

Journal Club
**Efficacy of treating pain to reduce behavioral
disturbances in residents of nursing homes with
dementia: cluster randomized clinical trial**

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Husebo, B. S., Ballard, C., Sandvik, R., Nilsen, O. B., & Aarsland, D. (2011). Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *British Medical Journal* , 343:d4065.

Abstract:

Objective: To determine whether a systematic approach to the treatment of pain can reduce agitation in people with moderate to severe dementia living in nursing homes.

Design: Cluster randomised controlled trial.

Setting: 60 clusters (single independent nursing home units) in 18 nursing homes within five municipalities of western Norway.

Participants: 352 residents with moderate to severe dementia and clinically significant behavioural disturbances randomised to a stepwise protocol for the treatment of pain for eight weeks with additional follow-up four weeks after the end of treatment (33 clusters; n=175) or to usual treatment (control, 27 clusters; n=177).

Intervention: Participants in the intervention group received individual daily treatment of pain for eight weeks according to the stepwise protocol, with paracetamol (acetaminophen), morphine, buprenorphine transdermal patch, or pregabalin. The control group received usual treatment and care.

Main outcome measures: Primary outcome measure was agitation (scores on Cohen-Mansfield agitation inventory). Secondary outcome measures were aggression (scores on neuropsychiatric inventory-nursing home version), pain (scores on mobilisation-observation-behaviour-intensity-dementia-2), activities of daily living, and cognition (mini-mental state examination).

Results: Agitation was significantly reduced in the intervention group compared with control group after eight weeks (repeated measures analysis of covariance adjusting for baseline score, $P < 0.001$): the average reduction in scores for agitation was 17% (treatment effect estimate -7.0 , 95% confidence interval -3.7 to -10.3). Treatment of pain was also significantly beneficial for the overall severity of neuropsychiatric symptoms (-9.0 , -5.5 to -12.6) and pain (-1.3 , -0.8 to -1.7), but the groups did not differ significantly for activities of daily living or cognition.

Conclusion: A systematic approach to the management of pain significantly reduced agitation in residents of nursing homes with moderate to severe dementia. Effective management of pain can play an important part in the treatment of agitation and could reduce the number of unnecessary prescriptions for psychotropic drugs in this population.

Commentary:

Strengths:

- 1) Cluster RCT: This allows us to say that underlying severity of dementia, the presence of co morbid conditions, and a host of other prognostic factors (unknown as well as known) are not contributing to the observed effect.
- 2) Concealment: Caregivers who were completing outcome measures and research assistants collecting the outcome data were blinded to treatment condition. Nursing staff and researchers conducting the intervention were not involved in data collection and were told not to share information with members of the healthcare team. Patients were divided into clusters so all patients on a give unit received the same intervention (either treatment or control) and nursing staff worked on one unit so they would not be aware of different treatment protocols.
- 3) Participants: Homogenous participant population at baseline with regards to age, medications, baseline outcome measures (disease, function, agitation, aggression, pain).
- 4) Effect size: The decreases in agitation score using standardized pain protocol in cognitively impaired patients were similar decreases seen with patients taking risperidone (RRR 17% compared to 3%, 13%, and 18% in 3 RCT's). It is interesting to know the same benefit can be achieved without the side effects of antipsychotic medications.
- 5) Applicability: The intervention could be widely adopted (a standardized analgesic protocol would be relatively easy to implement in long-term care facilities).

Weaknesses:

- 1) Patient Attribution: Patients were excluded to follow up based on non compliance. This questions validity because the reasons for not taking medication can be related to disease prognosis or severity (degree of dementia or coexisting agitation). In addition, patients who were lost to follow up often have different prognoses from those who are retained, and they may not be assessed as they may suffer from adverse outcomes (drowsiness, sedation, nausea and even death) or because they are doing well (no longer feel they needed the intervention).
- 2) Participants: Participants were primarily women (~75% in both groups). Maybe men would react differently to this intervention in terms of pathophysiology of agitation, metabolism and effect of pain medications. Trial had extensive exclusion criteria that included severe aggression, and palliative patients.
- 3) Effect size: The treatment and control interventions were unequal in some ways. There was no placebo medication administered to control arm patients. Depending on caregivers level of communication with the nursing facility they may have noticed their relative's medication administration and have a biased report. In addition nursing staff may have spent extra time with patients in treatment arm administering medication. This may have had some impact on outcome measures.
- 4) Applicability: The medications used in this protocol may not be first line medications in Canada (buprenorphine). In addition, morphine dose could have been adjusted in route and dose before moving to opioid patch.

Overall Summary:

This trial is rigorous in design, protocol and article presentation. The results illustrate that treating agitated dementia patients using a simple standardized protocol can significantly decrease agitation scores proportional to antipsychotic medications while also decreasing pain and aggression and maintaining cognition and function. In addition they were able to show the agitation and aggression increase to baseline with withdrawal of treatment. It is interesting that only Tylenol was required for majority of patients. More work may need to go developing a standardized protocol for Canadian patients. This article seems particularly relevant to palliative care experience because it further illustrates that a patient who cannot always express their pain may manifest

their pain in other ways (such as agitation) and management of these symptoms can improve patient, caregiver, and nursing staff experience.