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#### [Intervention Review]

## Haloperidol for agitation in dementia

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### ABSTRACT

#### Background

Agitation occurs in up to 70% of demented patients. Haloperidol has been used for decades to control agitation in dementia, but its effectiveness remains unclear. Previous meta-analyses examined only English language publications or compared haloperidol with other drugs rather than with placebo. To study the effectiveness of haloperidol a more widely based review was performed.

#### Objectives

To determine whether evidence supported the use of haloperidol in agitated dementia.

#### Search methods

We searched ALOIS - the Cochrane Dementia and Cognitive Improvement Group's Specialized Register on 2 June 2010 using the term: haloperidol.

The search of June 2010 retrieved no studiies for inclusion and/or exclusion within the review.

The previous searches of July 2005 and January 2008 retrieved no new studies for inclusion.

#### **Selection criteria**

Randomized, placebo-controlled trials, with concealed allocation, where subjects' dementia and agitation were assessed.

#### Data collection and analysis

- 1. Two reviewers extracted data from included trials
- 2. Data were pooled where possible, and analysed using appropriate statistical methods
- 3. Odds ratios of average differences were calculated
- 4. Only 'intention to treat' data were included
- 5. Analysis included haloperidol treated patients, compared with placebo

#### **Main results**

The five included trials led to the following results:

1. There was no significant improvement in agitation among haloperidol treated patients, compared with controls.

2. Aggression decreased among patients with agitated dementia treated with haloperidol; other aspects of agitation were not affected significantly in treated patients compared with controls.

3. Although two studies showed increased drop-outs due to adverse effects among haloperidol patients, there was no significant difference in drop-out rates, comparing all haloperidol treated patients with controls.

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4. The data were insufficient to examine response to treatment in relation to length of treatment, degree of dementia, age or sex of patients, and cause of dementia.

#### Authors' conclusions

1. Evidence suggests that haloperidol was useful in reducing aggression, but was associated with adverse effects; there was no evidence to support the routine use of this drug for other manifestations of agitation in dementia.

2. Similar drop-out rates among haloperidol and placebo treated patients suggested that poorly controlled symptoms, or other factors, may be important in causing treatment discontinuation.

3. Variations in degree of dementia, dosage and length of haloperidol treatment, and in ways of assessing response to treatment suggested caution in the interpretation of reported effects of haloperidol in the management of agitation in dementia.

4. The present study confirmed that haloperidol should not be used routinely to treat patients with agitated dementia. Treatment of agitated dementia with haloperidol should be individualized and patients should be monitored for adverse effects of therapy.

#### PLAIN LANGUAGE SUMMARY

# No evidence has been found of any significant general improvement in manifestations of agitation, other than aggression, among demented patients treated with haloperidol, compared with controls

Agitation is common in demented patients, and often takes the form of wandering, crying out, and aggression. It is presumed to reflect subjective distress and is associated both with risks to the patient and an increase in caregiver burden. In the present study haloperidol treatment was associated with a lower degree of aggression than was placebo. Adverse effects occurred more frequently in haloperidol treated patients than controls, but similar drop-out rates among treated and control patients suggested that for some patients adverse effects may have been tolerated because of better control of behaviour. Our findings indicated that there is little evidence to support a benefit of haloperidol on manifestations of agitation other than aggression, and that haloperidol should not be used routinely to treat patients with agitated dementia. Treatment of agitated dementia should be individualized, with careful monitoring of benefits and adverse effects.