The ethics of prescribing anti-psychotics in dementia

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Summay

- Distress
- Purpose
- Benefit and risk
- Double effect
- Appropriate care
Conflicting aims in dementia care

• Better palliative care of dementia aims to improve the quality of care of dementia and to alleviate distress.
• Pain needs to be identified and treated appropriately.
• But not all pain is physical, much, or perhaps more, is mental pain.
• Distress is pain: pain is distress.
• Alleviation of distress is a central issue on dementia care and will be central part of the response to demands for better palliative care of dementia.
Dementia

- 700,000 people in the UK currently have dementia; this number is set to double by 2038

- 1/3 of people with dementia live in a care home and 2/3 of all people living in care homes have a form of dementia

- Care homes are often poorly resourced (not enough staff, high staff turnover, not enough support or training)
The problem

• But Dementia care is often characterised by institutional care, institutionalisation and recourse to
• The use of anti-psychotic and sedative medicines to reduce distress, are seen as bad medicine which many would seek to ban.
• These drugs are known to be harmful.
• But may also effectively reduce severe distress
Principles of palliative care

• Palliative care is about the reduction of distress in those with terminal illnesses and an aim of supporting people to live well until they die.

• Palliative care recognises the importance of pain, but also recognises the concept of total pain;
  – Pain that is physical, mental and existential.
  – Physical pain is common in dementia but
  – Mental pain may be even commoner.
Distress in dementia

- May thus be due to
- Physical pain
- Mental pain
- Existential pain.
Key modalities for reducing distress in dementia are thus:

- Antidepressants
- Appropriate analgesia
- Appropriate use of anti-psychotics for severe distress
- Better care
- Person centred care
- Good spiritual care
- General good medical care and appropriate treatment of concurrent illness
Political imperatives

• Capacity
• Good dementias diagnosis and care for all who suffer it
• Reducing use of anti-psychotics
• Existing within our local means
<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
<tr>
<td>Apathy</td>
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<td>Hallucinations</td>
<td>12%</td>
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<tr>
<td>Euphoria</td>
<td>18%</td>
<td>8%</td>
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Behavioural and Psychological Symptoms in Dementia

BPSD can be problematic because they:

• Place the patient or others at risk of harm
• Distress the patient or their family
• Prevent basic care from being provided (washing, eating, drinking, dressing)
What causes BPSD?

- Thirst/hunger
- Boredom
- Pain
- Physical health problems (e.g., infection, respiratory disease, heart failure)
- Not being treated with dignity and respect
- Lack of social interaction
- Depression
- Psychosis
- Distress
How should we treat BPSD?

• By trying to understand the context in which the behaviour occurs and targeting the most likely cause
  – Non-pharmacological options include changes to the environment or staff approach, provision of activities, pet therapy etc
  – Pharmacological options include analgesics, antibiotics, inhalers, antidepressants ..........and antipsychotics
Are antipsychotics effective?

Schneider et al. NEJM Oct 16 2006
Are antipsychotics effective?

Clear separation from placebo on:
- Neuropsychiatric inventory
- BPRS total score
- BPRS hostility/suspiciousness
- BPRS agitation
A Randomised, Blinded, Placebo-Controlled Trial in Dementia Patients Continuing or Stopping Neuroleptics (The DART-AD Trial)

Participants: Patients currently prescribed the neuroleptics thioridazine, chlorpromazine, haloperidol trifluoperazine or risperidone for behavioural or psychiatric disturbance in dementia for at least 3 mo.

Interventions: Continue neuroleptic treatment for 12 mo or switch to an identical placebo.

51 per arm  No difference in outcomes on cognition or BPSD

Conclusions

For most patients with AD, withdrawal of neuroleptics had no overall detrimental effect on functional and cognitive status. Neuroleptics may have some value in the maintenance treatment of more severe neuropsychiatric symptoms, but this benefit must be weighed against the side effects of therapy.

Ballard et al, PLoS Medicine

Long term follow up

Interpretation There is an increased long-term risk of mortality in patients with AD who are prescribed antipsychotic medication; these results further highlight the need to seek less harmful alternatives for the long-term treatment of neuropsychiatric symptoms in these patients.

Ballard et al Lancet Neurology 2009 8 151-7
If they work, why do we worry?

If 1,000 people with BPSD receive an antipsychotic for 12/52, there would be:

- an additional 91–200 patients with behaviour disturbance showing clinically significant improvement
- an additional 10 deaths;
- an additional 18 CVAEs,
- an additional 58–94 patients with gait disturbance.

• For the UK
  – 1,620 severe CVAEs
  – 1,800 deaths per year
### Adverse outcomes

<table>
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<tr>
<th>Ballard &amp; Howard 2006 Nat Rev Neurosci</th>
<th>Adverse Outcomes</th>
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<tbody>
<tr>
<td>Risperidone</td>
<td>Stroke/CVAE</td>
<td>3-4</td>
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<tr>
<td>Atypical Antipsychotics</td>
<td>mortality</td>
<td>1.5-1.8</td>
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<tr>
<td>Atypical Antipsychotics</td>
<td>Accelerated Cognitive Decline</td>
<td>1.5-4</td>
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<tr>
<td>Risperidone (1-2mg)</td>
<td>Ankle Oedema</td>
<td>2.4-4.3</td>
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<tr>
<td>Risperidone (1-2mg)</td>
<td>Chest Infections</td>
<td>2.9</td>
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<td>Risperidone (1-2mg)</td>
<td>Extra-Pyramidal symptoms</td>
<td>1.8-3.4</td>
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<tr>
<td>Risperidone (1-2mg)</td>
<td>Sedation</td>
<td>2.4-4.5</td>
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<tr>
<td>Atypical Antipsychotics</td>
<td>Falls</td>
<td>Unresolved</td>
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NICE recommendations

- Pharmacological intervention should only be used if there is severe distress or the patient poses an immediate risk of harm to themselves/others

- Prior to a pharmacological intervention, should consider:
  - Aromatherapy, stimulation, therapeutic use of music/dancing, animal assisted therapy, massage
  - Cognitive stimulation/behaviour therapy

- Antipsychotic drugs should not be prescribed in mild-to-moderate BPSD due to the possible increased risk of cerebrovascular AEs & death
Recommendation to reduce antipsychotic use is widely supported

Early diagnosis and intervention in primary care

Dementia in the General Hospital

Dementia in Care homes

Reduction of antipsychotics

Support for carers

Quality outcomes for people with dementia: building on the work of the National Dementia Strategy
Target is \( \frac{2}{3} \) reduction in antipsychotic prescribing within the next year.
BUT!!!

• Is BPSD the same as distress?
• Or is it a way of expressing distress?
• That does not display all forms of distress?

• And can the treatment of BPSD be studied as a single entity?
Distress in dementia

- May be due to
  - Physical pain
  - Mental pain
  - Existential pain.
Distress a central concept

• Total Pain
• Dame Cicely Saunders
• Palliative care is about prognosis but also about
  – Palliation of distress and
  – Living well with dementia
Who attends to distress in dementia?

- In BBG 45 hospice beds (admitting 1-2 PWD /yr
- 4000 nursing and residential home beds
- 500 acute medical beds
- 50 NHSCC for dementia beds which deal with long term disability, and substantial distress and challenging behaviour with 30% dying each year
- Therefore mostly done by General Practice and Old Age Psychiatry with a bit of advice from palliative care
Palliative care of dementia

• Growing awareness
• Poor understanding of
  – When it is needed
  – What it is
  – Who does it
  – How to support dying at home and in homes
First do no harm

- There are some issues with this in palliative care, chemotherapy, treatments with side effects.

- In dementia we cannot avoid potentially harmful treatments which will help that person.

- While we must never intend to harm, we must intend to treat and reduce suffering when we can, but we must also accept that almost everything we do may be harmful.

- The avoidance of harming at all costs can set our most vulnerable patients on a course of suffering.
Hippocratic oath

- I will **prescribe** regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.

- In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill doing.

- To please no one will I prescribe a deadly drug, nor give advice which may cause his death.
Double effect

• Accept risk of harm for a clear benefit
• Classic example = opiates in pain, although in appropriate doses these may not be associated with shortening life
• Better examples =
  – Chemotherapy
  – Antipsychotics in dementia; known to be harmful but may be the only way to alleviate severe distress (UK Parliament)
Burdensomeness

- A crucial concept
- Helps us to be sure we act reasonably
Appropriate treatments

• Treatments given according to the cause of distress

• Diligence and care to identify the cause of distress
Leading to good outcomes

- Living well with dementia
Risk taking for benefit

improving lives

Oxleas NHS Foundation Trust
Severe distress, a better concept?

- Severe distress in those who cannot understand and cannot choose seems to us to be a stronger concept in terms of palliation than behaviour disturbance.
- It is as close as you can get to a “pure” problem.
- It enables a philosophical note to be made by those treating and caring for the patient that they must alleviate distress.
- It will still be the case that distress may be allowed as distress some of the time may be well worth it for the better periods of relief.
Signs and symptoms of distress in dementia

- Anger/ Frustration
- Aggression/Agitation
- Fear/ Anxiety
- Tearfulness/ misery
- Pain when still
- Discomfort on moving
- Restlessness
- Insomnia
- Calling out/ vocalisation
- Wandering
- Autonomic arousal, sweating, tachycardia, hypertension

To what extent are these symptoms different between mental and physical causes of distress/pain?

Is all mental distress merely a form of pain?

Does all pain therefore require an analgesic?
The Abbey Pain Scale
for the measurement of pain in people who cannot verbalise

- Vocalising  eg whimpering, groaning, crying
- Facial expression  eg looking tense grimacing, looking frightened
- Change in Body language  eg fidgeting, rocking, guarding part of body, withdrawn
- Behavioural change  eg increased confusion, refusing to eat, alteration in usual patterns
- Physiological change  eg temperature, pulse or BP outside normal limits
- Physical changes  eg skin tears, pressure areas, arthritis, contractures, previous injuries.
- Rate all absent to severe (1-4) score 3-7 mild pain, 8-13 moderate pain, 14+ severe pain.
- Abbey J et al. Medical research Foundation.
Underlying causes of severe distress

- Depression
- Psychosis
- Pain
- Poor understanding,
- Fear and anxiety
- Insomnia
- Hunger and diet
- Boredom, isolation and spiritual care
- Poor Environments including poor staff practices etc

This is the order we put them in, that may be wrong but that is, perhaps how we as a group of mainly doctors think. But we do strongly feel that to leave depression (which affects 30% +) and psychosis (?20 – 50%) which is also very common as the last things to treat after trying all else may be a severe error that leave severe distress untreated.
Treatment and management

- Is according to the cause of distress
- One size does not fit all
- So underneath each symptom then there is a recommended set of actions. Some are simple

- eg in Depression;
- We suggest that there should be a low threshold for the use of antidepressants in SDID. 1st line is an SSRI followed in the absence of benefit by, perhaps a more sedative antidepressant (eg Mirtazapine or Trazodone).
• Environment
• Environmental changes, good nursing, careful sensitive approach, spiritual care are important. The correct aids and appliances can be hugely effective in improving the experience of care for people with dementia.
• Fear
• Gentle calm approach, use of sedatives as a last resort. Seek underlying cause of fear, especially including environment, staff approach and psychosis.
• Pain
• Opiates are effective for pain, but again can be harmful if overused. In appropriate doses they are safe. Milder pain may be treated with weaker analgesics. Tramodol and fentanyl are useful and can be applied with skin patches. Varying position of those who are very immobile is important. Arthritic pain may respond well to non steroidal analgesics but the risk of gastric bleeding as well as anorexia and soreness needs considering.
• It is important not to undertreat pain.
Specific causes of BPSD and distress

- Continence and elimination
- Wandering
- Sexual disinhibition
- Sundowning
- Scabies
• **Scabies**

• We mention this just because scabies is a cause of huge suffering and has been seen to be a treatable cause of severe distress. Expertise in identifying and treating is essential. Where advanced dementia causes contractures and makes universal application of lotions impossible, oral Ivermectin should be given.
The issue of antipsychotics

- By focussing upon subsets of symptoms the overall balance of managing severe distress may be lost.
- For example
- Anti-psychotics are either
  - Bad as they cause stroke falls confusion or death
  - Or good as they make people calmer and give the staff an easier time
  - Or good as they actually help to alleviate severe distress
  - Or all of the above! (which is true)
Antipsychotics

• Are harmful
• causing stroke, falls, worsened confusion and also death. It’s a class effect. Strokes reported most with olanzapine and risperidone but not studies with others. Worsened confusion with Quetiapie. Recent study on death show older typicals are the worse.
• So use them if you need them and they are indicated after a clear discussion of harm with carers.
But antipsychotics are hugely overused.

Are often used as the only treatment for behaviour problems in dementia.

And yet the causes of behaviour disturbance in dementia are wide and varied.

And distress is **NOT** to be solely responded to with an antipsychotic.
Contrasting BPSD and distress

- The science is currently attached to BPSD.
- But
- Except that some behaviour disturbance in dementia is entirely reasonable and may be welcome as an expression of the problems of the illness or the care provided.
- Or in other words, we are all entitled to be behaviourally disturbed and so it is not a “pure” problem.
- Behaviour disturbance is a measure of the trouble caused to others by people with dementia rather than a measure of the patients suffering.
And

- There is a strong requirement to relieve severe distress in those with advanced dementia and
- the experience of here and now is (for those with dementia) arguably far more important than in those who are healthy and able to endure distress (eg saving for that big purchase) in the hope of a less distressed future.
Are anti-psychotics ethical?

- Yes if
- They reduce distress effectively and
- Are the least harmful alternative
- And the harms are outweighed by the benefit of distress reduction
Is withholding antipsychotics unethical?

- Yes in some clear circumstances
And even more importantly

- Really good quality care of dementia
- Person centred care
- Hope for home care
- Care that affirms the individual
- Care that brings comfort, warmth and dignity
Decision support tool

- National tool coming soon
Open discussion on how to deal with antipsychotics in care homes

Managing distress/Behavioural and Psychological Symptoms in Dementia

Managing schizophrenia, bipolar illness or depression using other guidance. Do not use dementia pathway!

Step 1: does the patient have a psychotic illness?

Step 2: Understand what behaviors the patient has and their context

Step 3: Identify the likely causes of their distress

Step 4: Use this information to inform a treatment strategy

Non-pharmacological
- Methods of communication
- Drinks and food
- Human contact
- Activities

Targeted pharmacological
- Analgesia
- Laxatives
- Antibiotics
- Antidepressants

Step 5: Antipsychotics appears indicated. Document indications

Consider weight while weighing

Perform risk benefit analysis with relatives/advocates. Antipsychotics against known risks (written communication is acceptable)

Ask relatives/advocates for ongoing feedback on any concerns

Use and review cycle

Consider dose reduction. Restart review cycle

If benefit continue for three months (six months max)

No benefit stop.

Glue antipsychotics. Sterling 0.25mg – 0.5mg tid for four weeks and review

improving lives

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