seizures (despite 221 participants having brain injuries or epilepsy)
  - Reported side effects to rTMS include HA (<17%), neck pain (<30%), tingling (<25%), presyncope / lightheadedness (<30%), and nausea (10%)
- Hong 2015: No major adverse effects in 76 children receiving TBS
  - HA 6.6%, tingling 2.6%
- Hearing protection again recommended, but no documented hearing changes

# SEIZURES DURING TMS MAPPING

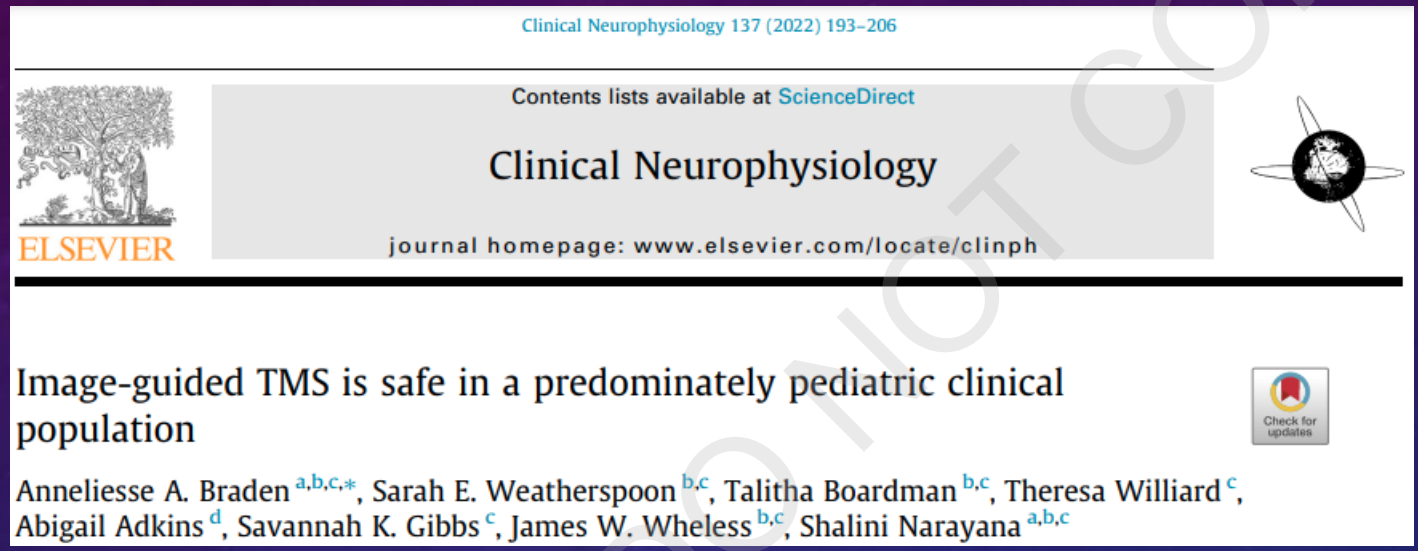


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Image-guided TMS is safe in a predominately pediatric clinical population

Anneliesse A. Braden [a,b,c,*], Sarah E. Weatherspoon [b,c], Talitha Boardman [b,c], Theresa Williard [c], Abigail Adkins [d], Savannah K. Gibbs [c], James W. Wheless [b,c], Shalini Narayana [a,b,c]

- TMS motor or language mapping carried out in 500 sessions (410 pediatric, 90 adult) in 429 patients. 399 sessions were in patients with dx of epilepsy
- 29 seizures occurred, 28 of which were in patients with epilepsy. Remaining 1 seizure occurred in patient with brain tumor
- Most common adverse event was transient pain at stimulation site

# “SAFETY TABLES”

## Rossi 2009

**Table 4**
Maximum safe duration (expressed in seconds) of single trains of rTMS. Safety defined as absence of seizure, spread of excitation or afterdischarge of EMG activity. Numbers preceded by > are longest duration tested. Consensus has been reached for this table.

| Frequency (Hz) | Intensity (% of MT) | | | | |
|---|---|---|---|---|---|
| | 90% | 100% | 110% | 120% | 130% |
| 1 | >1800[a] | >1800 | >1800 | >360 | >50 |
| 5 | >10 | >10 | >10 | >10 | >10 |
| 10 | >5 | >5 | >5 | 4.2 | 2.9 |
| 20 | 2.05 | 2.05 | 1.6 | 1.0 | 0.55 |
| 25 | 1.28 | 1.28 | 0.84 | 0.4 | 0.24 |

**Table 5**
Adapted from Table 4 (Part A) and Table 3 (part B) of Chen et al., 1997, with permission from the authors. Safety recommendations for inter-train intervals for 10 trains at <20 Hz. The maximum duration of pulses for individual rTMS trains at each stimulus intensity should not exceed those listed in the Part B of the table. A consensus has been reached in adopting this table at this point. However, there is a need to extend these investigations and provide more detailed guidelines that may apply also to non-motor areas.

| Inter-train interval (ms) | Stimulus intensity (% of MT) | | | |
|---|---|---|---|---|
| | 100% | 105% | 110% | 120% |
| *Part A* | | | | |
| 5000 | Safe | Safe | Safe | Insufficient data |
| 1000 | Unsafe (EMG spread after 3 trains) | Unsafe[a] | Unsafe (EMG spread after 2 trains) | Unsafe (EMG spread after 2 trains) |
| 250 | Unsafe[a] | Unsafe[a] | Unsafe (EMG spread after 2 trains) | Unsafe (EMG spread after 3 trains) |

| Frequency (Hz) | 100% | | 110% | | 120% | | 130% | |
|---|---|---|---|---|---|---|---|---|
| | Duration (s)/pulses | | Duration (s)/pulses | | Duration (s)/pulses | | Duration (s)/pulses | |
| *Part B* | | | | | | | | |
| 1 | >270 | >270 | >270 | >270 | >180 | >180 | 50 | 50 |
| 5 | 10 | 50 | 10 | 50 | 10 | 50 | 10 | 50 |
| 10 | 5 | 50 | 5 | 50 | 3.2 | 32 | 2.2 | 22 |
| 20 | 1.5 | 30 | 1.2 | 24 | 0.8 | 16 | 0.4 | 8 |
| 25 | 1.0 | 25 | 0.7 | 17 | 0.3 | 7 | 0.2 | 5 |

[a] These stimulus parameters are considered unsafe because adverse events occurred with stimulation of lower intensity or longer inter-train interval, but no adverse effects were observed with these parameters.

# BUT REMOVED IN 2021!

Despite such variety, as reviewed for these guidelines, neither seizure occurrence nor other AEs emerged consistently, thus indicating that whatever the protocol of intervention, the technique can be considered basically safe. Therefore, we have decided not to provide a formal update of the previous safety tables, and that, instead, we propose "operational guidelines". Clearly, the parameters of stimulation used for MST should not be exceeded. The usual lowest parameters of stimulation to induce seizures during MST are 100% of maximal stimulator output (at least for these commercially available devices), frequency of 25 Hz, delivered in a single train lasting up to 10 s. Therefore, every combination of inten-

**Recommendations**: we propose that in all clinical trials and scientific studies that use conventional rTMS protocols, the Principal Investigator (PI) has to: (i) balance the overall risk/benefit ratio of the proposed intervention, (ii) use neurophysiological monitoring (i.e., emergence of motor twitches during stimulation) as a warning for increased cortical excitation, in case the combination of parameters of stimulation exceeds the 2009 safety guidelines, (iii) reconsider the protocol of the trial if a seizure occurs under these circumstances, and iv) alert the scientifc community through dedicated scientific Journals about the new possibly unsafe combinations of parameters.

# WHAT ABOUT OTHER DEVICES

MRI

- Conventional TMS coils and systems are NOT MRI-compatible
- Special MRI-compatible coils are available, restricted to 3T or less scanners

# IMPLANTED DEVICES

- TMS pulses delivered >10 cm from implanted pulse generator (IPG) have minimal effective electric field
  - Kuhn 2004: TMS at 2-10 cm from IPG caused malfunction. TMS < 2cm caused permanent damage
  - Considered safe in patients with pacemakers, ICDs
  - We delivered rTMS in patient with ventricular assist device without any complications
- TMS is safe in patients with Vagal Nerve Stimulation (VNS) devices providing stimulation is not applied to the neck

# INTRACRANIAL IMPLANTS

- TMS causes minimal heating / displacement of titanium plates / rods / clips
- TMS is NOT safe in patients with cochlear implants
- In patients with DBS, TMS may be not safe if
  - < 10 cm from IPG
  - OR TMS is close to lead, there are loops in the electrode wires under the coil, and high TMS pulses are used (Phielipp 2017)
- Recent work suggests that TMS may be safe in patients with implanted stereotactic EEG electrodes for epilepsy monitoring (Wang 2022 Bioarxiv)

# SUMMARY

- TMS is generally safe and very well-tolerated
- The most common side effects are musculoskeletal pain and headache
- Seizures are very rare outside of patients with epilepsy
- TMS can be performed in patients with implanted devices, provided safety guidelines are adhered to