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
Effect on Continuous Outcomes
MADRS and HAMD24 Rating Scales

MADRS Total Score
Baseline to Endpoint Change

Baseline | Week 2 | Week 4 | Week 6
---|---|---|---
P = .057 | P = .058 | P = .038 | P = .052

HAMD24 Total Score
Baseline to Endpoint Change

Baseline | Week 2 | Week 4 | Week 6
---|---|---|---
P = .051 | * | * |

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

<table>
<thead>
<tr>
<th>Manuf.</th>
<th>Neuronetics</th>
<th>Brainsway</th>
<th>Magstim</th>
<th>Magventure</th>
<th>Nextstim</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA cleared for depression:</td>
<td>Yes</td>
<td>Yes</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>
<td>Purchase</td>
<td>Mixed (purchase + tracker)</td>
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</tbody>
</table>
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. initiate?
   - N: Consider ECT
   - Y: Induction
4. Responder
   - N: Induction
   - Y: Maintenance vs. reinduction
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>
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</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)

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
- “Continuation” vs. “Maintenance”
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 across USA
- 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
Percent Improvement (NIIBS – Sham)

- Motor stroke tDCS
- Motor stroke rTMS
- Parkinsons
- Pain tDCS
- Pain rTMS
- Tinnitus
- Nontargeted
- Bi Anodal
- Cathodal
- Ipsil
- Contra
- Non M1
- M1
- Prefrontal
- Targ
Model for therapy

Expertise in brain stimulation

Expertise in the disorder

Expertise in brain stimulation

Expertise in the disorder

Team-based approach

Clinician-based approach

Clinical Standards Committee of Clinical TMS Society
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?