AHCA/NCAL Quality Initiative for Assisted Living Webinar Series: Safely Reducing the Off-Label Use of Antipsychotics

Risks of Antipsychotics use In Dementia

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Dementia

• A patient has cognitive loss in two or more domains, such as memory, language, calculations, orientation, and judgment. In addition, the loss must be of sufficient severity to cause social or occupational disability.

Amyvid – Alzheimer’s
The ultimate clinical value of florbetapir imaging awaits further studies to assess the role, if any, that it plays in providing prognostic and predictive information.

Antipsychotics use in Dementia

• “these drugs are not approved for the treatment of behavioural symptoms in elderly patients with dementia.”

• *After 2002, an association between stroke and antipsychotic use in Dementia was reported in clinical trials and large database studies.*
FDA Advisory

• Treatment with Atypical Antipsychotic drugs may cause a nearly 2-fold increase in the rate of death in elderly dementia patients, warned the Food and Drug Administration (FDA).

FDA Advisory

• Analyses of 17 placebo-controlled studies of four drugs—olanzapine, aripiprazole, risperidone, and quetiapine.

• This revealed a 4.5% mortality rate among elderly patients with dementia who had been treated for behavioral symptoms with these second-generation antipsychotics compared with a 2.6% mortality rate among patients treated with a placebo.
FDA Advisory

• The studies were, on average, 10 weeks in duration and enrolled a combined 5106 patients with dementia.

• The causes of death varied, although most were related to cardiovascular problems, including heart failure and sudden death or infections such as pneumonia.

FDA Advisory

• The exact mechanism for the increased risk has not been identified.
Clinical Studies

Exposure to antipsychotics and risk of stroke: self controlled case series study

- Both typical and atypical antipsychotic drugs are associated with an increased risk of stroke and this association is unlikely to be caused by confounding
- The risk of stroke in patients receiving antipsychotics seems to be greater in those with dementia than those without dementia.

Douglas et al. BMJ 2008;337:a1227
### Exposure to antipsychotics and risk of stroke: self controlled case series study

<table>
<thead>
<tr>
<th>Time after Treatment</th>
<th>All patients (n=6790)</th>
<th>Typical-only</th>
<th>Atypical only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposed v unexposed periods</td>
<td>1.73 (1.60 to 1.87)</td>
<td>1.69 (1.55 to 1.84)</td>
</tr>
<tr>
<td></td>
<td>Days after treatment: 1-35</td>
<td>1.73 (1.58 to 1.91)</td>
<td>1.69 (1.52 to 1.89)</td>
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<tr>
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<td>36-70</td>
<td>1.66 (1.44 to 1.90)</td>
<td>1.65 (1.41 to 1.88)</td>
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<tr>
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<td>71-105</td>
<td>1.61 (1.37 to 1.90)</td>
<td>1.57 (1.32 to 1.87)</td>
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<tr>
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<td>106-140</td>
<td>1.23 (1.02 to 1.51)</td>
<td>1.27 (1.03 to 1.56)</td>
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<tr>
<td></td>
<td>141-175</td>
<td>1.06 (0.84 to 1.33)</td>
<td>1.06 (0.83 to 1.35)</td>
</tr>
</tbody>
</table>

### Atypical antipsychotic drugs and risk of ischemic stroke: population based retrospective cohort study

- **Objective** To compare the incidence of admissions to hospital for stroke among older adults with dementia receiving atypical or typical antipsychotics.
- **Design** Population based retrospective cohort study.
- **Setting** Ontario, Canada.
- **Patients** 32 710 older adults (≤ 65 years) with dementia (17 845 dispensed an atypical antipsychotic and 14 865 dispensed a typical antipsychotic).
- **Main outcome measures** Admission to hospital with the most responsible diagnosis (single most important condition responsible for the patient's admission) of ischemic stroke. Observation of patients until they were either admitted to hospital with ischemic stroke, stopped taking antipsychotics, died, or the study ended.

Atypical antipsychotic drugs and risk of ischemic stroke: population based retrospective cohort study

• **Results** After adjustment for potential confounders, participants receiving atypical antipsychotics showed no significant increase in risk of ischemic stroke compared with those receiving typical antipsychotics (adjusted hazard ratio 1.01, 95% confidence interval 0.81 to 1.26).

• **Conclusion** - Older adults with dementia who take atypical antipsychotics have a similar risk of ischemic stroke to those taking typical antipsychotics.


Atypical antipsychotics for aggression and psychosis in Alzheimer’s disease (Review) - 2012 - The Cochrane Collaboration

• Evidence suggests that risperidone and olanzapine are useful in reducing aggression and risperidone reduces psychosis, but both are associated with serious adverse cerebrovascular events and extra-pyramidal symptoms.

• Despite the modest efficacy, the significant increase in adverse events confirms that neither risperidone nor olanzapine should be used routinely to treat dementia patients with aggression or psychosis unless there is marked risk or severe distress.

Cochrane Database Syst Rev. 2006 Jan 25;
Antipsychotic medications that may make people drowsy or quiet can be helpful in certain limited circumstances, such as
- when treating a diagnosed psychotic condition (like schizophrenia) or
- to temporarily alleviate a situation (such as when someone is dangerous to him or herself or others).

USE

- CMS hopes to reduce unnecessary antipsychotic medication use in nursing homes and eventually other care settings as well.
- Antipsychotic medications are the initial focus of the partnership – CMS.
- According to CMS’s Quality Measure/Quality Indicator report, between July and September 2010, **39.4% of nursing home residents** nationwide who had cognitive impairment and behavioral issues but no diagnosis of psychosis or related conditions received antipsychotic medications.
Provider, Prescriber, and Consumer Training

Average Use of Antipsychotic Medications on Long-Term Care Residents

- In August, 2012, an average of 21.1% of California’s LTC residents received an antipsychotic medication.
- Goal: Initial 15% Reduction By December, 2012
- Goal: Total of 30% Reduction By June, 2013
- National Average: 23.4% - December, 2012
- California Average: 21.1% - December, 2012
- California Partnership Goal: By June, 2013, no more than 15% of LTC residents will receive an antipsychotic medication.
International Efforts

Desired Goal

- All people with dementia who are receiving antipsychotic drugs should undergo a clinical review to ensure that their care is compliant with current best practice and guidelines, that alternatives to their prescription have been considered and a shared decision has been agreed regarding their future care.
Non-pharmacological Approaches in Dementia Care

Dr. Anna Fisher
Prevalence of Challenging Behaviors

- 80% of people with dementia residing in care environments experience behavioral and psychological symptoms of dementia:
  - Agitation (75%)
  - Wandering (60%)
  - Depression (50%)
  - Psychosis (delusions, hallucinations, distorted perceptions of reality) (30%)
  - Anxiety (25%-40%)

Source: Lawlor, 2002

Interpretation of Behaviors

- Behavior is a form of communication
- How are we responding?
Interpretation of Behaviors

- **Unmet needs**
  - Repetitive vocalizations may provide auditory stimulation

- **Learning and behavioral**
  - Inadvertent reinforced behaviors such as learning to get attention by screaming

- **Environmental**
  - Mismatch between person’s environment and ability to cope with the situation (e.g., too much noise)

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Psychosocial Needs

- Cognitive stimulation
- Express themselves
- Sense of belonging and purpose
- Need a feeling of self-worth

~ Many problems associated with dementia can be traced to inability to meet these needs ~
Non-pharmacological Approaches

- As the dementia progresses, people become less able to instigate meaningful activities
- This does not mean that they do not want to engage in activities, only that they can no longer start them themselves
- Engage in creative and purposeful activity

Source: Dodd, 2010; Kerr, 2007

Non-pharmacological Approaches

- Therapeutic ambient music
  - Memory stirring activity
  - Keep sessions short as the residents can tire quickly
- Aromatherapy
  - Can relieve anxiety and emotional disturbances
- Pet therapy
  - Tactile stimulation
  - Groom the animal, toss a ball, go for a short walk
Non-pharmacological Approaches

- Art therapy
  - Allows communication in a non-verbal way
  - Expresses thoughts
  - Improved concentration
  - Can improve mood, promote relaxation
  - Closer relationships

Non-pharmacological Approaches

- Greeters: breakfast, lunch, dinner
- Setting tables
- Shredding paper
- Fold and hang clothes
- Roll yarn
- Sort
Montessori Method

- “Montessori is one approach that maximizes activity engagement for any one of the non-pharmacological approaches.”
- Dr. Cameron Camp, research scientist
  - Conducted studies for NIH on Montessori and dementia
  - Began developing uses for the dementia community approximately 15 years ago

Source: Dr. Cameron Camp, 2013

Montessori Principles

- Use real life materials: can be used on any non-pharmacological approach
- Progress from simple to complex
- Activities are structured so that they are in clear steps with visual cues to help ensure success
Motor Skills

Pincer Grip

Transfer Activity

With Tongs
Hand-Eye Coordination Activities

- Color tablets
- Tearing paper
- Pink Tower
- Seriation activities
  - Measuring cups
  - Spoons
- Folding cloths
- Sorting
- Knobbed cylinders

Non-pharmacological Approaches

- Effects are dose dependent
- The effectiveness of each technique or intervention will depend on the response of the person.
- To have strongest effect:
  - Provide programming throughout the day
  - Instead of a one-time event
- Purposeful activities are more powerful
Best Practice Recommendations

- Customize the activity for each individual
- Addresses the abilities of every person
- Improved ability to perform a task
- Reduced problematic behaviors
- Everyone is capable of something