Setting up aTMS Clinic

Daniel Press, M.D.
Associate Professor in Neurology,
Harvard Medical School and
Beth Israel Deaconess Medical Center
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]
TMS Timeline


Anthony Barker
Single Pulse TMS

1984

Cadwell
Repetitive TMS
(rTMS)

1987

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

1996

FDA
clearance

2007

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

2008

Coverage from
Most insurers,
Brainsway
Clearance

2012

Neuronetics Phase III
trial of rTMS for
Medication-resistant
depression

2013-4

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## 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>
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<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?
    - N (Consider ECT)
    - Y (Induction)
      - N (Responder)
      - Y (Maintenance vs. reinduction)
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>
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<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>
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<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</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
Model for therapy

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?