

Risperidone for treatment of behavioural symptoms in dementia

(also known as changed or responsive behaviours)

This sheet explains current knowledge about risperidone for people with dementia, how the drugs work and what questions people should ask their doctor if being prescribed these drugs.

What is Risperidone?

It is an antipsychotic medication which is approved in Australia for the treatment of persistent behavioural disturbances such as psychotic symptoms and aggression in people with moderate to severe Alzheimer's disease, where non-drug methods have not worked. Risperidone is not recommended for use in people with other forms of dementia.

For information about other drug treatments that might be used, see *Dementia Q&A Sheet 4: Drugs used to relieve behavioural and psychological symptoms (changed or responsive behaviours) of dementia*.

Should medications be used in the treatment of behavioural symptoms of dementia?

It is important to realise that the treatment of behavioural and psychological symptoms of dementia with antipsychotic medications is considered a second-line treatment. Drugs should be used only after non-drug approaches have been extensively trialled. A variety of factors can contribute to behavioural symptoms, including unreported pain, other illnesses, anxiety, depression, environmental factors and interactions with other people. Managing the underlying causes of behaviours with non-drug strategies should be tried before drug treatment, as medications may be of limited benefit and might cause serious side-effects.

It is important that the person has a proper assessment to identify possible reasons for the behavioural symptoms. Identifying and modifying triggers for behaviours may help avoid the need for drug therapy altogether. It is appropriate to request that a medical practitioner consider whether illness, other medications, the environment or interactions

with others are contributing to behavioural disturbances. Combinations of non-drug interventions tailored to the needs of individuals may benefit both the person with dementia and their family and carers.

However, if symptoms continue and non-drug interventions are not successful, it is sometimes necessary to resort to medications.

What is recommended?

Behavioural and psychological symptoms of dementia can be very distressing. It is important that a considered decision about the use of risperidone or other antipsychotic medications be made by medical professionals, the family and, if possible, the person with dementia. At all times, individuals should be carefully monitored with a view to ceasing or reducing the dose at an appropriate time.

The Cochrane review on antipsychotics concluded that 'neither risperidone nor olanzapine (another antipsychotic) should be used routinely to treat dementia patients with aggression or psychosis unless there is severe distress or risk of physical harm to those living and working with the patient'. Medical guidelines for the treatment of behavioural and psychological symptoms of dementia make the same recommendation. See, for example, the Clinical Practice Guidelines and Principles of Care for People with Dementia produced by the NHMRC Partnership Centre for Dealing with Cognitive and Related Functional Decline in Older People.

Atypical antipsychotics and risperidone

Risperidone is an 'atypical' antipsychotic drug. Atypical antipsychotics are a class of medications used to treat psychotic symptoms (delusions, hallucinations and thought disorders) in a variety of illnesses. They work by changing the effects of chemicals in the brain.

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'Typical' antipsychotic medications are older and have more side-effects characterised by Parkinson's disease-like symptoms, involuntary movements and facial grimacing. However, the newer atypical antipsychotics can still have severe side-effects and it is important to consider this when deciding on treatment options.

Risperidone is the only atypical antipsychotic approved by the Pharmaceutical Benefits Scheme (PBS) to treat behavioural disturbance in people with Alzheimer's disease at a subsidised cost. It has been shown to provide modest improvements in some people in symptoms such as aggression, agitation and psychosis. There is no evidence that risperidone is any more effective than other atypical antipsychotics, but it has been tested on more patients than the others.

Risperidone is currently listed on the PBS to treat psychotic symptoms and aggression in patients with Alzheimer's disease where non-drug methods have been unsuccessful. The PBS listing applies to risperidone tablets, orally disintegrating tablets and oral solution, all available in several doses. The treatment should be reviewed every 4 to 12 weeks and limited to a maximum duration of 12 weeks.

Some trials of risperidone and other atypical antipsychotics have suggested they may be helpful in modifying such symptoms as psychosis and aggression, whilst other studies have found little evidence that they help. The benefit of these drugs in dementia remains controversial as a consequence of these disparate findings.

Side-effects

Risperidone is associated with a range of potential side-effects. In general, older people are more susceptible than younger people to the adverse effects of risperidone. Many side-effects are dose related, so it is important to start treatment on the lowest dose possible, and gradually increase if necessary, in consultation with a doctor.

Side-effects of risperidone may include sleepiness, agitation, anxiety, headache, trembling, excessive saliva, stiffness, leg restlessness, dizziness and fast heart rate. Although atypical antipsychotics are less prone to cause side-effects such as muscle twitching and Parkinson's disease-like movement problems, such symptoms can still occur, especially at higher doses. Not everyone who takes risperidone will experience side-effects.

People with dementia with Lewy bodies or Parkinson's disease are usually much more sensitive to the effects of atypical antipsychotics. It is not recommended that risperidone be subscribed to such individuals, as there is a greater risk of side-effects and possibly sudden death.

Finally, all antipsychotics have the potential to raise appetite and may be associated with weight gain and the development of diabetes. People taking risperidone should be weighed regularly and have regular monitoring of their blood sugar levels.

Safety concerns

In addition to the side-effects listed above, risperidone and other antipsychotics have been associated with some significant safety concerns around the possible risks of death and stroke.

Some trials have found that older people with dementia being treated with atypical antipsychotics have an increased risk of death compared to those not taking these drugs. Reviews of these trials indicate that the risk of death was around 1.5 times higher in people with dementia being treated with atypical antipsychotics. In placebo-controlled trials of risperidone in people with dementia, 4.0% of risperidone treated patients died, compared to 3.1% of placebo treated patients. So the increase in the number of deaths is small. Most of the causes of death were related to cardiovascular events or infections.

Additionally, antipsychotics may increase the risk of stroke. Results from controlled clinical studies have found an increased risk of cerebrovascular adverse events for people with vascular or mixed dementia being treated with risperidone, compared with those with Alzheimer's disease.

People taking risperidone should immediately report signs and symptoms of potential stroke such as weakness or numbness in the face, arms or legs, and speech or vision problems, so that diagnosis can be made and treatment options considered, including discontinuation of the drug without delay. Extreme caution is advised if prescribing antipsychotic medication in people prone to cerebrovascular disease. In general the risk of stroke is considerably higher in those with untreated hypertension, diabetes, atrial fibrillation or previous stroke.

What questions should you ask your doctor about any drug being prescribed?

- What are the potential benefits of taking this drug?
- How long before improvement may be noticed?
- What action should be taken if a dose is missed?
- What are the known potential side-effects?
- If there are side-effects, should the dose be reduced or should the drug be stopped?
- If the drug is stopped suddenly, what happens?
- What other drugs (prescription and over-the-counter) might interact with the medication?
- How might this drug affect other medical conditions?
- Are there any changes that should be reported immediately?
- How often will a visit to the doctor who prescribed the drug be needed?
- Is the drug available at a subsidised rate?

References

- Ballard C et al (2006). Atypical antipsychotics for aggression and psychosis in the treatment of Alzheimer's disease. *Cochrane Data-base of Systematic Reviews*, Issue 1, Art. No.CD003476.
- Guideline Adaptation Committee (2016). Clinical Practice Guidelines and Principles of Care for People with Dementia. GAC: Sydney.
- Huybrechts KF et al (2011). Risk of death and hospital admission for major medical events after initiation of psychotropic medications in older adults admitted to nursing homes. *Canadian Medical Association Journal*, DOI:10.1503/cmaj.101406
- Karlawish J (2006). Alzheimer's disease- clinical trials and the logic of clinical purpose. *N Eng J Med*, 355:1604-1605.
- Mittal V et al (2011). Risk of cerebrovascular adverse events and death in elderly patients with dementia when treated with antipsychotic medications: A literature review of the evidence. *Am J Alzheimers Dis Other Demen*, 26(1):10-28.
- National Prescribing Service (2007). Prescribing Practice Review 37: *Role of antipsychotics in managing behavioural and psychological symptoms of dementia*. NPS: Sydney.
- Schneider L et al (2006). Effectiveness of atypical antipsychotic drugs in patients with Alzheimer's disease. *N Eng J Med*, 355:1525-1538.
- Therapeutic Goods Administration (2015). Medicines Safety Update, Volume 6, Number 4, August 2015 <https://www.tga.gov.au/publication-issue/medicines-safety-update-volume-6-number-4-august-2015>
- Woodward, M. 2005, 'Pharmacological Treatment of Challenging Neuropsychiatric Symptoms of Dementia', *Journal of Pharmacy Practice and Research*, 35: 228-234.

FURTHER INFORMATION

Dementia Australia offers support, information, education and counselling. Contact the National Dementia Helpline on **1800 100 500**, or visit our website at **dementia.org.au**



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