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

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


Anthony Barker
Single Pulse TMS

Cadwell
Repetitive TMS (rTMS)

Pascual-Leone, et. al.
George, et. al.
rTMS for depression

Neuronetics Phase III trial of rTMS for Medication-resistant depression

FDA clearance

NHIC Medicare Approval (MA,NH,VT and RI)

Coverage from Most insurers, Brainsway Clearance

Brainsway Clearance

Medicare Approval (MA,NH,VT and RI)

Coverage from Most insurers, Brainsway Clearance
TMS Timeline 2014-present

- 2015: Magstim 510k approval
- 2016: Nextstim MRI-based system
- 2018: OCD Approval
- 2019: SAINT
- 2020:

Three-D trial iTBS vs 10hz
# 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>
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</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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</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
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 symptom profile (anxiosomatic vs. dysphoric Siddiqi et. al)
• Using MRI guidance for targeting
• SAINT
• Pharmacology (d-cycloserine)
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

Time
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
Model for therapy

- Expertise in brain stimulation
- Expertise in the disorder

Team-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?