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
---|---|---|---
Change from Baseline

-6 | -5 | -4 | -3

P = .057 P = .058
P = .038 P = .052

HAMD24 Total Score
Baseline to Endpoint Change

Baseline | Week 2 | Week 4 | Week 6
---|---|---|---
Change from Baseline

-7 | -6 | -5 | -4

P = .051

* P < 0.05, LOCF analysis

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


Anthony Barker
Single Pulse TMS

Cadwell
Repetitive TMS (rTMS)

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

FDA clearance

Neuronetics Phase III trial of rTMS for Medication-resistant depression

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

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>
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<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
How we saw it...

- Patient referred by psychiatrist
- Neuro + Psych Evaluation
  - initiate?
  - Consider ECT
  - Induction
  - Responder
    - Y: Maintenance vs. reinduction
    - N: Consider ECT

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
<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</td>
<td>10 Hz</td>
<td>4 seconds</td>
<td>26 seconds</td>
<td>75 (3000 pulses)</td>
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<tr>
<td></td>
<td>(120% MT)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>DLPFC</td>
<td>Right</td>
<td>1 Hz</td>
<td>1600 seconds</td>
<td>N/A</td>
<td>1 (1600 pulses)</td>
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<tr>
<td></td>
<td>(110% MT)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brainsway</td>
<td>Left DLPFC</td>
<td>18 Hz</td>
<td>2 seconds</td>
<td>20 seconds</td>
<td>55 (1980 pulses)</td>
</tr>
<tr>
<td></td>
<td>(120% MT)</td>
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</tr>
<tr>
<td>DLPFC (5.5 cm)</td>
<td>Left DLPFC</td>
<td>20 Hz</td>
<td>2 seconds</td>
<td>28 seconds</td>
<td>40 (1600 pulses)</td>
</tr>
<tr>
<td></td>
<td>(110% MT)</td>
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</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)

<table>
<thead>
<tr>
<th>Time</th>
<th>N=170</th>
<th>n=165</th>
<th>n=146</th>
<th>n=123</th>
<th>n=71</th>
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<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Week 1</td>
<td></td>
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<td>Week 2</td>
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<td>Week 3</td>
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<tr>
<td>Week 4</td>
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</table>
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

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?