Setting up aTMS Clinic

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Contents

- Safety and training of personnel
- Equipment
- Certification
- Evaluation and Consent
- Treatment Protocol
- Assessment
- Maintenance
- Cost/Billing
- Future Developments

Starting program

Managing patients

Long term plans
Setting up a TMS treatment Program

**Safety**
1. Protocols for TMS and management of seizure
2. Safety equipment
3. Patient Screening

**Training**
1. Program Director
2. Psychiatrist
3. TMS Technician

**Equipment**
1. Rapid stimulator
2. Safety equipment
3. Supplies

**Certification**
1. FDA-cleared device
2. Local safety committee/IRB
3. Informed consent
Personnel

• Clinicians (Neurology / Psychiatry)
• Administrative support
  – Scheduling
  – Providing information to prospective patients
  – Data collection
• Technicians
  – TMS trained
  – Basic Life Support
  – Patient interaction
Safety

• Patient selection- seizure risk
• TMS protocol- 10-20hz vs. 1hz
• Safety equipment
  – In hospital
  – Clinic/outpatient setting
• Training of staff in management of seizures
Equipment

• TMS machine
  – Approved device options
  – Cooled coil
  – We use both neuronetics and magstim
• Earplugs and swimming cap
• Safety equipment
  – Tylenol
  – To treat a seizure
  – Emergency medical services
Neurostar TMS Therapy

Senstar™ Treatment Link
- Contact sensing
- Dose confirmation
- Surface field cancellation
- Hygiene barrier

Mobile Console
Display
Treatment Coil
Effect on Continuous Outcomes
MADRS and HAMD24 Rating Scales

MADRS Total Score
Baseline to Endpoint Change

HAMD24 Total Score
Baseline to Endpoint Change

...P-Values with correction for baseline imbalance in Total MADRS Score
[N=6 patients censored w/Total MADRS < 20 at baseline]

* P < 0.05, LOCF analysis
**TMS Timeline**

- **1984**: Anthony Barker, Single Pulse TMS
- **1987**: Cadwell, Repetitive TMS (rTMS)
- **1996**: Pascual-Leone, et al., Repetitive TMS for depression
- **2007**: Neuronetics Phase III trial of rTMS for Medication-resistant depression
- **2008**: FDA clearance
- **2012**: NHIC Medicare Approval (MA, NH, VT and RI)
- **2013-4**: Coverage from Most insurers, Brainsway Clearance

**PLEASE DO NOT COPY**
# Devices and Financial Models

<table>
<thead>
<tr>
<th>Manuf.</th>
<th>Neuronetics</th>
<th>Brainsway</th>
<th>Magstim</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA cleared for depression:</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Purchase model</td>
<td>Mixed (Purchase + starstim)</td>
<td>Rental</td>
<td>Purchase</td>
</tr>
</tbody>
</table>

*PLEASE DO NOT COPY*
Initial Evaluation

- Referral from treating psychiatrist
- Neurology
  - Contraindications
  - Effect of medication on TMS
- Psychiatry
  - Caution if: Psychotic depression, bipolar, personality disorders
  - At least one adequate trial of antidepressant medication
How we saw it...

1. Patient referred by psychiatrist
2. Neuro + Psych Evaluation
3. Consider ECT
4. Induction
5. Responder
   - Y: Maintenance vs. reinduction
   - N: Go back to consider ECT

Initiate? (Decide whether to proceed with treatment or not)
How Lean Saw it...
Consent

- Local ethical/safety committee (not IRB!)
- Discussion of on-label vs. off-label treatment
- Explanation of side-effects
  - Seizure
  - Headache
  - Tinnitus/hearing loss
## BIDMC Treatment Protocol

<table>
<thead>
<tr>
<th>Site</th>
<th>Hemisphere</th>
<th>Frequency</th>
<th>Duration</th>
<th>Wait time</th>
<th>Repetitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuronetics</td>
<td>Left DLPFC (120% MT)</td>
<td>10 Hz</td>
<td>4 seconds</td>
<td>26 seconds</td>
<td>75 (3000 pulses)</td>
</tr>
<tr>
<td>DLPFC</td>
<td>Right (110% MT)</td>
<td>1 Hz</td>
<td>1600 seconds</td>
<td>N/A</td>
<td>1 (1600 pulses)</td>
</tr>
<tr>
<td>Brainsway</td>
<td>Left DLPFC (120% MT)</td>
<td>18 Hz</td>
<td>2 seconds</td>
<td>20 seconds</td>
<td>55 (1980 pulses)</td>
</tr>
<tr>
<td>DLPFC (5.5 cm)</td>
<td>Left DLPFC (110% MT)</td>
<td>20 Hz</td>
<td>2 seconds</td>
<td>28 seconds</td>
<td>40 (1600 pulses)</td>
</tr>
</tbody>
</table>
Initiation Phase

• Treatments daily (excluding weekends)
• Mood assessed weekly
• Minimum 2 weeks
• Maximum 6 weeks
• Taper?
Alternatives being investigated

• Choosing protocol on clinical parameters (anxiety, risk of mania/sz)
• Using MRI guidance for targeting
• Using anatomical MRI to help with intensity of stimulation (particularly in elderly)
• Others: mood induction, more than one session/day
Assessment tools

• Beck, Hamilton, Visual-analogue scale
• Target symptoms
• Clinician evaluation of patient
• Other sources of information (e.g. family, referring psychiatrist)
• Side effects questionnaire

• Weekly meeting of all staff to discuss progress
Overall Results from Clinical Program

BDI score (mean +/- SD)

Time

Baseline   Week 1  Week 2  Week 3  Week 4

N=170    n=165     n=146     n=123    n=71
Maintenance Phase

• Minimal evidence (absence of evidence, not evidence of absence)

• Relapse prevention
  – Start with weekly treatment
  – Gradually space out sessions

• “Watchful Waiting”/reinduction
  – Patient presents when feeling worse
### Maintenance:

| Initial Course | Maint 1 week | Q 2 weeks | Q 3-4 weeks |

### Reinduction:

| Initial Course | Taper 2 to 1x/wk | Stop | if relapse 2-3/wk | Taper |
Cost

- Medicare coverage in 4 of 12 districts
- Insurance Coverage
- $400-$500 initial session with MT, then $350-$400 non-MT session
- How frequently to measure MT?
- Helping with reimbursement, creating fund for low income patients
Reimbursement for TMS

• Currently its approved by most payers (Medicare, BC/BS, Tufts)
• Each carrier has slightly different criteria
• New devices are coming on line
Future Developments

• Targeting (use of structural MRI’s and fMRI’s for intensity and targeting?)
• Interaction of rTMS with medications
• Predictors of response
• Monitoring response biologically
• Other indications (pain, seizures, stroke recovery, Parkinson’s disease)
Questions?