Electroconvulsive Therapy for Behavioural and Psychological Symptoms of Dementia

A Prospective Study at Ontario Shores OS Mental Health Conference 2019
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• Dementia involves cognitive decline that impedes independent functioning, yet the non-cognitive features of this disorder are most closely affiliated with quality of life.

• These “Behavioural and Psychological Symptoms of Dementia” (BPSD) encompass abnormalities in psychomotor activity, behaviour, affect, and reality testing that affect fifty to ninety percent of those affected.

• Agitation and aggression are associated with increased risk of institutionalization, psychotropic medication use, caregiver burden, and mortality.

• Safe and effective treatments for BPSD are lacking. Antipsychotics have the most evidence of benefit in BPSD. However, their use is offset by risks that have led regulatory authorities in Canada to issue serious warnings about their use for this indication.
• Research has established the safety and efficacy of electroconvulsive therapy (ECT) in elderly patients with depression, mania, and schizophrenia. Clinical experience suggests that ECT is a valuable treatment option for BPSD after non-pharmacologic and pharmacologic options have been exhausted. To our knowledge, only two retrospective case series and a handful of case reports have been published.

• The benefit of prospective data is that it enables the planning of outcome measures beforehand rather than attempting to reconstruct them from clinical notes.
The Progression of Alzheimer’s Disease

Years

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6 6.5 7 7.5 8 8.5 9

MMSE score

0 5 10 15 20 25 30

Cognitive symptoms
Loss of ADL
Behavioral problems
Nursing home placement
Death

Early diagnosis
Mild-moderate
Severe

PSYCHIATRY INVOLVEMENT

Ashford et al., 1995
STUDY DESIGN

- This is a prospective, open-label, observational study of the efficacy and safety of ECT for BPSD. There is no control or comparison group.
- Subjects will be compared on outcome measures pre- and post-ECT including scoring on the Neuropsychiatric Inventory and Pittsburgh Agitation Scale.

Sample and recruitment:
- Patients with dementia (as per DSM-IV-TR definition) and BPSD will be recruited from the Geriatric Psychiatry inpatient units at Ontario Shores.
INCLUSION CRITERIA

- **Severe BPSD:** BPSD of sufficient severity that the safety of the patient or others precludes the possibility of discharge to any non-hospital environment.

- **Failed “standard of care for BPSD”:**
  - Non-pharmacological treatments are of insufficient benefit to allow discharge to any non-hospital environment, **and**
  - Pharmacological treatments are of insufficient benefit to allow discharge to any non-hospital environment (2 failed trials of psychotropic medications at adequate dose/duration or stopped due to adverse effects)

- Provide informed consent

- Only patients meeting criteria will be identified as potential study participants to the PI by the attending psychiatrist.
BASELINE DATA

- Date of admission
- Capacity to consent to ECT
- Capacity to consent to study
- Relationship to SDM (if applicable)
- Gender
- Month and Year of Birth
- Ethnicity
- Educational attainment
- Occupational attainment
- Marital status
- Primary caregiver
- Handedness
- Residence
- Psychiatric Diagnosis – Past/ Present

- Dementia type(s) and Severity, Onset
- Family neuropsychiatric history
- Labwork and Imaging
- Medical co-morbidities listed and rated with the Cumulative Illness Rating Scale
- Vascular risk factors
- Current medications
- Previous medications for BPSD, durations, doses
- Previous ECT: Dates, indications, unilateral/bilateral, therapeutic response, adverse effects

Ontario Shores
Centre for Mental Health Sciences
Neuropsychiatric Inventory (NPI)

The NPI assesses behavioural domains commonly affected in dementia on 12 subscales. This will be completed 7 days pre-ECT, every 2 weeks during treatment, and post-ECT (day 0, day 7, and day 14 after treatment termination). It can be completed with information from the patient and the chart along with input from the patient’s attending physician and clinical team. It takes 15-30 minutes to administer.

Specific hypothesis:

NPI total scores will improve post-ECT with a large effect size (Cohen’s $d = 0.8$)

Analysis: Paired t-test of NPI total pre- vs. post-ECT (7 days pre-treatment vs. post-treatment day 7)

Power: A priori power analysis
C. **Agitation/Aggression**

Does the patient have periods when he/she refuses to cooperate or won’t let people help him/her? Is he/she hard to handle?

NO (If no, proceed to next screening question). YES (If yes, proceed to subquestions).

If the screening question is confirmed, determine the frequency and severity of the agitation.

**Frequency:**
1. Occasionally - less than once per week.
2. Often - about once per week.
3. Frequently - several times per week but less than daily.
4. Very frequently - once or more per day.

**Severity:**
1. Mild - behavior is disruptive but can be managed with redirection or reassurance.
2. Moderate - behaviors are disruptive and difficult to redirect or control.
3. Marked - agitation is very disruptive and a major source of difficulty; there may be a threat of personal harm. Medications are often required.

**Distress:**
How emotionally distressing do you find this behavior?
0. Not at all
1. Minimally
2. Mildly
3. Moderately
4. Severely
5. Very severely or extremely
SECONDARY OUTCOME MEASURE - PAS

- Pittsburgh Agitation Scale (PAS)

  The PAS assesses agitation in patients with dementia. It is completed by research personnel during direct observation of the patient. The PAS will be completed pre-ECT, every two weeks during treatment, and post-ECT (post-treatment day 0, day 7, day 14). Administration time is less than one minute.

- Specific hypothesis:
- PAS scores will decrease with ECT.

- Analysis: Repeated measures ANOVA powered to detect large effect size.
### Behavior Groups

**Aberrant Vocalization**
(repetitive requests or complaints, nonverbal vocalizations, e.g., moaning, screaming)

**Motor Agitation**
(pacing, wandering, moving in chair, picking at objects, disrobing, banging on chair, taking others’ possessions. Rate “intrusiveness” by normal social standards, not by effect on other patients in milieu. If “intrusive” or “disruptive” due to noise, rate under “Vocalization.”)

### Intensity During Rating Period

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<tr>
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<tbody>
<tr>
<td>0. Not present</td>
<td>1. Low volume, not disruptive in milieu, including crying</td>
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<tr>
<td></td>
<td>2. Louder than conversational, mildly disruptive, redirectable</td>
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<td></td>
<td>3. Loud, disruptive, difficult to redirect</td>
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<td></td>
<td>4. Extremely loud screaming or yelling, highly disruptive, unable to redirect</td>
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<tbody>
<tr>
<td>0. Not present</td>
<td>1. Pacing or moving about in chair at normal rate (appears to be seeking comfort, looking for spouse, purposeless movements)</td>
</tr>
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<td></td>
<td>2. Increased rate of movements, mildly intrusive, easily redirectable</td>
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<tr>
<td></td>
<td>3. Rapid movements, moderately intrusive or disruptive, difficult to redirect</td>
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<tr>
<td></td>
<td>4. Intense movements extremely intrusive or disruptive, not redirectable verbally</td>
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**SECONDARY OUTCOME MEASURE**

- **Cornell Depression Scale**
- The Cornell Depression Scale measures depression in patients with dementia.
- Information is elicited with two semi-structured interviews; an interview with the patient and an interview with an informant (attending psychiatrist/clinical team member). This scale will be completed 7 days pre-ECT, every 2 weeks during treatment, and post-ECT (day 0, day 14). It takes approximately 20 minutes (total) to administer.

- **Specific hypothesis:**
  - *Cornell-Brown Depression scores will decrease with ECT.*
- **Analysis:** Repeated measures ANOVA powered to detect large effect size (see power analysis for #2).
SECONDARY OUTCOME MEASURE

- Cornell-Brown Quality of Life Scale
  - The Cornell-Brown Quality of Life Scale measures quality of life in patients with dementia. This will be measured 7 days pre- vs. post-ECT (day 7). It can be completed with information from the chart and with input from the attending psychiatrist in under 10 minutes.

- Specific hypothesis:
  - Cornell-Brown Quality of Life scores will increase with ECT.
  - Analysis: Paired t-test of total score pre- vs. post-ECT.
• The Columbia ECT subjective side effects schedule
  • This 32 item scale will be administered at baseline (7 days pre-ECT) and in the afternoon following the 1<sup>st</sup>, 4<sup>th</sup> and 8<sup>th</sup> treatments and in the week following the course of ECT (post-treatment day 7).
  • Subjective side-effect reports will be analyzed separately for their occurrence and severity. In addition to analyses on individual side-effect items, three subcategory groupings: physical, cognitive and mood will also be analyzed.
• Specific hypothesis:
• ECT side effect scale total scores will not significantly change over treatment.
• Analysis: Repeated measures ANOVA powered to detect large effect size.
SECONDARY SAFETY MEASURE

- The Folstein Mini-Mental Status Examination (MMSE) and the Functional Assessment Staging of Alzheimer’s Disease (FAST)

- The FAST scale is a functional scale designed to evaluate patient at the moderate to severe stages of dementia when the MMSE no longer can reflect changes in a meaningful clinical way. This information can be collected from the chart and from the attending psychiatrist. The MMSE and/or the FAST (depending on what is most appropriate for a given patient) will be collected 7 days pre-ECT, every two weeks during ECT, and post-ECT (day 0, day 7, day 14, day 21).

- **Specific hypothesis:**

- Cognition or functional status will not significantly and persistently worsen in association with treatment.

- Analysis: Repeated measures ANOVA powered to detect large effect size.
Preliminary Results
## Baseline demographics

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<tr>
<td><strong>Age mean</strong></td>
<td>72.6</td>
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<tr>
<td><strong>Age range</strong></td>
<td>62-88</td>
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<tr>
<td><strong>Male gender %</strong></td>
<td>56.2</td>
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<tr>
<td><strong>History of depression %</strong></td>
<td>38.4</td>
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<tr>
<td><strong>Married %</strong></td>
<td>30.7</td>
</tr>
<tr>
<td><strong>NPI mean ( SD)</strong></td>
<td>63.09 (25.4)</td>
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<tr>
<td><strong>Baseline MMSE ( Mean)</strong></td>
<td>5.2</td>
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## Dementia severity and type

<table>
<thead>
<tr>
<th></th>
<th>Alzheimer’s disease</th>
<th>Mixed</th>
<th>Vascular dementia</th>
<th>Fronto-temporal</th>
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<tbody>
<tr>
<td>FAST = 5</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>FAST=6</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>FAST=7</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
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Paired T test: Comparison of scores before and after ECT

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<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Final week</th>
<th>P</th>
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<tbody>
<tr>
<td>NPI</td>
<td>63</td>
<td>34.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cornell depression</td>
<td>15.3</td>
<td>6.6</td>
<td>0.002</td>
</tr>
<tr>
<td>Pittsburg agitation</td>
<td>6.75</td>
<td>3</td>
<td>0.040</td>
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<tr>
<td>MMSE</td>
<td>5.2</td>
<td>6.7</td>
<td>0.1</td>
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Discussion

- Depression scores improved alongside improvement in NPI scores
- Cognitive measures didn’t worsen
- Agitation improved
- UBC data
- Role of Maintenance ECT in this population