

# Behavior management approach for agitated behavior in Japanese patients with dementia: a pilot study

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**Background:** Agitated behaviors are frequently observed in patients with dementia and can cause severe distress to caregivers. However, little evidence of the efficacy of nonpharmacological interventions for agitated behaviors exists for patients with dementia. The present pilot study aimed to evaluate a behavioral management program developed by the Seattle Protocols for patients with agitated behaviors in Japan.

**Methods:** Eighteen patients with dementia (Alzheimer's disease, n = 14; dementia with Lewy bodies, n = 4) participated in an open study testing the effectiveness of a behavioral management program. The intervention consisted of 20 sessions over the course of 3 months. The primary outcomes were severity of agitation in dementia, as measured using the Agitated Behavior in Dementia scale (ABID) and the Cohen-Mansfield Agitation Inventory (CMAI).

**Results:** The behavioral management program resulted in significant reductions in total scores on both the ABID and CMAI. Although both physically agitated and verbally agitated behavior scores on the ABID improved significantly, symptoms of psychosis did not improve after the intervention.

**Conclusion:** The behavioral management technique may be beneficial to distressed caregivers of patients with dementia. In the future, a well designed study to develop the behavioral management program more fully is needed.

**Keywords:** Alzheimer's disease, dementia with Lewy bodies, agitated behavior, behavioral management, Agitated Behavior in Dementia scale

## Introduction

Agitated behaviors are common in patients with Alzheimer's disease, dementia with Lewy bodies, and frontotemporal dementia.<sup>1</sup> The prevalence of agitation increases with the severity of dementia,<sup>2</sup> resulting in serious daily functional impairments because agitated behaviors are complex phenomena affected by interactions between cognitive impairment, pain, mental discomfort, and environmental factors, including the need for social contact and overstimulation.<sup>3</sup> Agitated behaviors are problematic because they can cause severe distress to the caregivers of patients with dementia.

Antipsychotic medications have long been used to treat agitated behaviors in patients with dementia. Although atypical antipsychotic medications are known to be effective,<sup>4</sup> the US Food and Drug Administration issued a warning in 2005 indicating that the pharmacological treatment of behavioral problems in patients with dementia was associated with an increased mortality risk. Several recent meta-analyses have agreed that serious adverse effects, such as cerebrovascular events, may occur in patients with dementia who receive antipsychotic medications.<sup>5,6</sup> Thus, nonpharmacological

interventions are needed to manage agitated behaviors in this group of patients.

A number of nonpharmacological interventions have been devised. However, little evidence of the efficacy of these interventions for neuropsychiatric symptoms is available. A few placebo-controlled, randomized clinical trials of behavioral management techniques have demonstrated significant effects in reducing behavior problems in patients with dementia.<sup>7-9</sup> These trials have been conducted as the Seattle Protocols and were developed by researchers in Seattle, WA. Several recent reviews<sup>10-12</sup> have indicated that while other randomized clinical trials for nonpharmacological interventions have resulted in clinical meaningful improvements, insufficient research is available to generalize the efficacy of nonpharmacological interventions for behavioral problems in patients with dementia. In terms of some non-dementia-specific psychological tasks, interventions focused on direct-care nursing tasks associated with activities of daily living<sup>13</sup> did not produce significant reduction in any disruptive behaviors. Suhr et al<sup>14</sup> observed significant reductions in behavioral symptoms after the use of behavioral management techniques, including progressive muscle relaxation. However, this randomized clinical study had a small sample ( $n = 17$ ). It is important that not only family members, but also professional staff in nursing and residential homes, receive sufficient education and training in communication techniques and behavioral management for dementia patients. Recent reviews<sup>12,15</sup> have shown that several studies with structured staff education programs have yielded high-quality randomized clinical trial designs.

Some studies<sup>16,17</sup> have had well trained staff educate family members either by performing family visits or making telephone contact. Other studies<sup>18,19</sup> have directly trained health professionals, such as assisted living residence or care staff in nursing or residential homes, to develop skills in behavioral management. Although these studies resulted in significant clinical improvements in some aspects of either patient or caregiver outcome (eg, depression, perceived changes in well-being, burden), they failed to observe a significant reduction in behavioral problems, such as agitated behaviors, in dementia patients. Together, these findings suggest a lack of evidence supporting a decrease in behavioral problems after behavioral management interventions in patients with dementia.

Except for case reports,<sup>20</sup> the use of behavioral management techniques for patients with dementia has not yet been established in Japan. Here we report a 12-week, open-label, prospective, pilot study which aimed to examine

the effectiveness of a behavioral management program for patients with dementia and agitated behaviors.

## Materials and methods

### Participants

The baseline sample consisted of Japanese patients with Alzheimer's disease or dementia with Lewy bodies who attended the outpatient clinic of Yagoto Hospital between December 2010 and March 2012. The diagnostic evaluation included a complete history and physical examination, routine blood tests (including evaluation of serum vitamin B12 levels and thyroid function), either a magnetic resonance imaging or computed tomography scan of the brain, and neuropsychological testing. Inclusion criteria were a diagnosis of probable Alzheimer's disease according to National Institute of Neurological and Communication Disorders and Stroke/Alzheimer Disease and Related Disorders Association criteria<sup>21</sup> or a diagnosis of probable dementia with Lewy bodies according to consensus guidelines,<sup>22</sup> either the absence of antipsychotic medications or a stable dose of antipsychotic medications during the intervention period, and at least a 2-week history of two or three agitated behaviors occurring at least once weekly.

Patients were excluded if other neurological diseases were present, there was a previous history of mental illness or substance abuse before the onset of dementia, either an magnetic resonance imaging or a computed tomography scan had revealed focal brain lesions, the patient's Mini-Mental State Examination<sup>23</sup> score was less than 11, or reliable informed consent could not be obtained from the patient and/or relatives. The study protocol was approved by the ethics committee of Yagoto Hospital. Both the subjects and the caregivers were informed of the purpose of this study and its procedures, and were asked to sign a consent form.

### Clinical assessments

Before the start and after the completion of the intervention, the following tests were conducted to assess cognitive and behavioral problems. Two interview-based questionnaires and one self-reported questionnaire were administered to all the caregivers, and one questionnaire was used to assess the patients with dementia. A well trained neuropsychologist who was blinded to the intervention administered the questionnaires, except for the self-reported questionnaire.

### Agitated Behavior in Dementia scale

The Agitated Behavior in Dementia (ABID) includes items identified by Logsdon et al<sup>24</sup> as being the most problematic in

individuals with dementia and can be observed and described objectively. The caregivers first rated each behavior according to the frequency of occurrence during each of the 2 weeks immediately before the assessment on a scale of 0 to 3 (0, did not occur during the week; 1, occurred 1–2 times during the week; 2, occurred 3–6 times during the week; 3, occurred daily or more often). The two weekly scores for each item were then added together, and the resulting item scores ranged from 0 to 6. The item scores were summed to obtain a total score, with possible scores ranging from 0 to 96. The caregivers then rated their own reactions to each problem behavior on a scale of 0 to 4 (0, not upset; 4, extremely upset). The caregiver's reactions were rated once for each item and then summed. The total reaction scores had a possible range of 0 to 64. The reliability and the validity of the Japanese version of the ABID have been confirmed.<sup>25</sup> Three factors underlying the agitated behavior as evaluated using the Japanese version of the ABID were identified, ie, physically agitated behavior, verbally agitated behavior, and psychotic symptoms.

### Cohen-Mansfield Agitation Inventory

The Cohen-Mansfield Agitation Inventory (CMAI) was originally developed to measure agitation in nursing home residents.<sup>26</sup> The test consists of 29 observable agitated behaviors rated using a seven-point Likert-type scale according to the frequency of occurrence during the previous 2 weeks (0, never occurred; 7, occurred several times per hour). The reliability and validity of the CMAI have been established.<sup>26</sup> A revised and expanded version of the CMAI, including 36 items, has been developed as an instrument to assess agitation among persons living in the community and has been used for senior day center participants.<sup>27</sup> Homma et al<sup>28</sup> confirmed the reliability and validity of the original 29 items of the CMAI in nursing home residents.

### Zarit Burden Interview

The Zarit Burden Interview (ZBI) consists of 22 items rated using a five-point Likert scale (never, 0; nearly always, 4) with the aim of assessing caregiver burden.<sup>29</sup> The total burden is obtained by adding the scores for all items, with a range of 0 to 88, and higher scores indicating a greater burden. The reliability and the validity of the Japanese version of this test battery have been confirmed.<sup>2</sup>

### Mini-Mental State Examination

The Mini-Mental State Examination<sup>23</sup> is a 30-point cognitive screening measure that is widely used to assess the severity

of Alzheimer's disease. A lower score indicates greater impairment of cognitive function.

## Treatment

Individual treatment intervention led by an experienced psychiatrist was performed based on the guidelines for Managing and Understanding Behavior Problems in Alzheimer Disease and Related Disorders.<sup>30</sup> The treatment consisted of 12 sessions, each lasting 90 minutes once a week. Behavior management combines caregiver education and training in specific behavior techniques.<sup>31</sup> The behavioral management program consisted of the following: sessions 1 and 2, which included psychoeducation regarding the nature of behavior problems in patients with dementia, and sessions 3 and 4, which began with the teaching of the ABCs of behavior change.<sup>30</sup> In this approach, caregivers learn that "A" is the antecedent or triggering event that precedes the problem behavior, "B" is the behavior of concern, and "C" is the consequence of that behavior. The behavior management intervention was started following the instructions regarding the ABCs. First, caregivers were instructed to gather information about the circumstances surrounding problems and to identify these problems according to the ABC approach. Caregivers were then asked to complete a weekly diary to monitor behavior problems. The therapist then checked the diary and instructed the caregiver with regard to how he or she might improve his or her skills so as to reduce the behavior problems identified. The remaining sessions focused on developing strategies to cope with behavior problems in patients with dementia according to the ABC approach. Caregivers were given homework tasks to apply the ABC approach by themselves. During these sessions, both the therapist and the caregivers reviewed the homework, and the therapists provided feedback to modify and develop the skills of the caregivers. Finally, the caregivers were instructed to discuss their issues and to make treatment plans for self-management in the future.

## Statistical analysis

We used the Statistical Package for the Social Sciences (Windows version 17.0) (SPSS Inc, Chicago, IL, USA) for the statistical analyses. All the statistical tests were two-tailed, and a *P* value < 0.05 was regarded as being statistically significant for changes in clinical treatment effects before and after the intervention. Because our sample size was relatively small, we used nonparametric tests and the Wilcoxon's signed rank test. This study was conducted as exploratory research. Based on several similar previous studies,<sup>7,9</sup> we estimated that a sample size of about 18 participants was needed.

## Results

### Demographic and clinical characteristics

Baseline demographic data for the patients with dementia are summarized in Table 1. Of the 22 patients with dementia (patients with Alzheimer's disease,  $n = 14$ ; patients with dementia with Lewy bodies,  $n = 8$ ) who participated in the intervention study, four patients suffering from dementia with Lewy bodies did not complete the study because they were transferred to another hospital. Among the remaining 18 patients, four with Alzheimer's disease were taking risperidone 0.5 mg/day, and this dose was maintained throughout the intervention. The risperidone had been first prescribed approximately 6 months before the start of the presently reported intervention.

### Clinical findings before and after treatment

As shown in Table 2, mean total CMAI and ABID scores decreased dramatically after 12 weeks of behavioral management ( $P < 0.001$ ). Furthermore, the mean ZBI score also decreased significantly after behavioral management. Physically and verbally agitated behavior scores improved significantly on the ABID, although symptoms of psychosis did not improve after the intervention. Further, the mean Mini-Mental State Examination score did not change significantly after the intervention. Significant differences in clinical outcomes after treatment were not observed between male and female patients with dementia.

## Discussion

In the present pilot study, we examined the effectiveness of behavioral management with regard to agitated behaviors in patients with dementia. As far as we know, this is the first study to examine the use of behavioral management techniques in Japan. Significant reductions in agitated behavior were observed in patients with dementia when evaluated using

**Table 1** Demographic and clinical characteristics of dementia patients and caregivers

	Mean $\pm$ SD ( $n = 18$ )	
	Patients	Caregivers
Type of dementia		
AD	14	–
DLB	4	–
Male/female	7/11	11/7
Age, years	71 $\pm$ 5.7	70 $\pm$ 6.1
Education, years	9.5 $\pm$ 0.5	9.6 $\pm$ 0.5
Duration of illness, years	4.1 $\pm$ 1.2	–

**Note:** Data are presented as the mean  $\pm$  SD.

**Abbreviations:** AD, Alzheimer's disease; DLB, dementia with Lewy bodies.

**Table 2** Clinical findings before and after behavior management approach in dementia patients

	Mean $\pm$ SD		P
	Baseline	After intervention	
MMSE	15.2 $\pm$ 3.6	14.8 $\pm$ 3.5	0.166
ZBI	44.1 $\pm$ 19.9	36.3 $\pm$ 16.9	<0.001
CMAI	39.1 $\pm$ 27.1	32.3 $\pm$ 25.2	0.003
<b>ABID</b>			
Frequency questions	51.1 $\pm$ 12.6	43.7 $\pm$ 11.4	<0.001
Physical agitated behavior	14.5 $\pm$ 10.3	11.5 $\pm$ 8.4	0.001
Verbally agitated behavior	28.7 $\pm$ 7.6	24.6 $\pm$ 6.3	<0.001
Psychosis symptoms	7.8 $\pm$ 3.6	7.5 $\pm$ 4.1	0.366
Reaction ratings	54.9 $\pm$ 28.4	43.3 $\pm$ 24.3	<0.001
Physical agitated behavior	17.6 $\pm$ 14.4	13.5 $\pm$ 11.7	0.001
Verbally agitated behavior	32.6 $\pm$ 16.1	25.2 $\pm$ 12.9	<0.001
Psychosis symptoms	4.6 $\pm$ 3.5	4.5 $\pm$ 3.6	0.748

**Notes:** Data are presented as the mean  $\pm$  SD. Except for the MMSE score and the psychosis symptoms of the ABID, significant differences before and after intervention were observed for all the items.

**Abbreviations:** MMSE, Mini-mental state examination; ZBI, Zarit Burden Interview; CMAI, The Cohen-Mansfield Agitation Inventory; ABID, Agitated Behavior in Dementia scale.

both the ABID and the CMAI. Furthermore, large reductions in the care burden of caregivers, as evaluated using the ZBI, were also observed. Thus, our study provides additional support for the effectiveness of nonpharmacological interventions for agitated behaviors in patients with dementia.

However, the present study had several limitations. First, although the physically and verbally agitated behavior scores improved on the ABID, our study failed to show any improvement in symptoms of psychosis according to this scale. Psychotic symptoms are well known to be distinct from agitation in patients with dementia.<sup>32</sup> Delusions in dementia can be categorized into several types, including persecutory delusions and misidentification delusions associated with false beliefs. These delusions are regarded as being associated with various types of cognitive dysfunction, but mainly executive dysfunction.<sup>33</sup> Changes in behavior are difficult to achieve in patients with dementia suffering from both delusions and hallucinations.

Second, although all patients with Alzheimer's disease completed the study, half of the patients suffering from dementia with Lewy bodies ( $n = 4$ ) did not. Dementia with Lewy bodies is characterized by recurrent visual hallucinations, fluctuations in attention, and rapid eye movement sleep disorders. Neuropsychiatric symptoms are more severe and prevalent in patients who have dementia with Lewy bodies than in those with Alzheimer's disease.<sup>1</sup> Thus, these severe symptoms are major sources of difficulty in identifying behavior problems according to the ABC approach.

Third, our study did not include placebo control group. We relied on within-group changes to examine the effects of behavioral management techniques. In addition, the sample size was relatively small. Thus, our results may overestimate the effect of behavioral management. A large-scale, randomized clinical trial is needed to clarify the effect of behavioral management on agitated behavior in patients with dementia.

Fourth, whether the effects of behavioral management techniques persisted after the end of the study is unclear. Weiner et al<sup>34</sup> conducted a 12-month follow-up study of a 4-month randomized clinical trial and failed to show any long-term effects of behavioral management.

Fifth, Cohen-Mansfield<sup>35</sup> proposed that agitated behaviors could be divided into two dimensions, ie, aggressive versus nonaggressive, and verbal versus physical behaviors.<sup>35</sup> Several items (eg, “harmful to self”) that were included in the physically agitated behavior item in the ABID corresponded to the agitated behaviors that Cohen-Mansfield<sup>35</sup> described as being physically aggressive. However, in an examination of the factor structure of the ABID in our previous study,<sup>25</sup> agitated behaviors were clearly not divided into two dimensions (aggressive versus nonaggressive). Unlike the CMAI, the ABID may not have the sensitivity to discriminate between physically aggressive and nonaggressive behaviors.

Sixth, the main strategy of this study was to provide a basis for consequent strategies. However, in terms of geriatric psychiatry, an antecedent control, such as alteration of the environment to preclude behavioral problems, is regarded as a clinically more useful approach.<sup>20,36</sup> An antecedent control is an appropriate approach for patients with dementia, requiring less input from caregivers in terms of effort and time. Thus, in future studies, we plan to develop more adaptive antecedent controls for agitated behavior in patients with dementia aimed at providing more benefits relative to this study.

Despite these limitations, behavioral management is easy and safe to perform, and is likely to be beneficial to caregivers suffering from distress because of agitated behaviors. In the future, a well designed study to develop more fully the potential of behavioral management techniques is needed for a variety of environments, including nursing homes.

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## Disclosure

The authors report no conflicts of interest in this work.

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