

TMS: Full Board or Expedited?

Transcranial Magnetic Stimulation:

- Neurostimulation or neuromodulation technique based on the principle of electro-magnetic induction of an electric field in the brain.
- Significant expansion over last 3 decades: typing TMS in Medline brings up 10678 papers
 - 18 papers in 1978, 722 in 2018 simply by typing TMS in Medline
- We see an increasing number of TMS studies at Ethics Boards
- Some can probably be reviewed as "expedited" due to low risk.

Transcranial Magnetic Stimulation:

- Neurostimulation or neuromodulation technique based on the principle of electro-magnetic induction of an electric field in the brain. This is often considered and called "non-invasive" (as opposed to DBS or ECT) as it does not even require sedation and fairly is painless (I did it and completed the study... and I am a chicken!... If it had hurt, I would have run)
- Use as single pulse or repetitively (rTMS); acutely or chronically
- Repetitively, it can modulate cortical excitability (inhibition or excitation) depending on the parameters
- Basic research and therapeutic applications
- Multiple pulse sequences have been developed

- Therapeutically, it is being used, more or less successfully, for a multitude of disorders: depression and depressive disorders, mania, schizophrenia, PTSD, catatonia, OCD, AD, tinnitus, tics, movement disorders (PD, dystonia, spasticity..), pain syndromes, addiction, stroke.

TMS is also a valuable tool to study cognition, brain-behavior relations through modulation of brain activity, pathophysiology of neurologic and psychiatric disorder, as well as pure electrophysiology studies

NOT PROPOSED FOR EXPEDITED

Therapeutic interventions (often performed over weeks of daily stimulation in patient populations) would continue to be reviewed at Full Board

Deep Transcranial Stimulation (Deep TMS), even acutely, should probably remain at Full Board for the time being (TMS pulse going up to 6 cm in the brain) as there are still little published studies. None are being done at UBC that I know off.

Today I want to bring up ONLY its application in "basic science", such as **acute interventional neurophysiology**, i.e. modulation of brain activity in specific distributed cortico-subcortical networks to induce controlled and controllable manipulation of behavior (muscle or individual). These can be done in Healthy Controls or Patients and are done acutely, i.e. once day or maybe a few times over weeks with over a week interval between studies

Example of electrophysiology studies: using both single pulse, repetitive TMS or patterned TMS (like theta burst)

- Cortico-cortical interaction
- Measure of intra-cortical facilitation and inhibition
- Mapping motor cortical outputs
- Central conduction times
- Paired pulse techniques with one or 2 coils to deliver stimulations to 2 regions simultaneously
- Pairing with peripheral stimulations (Paired Associated Stimulation or PAS)

Safety guidelines from a 2008 Safety of TMS Consensus conference
(Rossi et al. 2009 Clinical Neurophysiology updated in 2011)

Screening 13-item Questionnaire for rTMS Candidates

- (1) Do you have epilepsy or have you ever had a convulsion or a seizure?
- (2) Have you ever had a fainting spell or syncope? If yes, please describe on which occasion(s)?
- (3) Have you ever had a head trauma that was diagnosed as a concussion or was associated with loss of consciousness?
- (4) Do you have any hearing problems or ringing in your ears?
- (5) Do you have cochlear implants?
- (6) Are you pregnant or is there any chance that you might be?
- (7) Do you have metal in the brain, skull or elsewhere in your body (e.g., splinters, fragments, clips, etc.)? If so, specify the type of metal.
- (8) Do you have an implanted neurostimulator (e.g., DBS, epidural/subdural, VNS)?
- (9) Do you have a cardiac pacemaker or intracardiac lines?
- (10) Do you have a medication infusion device?
- (11) Are you taking any medications? (please list)
- (12) Did you ever undergo TMS in the past? If so, were there any problems.
- (13) Did you ever undergo MRI in the past? If so, were there any problems.

Standard TMS risks: UBC has very good track record

- Headaches, neck aches, scalp numbness
- Hearing threshold (loud clicks)
- Heating of metal on scalp/head
- Fainting (mostly not related to brain effects, more often to anxiety)
- Seizures (very rare; not encountered at UBC in acute protocols)
- Unforeseen

Risks that can be added due to associated procedures

- MRI (neuro-navigation; structure identification) - expedited
- EEG - expedited
- EMG - expedited.

- PET (Full board)
- Other procedures on case by case basis.

Finally, I also propose to include tDCS (transcranial direct current stimulation) in expedited review process, with same restrictions as TMS. It has less risks and while we have not encountered many such protocols, we can expect to get quite a few in next years based on numbers of publications in recent years. A medline search using tDCS as term shows 80 papers in 2008 but 597 already in 2018.

Transcranial direct current stimulation (tDCS) is a form of neurostimulation that uses constant, low direct current delivered via electrodes (foam pads anodal and cathodal) on the head. It is possible to find “recipes” on line to make your own devices using 9V batteries. This has led to the most risks and SAE/AE to enterprising individuals.... Burns on scalp due to improper use of foam pad (mostly not enough humidity for proper conduction) . This however is a low risk in a clinical setting. As TMS, people prone to seizure should not receive tDCS. Like TMS it is believed to be able to induce LTD and LTP.

tDCS is now tried for as many applications as TMS and due to ease of use and the fact that patients can do it themselves at home with minimal training, it is cost effective and while so far seems to have milder therapeutic effects (if any aside from depression), it is “hot” topic and likely to come soon to a REB near you..

Thanks you for your attention.....

Questions? Concerns?

Should we work on a guideline or stay
With case by case scenario?