

していくこと、ADL、うつや、QOL (quality of life) との相関が極めて良好で、虚弱の指標としての有用性を示している¹²⁾。

また、最近多くの虚弱因子や転倒率と関連する足関節 Dorsiflex meter を開発したわれわれは、虚弱者に多い、歩行機能異常、転倒、もの忘れ、頻尿などについて、大脳の白質病変との関連を示した。

おわりに

骨に対するビスホスホネート、筋肉に対するビタミンDと並んで、動脈硬化疾患に対する治療法の中で、虚弱予防にも効果がある薬物療法や生活指導が今後の老年医学の大きな課題である。

文 献

- 1) Nourhashemi F, Andrieu S, Gillette-Guyonnet S, et al : Instrumental activities of daily living as a potential marker of frailty : a study of 7364 community-dwelling elderly women (the EPIDOS study). *J Gerontol Series A Biol Sci Med Sci* **56** : M448-453, 2001.
- 2) Blazer DG, Fillenbaum G, Burchett B : The APOE-E4 allele and the risk of functional decline in a community sample of African Americans and white older adults. *J Gerontol Med Sci* **56A** : M785-789, 2001.
- 3) Bader G, Zuliani G, Kostner GM, Fellin R : Apolipoprotein E polymorphism is not associated with longevity or disability in a sample of Italian octo- and nonagenarians. *Gerontology* **44** (5) : 293-299, 1998.
- 4) Morley JE, Kaiser FE, Sih R, et al : Testosterone and frailty. *Clin Geriatr Med* **13** : 685-695, 1997.
- 5) Morrison MF, Katz IR, Parmelee P, et al : Dehydroepiandrosterone sulfate (DHEA-S) and psychiatric and laboratory measures of frailty in a residential care population. *Am J Geriatr Psychiatry* **6** : 277-284, 1998.
- 6) Carvalhaes-Neto N, Huayllas MK, Ramos LR, et al : Cortisol, DHEAS and aging : resistance to cortisol suppression in frail institutionalized elderly. *J Endocrinol Invest* **26** (1) : 17-22, 2003.
- 7) Cohen HJ, Pieper CF, Harris T, et al : The association of plasma IL-6 levels with functional disability in community-dwelling elderly. *J Gerontol A Biol Sci Med Sci* **52** (Special Issue) : M201-208, 1997.
- 8) Ranieri P, Rozzini R, Franzoni S, et al : Serum cholesterol levels as measure of frailty in elderly patients. *Exp Aging Res* **24** : 167-179, 1998.
- 9) Corti MC, Guralnik JM, Salive ME, Sorkin JD : Serum albumin level and physical disability as predictors of mortality in older persons. *JAMA* **272** : 1036-1042, 1994.
- 10) Akishita M, Yamada S, Nishiya H, et al : Testosterone and comprehensive geriatric assessment in frail elderly men. *J Am Geriatr Soc* **51** : 1324-1326, 2003.
- 11) 鳥羽研二 : 厚生科学研究費補助金痴呆・骨折臨床研究事業「寝たきりの主要因に対する縦断介入研究を基礎にした介護予防ガイドライン策定に関する研究」, 平成16年度報告書。
- 12) Matsubayashi K, Okumiya K, Wada T, et al : Secular improvement in self-care independence of old people living in community Kaho-ku, Japan. *Lancet* **347** : 60, 1996.
- 13) Campbell AJ, Buchner DM : Unstable disability and the fluctuations of frailty. *Age & Ageing* **26** : 315-318, 1997.
- 14) 鳥羽研二ほか : 「高齢者総合的機能評価ガイドライン」, 厚生科学研究所, 2003.
- 15) Hamerman D : Toward an understanding of frailty. *Ann Intern Med* **130** : 945-950, 1999.
- 16) Owens NJ, Fretwell MD, Willey C, Murphy SS : Distinguishing between the fit and frail elderly, and optimizing pharmacotherapy. *Drugs Aging* **4** (1) : 47-55, 1994.

- 17) Strawbridge WJ, Shema SJ, Balfour JL, et al : Antecedents of frailty over three decades in an older cohort. *J Gerontol Series B Psychol Sci Soc Sci* **53** : S9-16, 1998.
- 18) Rockwood K, Stadnyk K, MacKnight C, et al : A brief clinical instrument to classify frailty in elderly people. *The Lancet* **353** : 205-206, 1999.
- 19) Rolfson DB, Majumdar SR, Tahir A, Tsuyki RT : Development and validation of a new instrument for frailty. *Clin Invest Med* **23** : 336 (abs), 2000.
- 20) 鳥羽研二, 大河内二郎, 高橋 泰ほか : 転倒リスク予測のための「転倒スコア」の開発と妥当性の検証. *老医誌* **42** : 346-352, 2005.
- 21) 鳥羽研二 : ロコモティブシンドロームの予防 1) 虚弱の概念と予防. *Progress in Medicine* **30**(12) : 3061-3065, 2010.

高齢者診療をめぐる現場の知識と実践の技



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大学で臓器の専門医として臨床で腕をふるい、教職も務め、「最近どの診療科も高齢者が増え、どの科も老人を診ているので、特に老年内科などという科はいらぬ」と認識し、公式にも発言していた方が、定年後、老人保健施設の医師になった。入所者から「先生、腰が痛く、トイレが近く、夜中に起きてしまうからなんとかしてください」と言われ、職員から「同じことを何度も聞くし、夕方には不穏になります、食事時にむせることも増えてきました」とも追加情報があった。「整形、泌尿器、精神科、耳鼻科など受診したのか？」と職員に聞くと、「退所しなくては受診できません」と言われ、困っていると、入所者に「先生、年寄りのこと何も知らないね」と容赦なくつぶやかれ、胸に堪えた。

このように老年医学の専門医であれば、1人でごく普通に日常診療で複数の老年症候群の診断と治療、生活指導までこなしていることが、専門診療科と異なる特色である。

本書は、前記のエピソードとまったく正反対の、医師人生後半を老人保健施設で過ごした「達人」による教科書である。高齢者医療の現場で従来の内科では解決がつかない症状に出会い、残念なことに老年医学のテキストも実践的記述が不十分なため、即戦力にならない。こんな時、外国文献に当たり、看護師の工夫を拾い、独自のアイデアを実践して、10年かけて積み上げたら立派な教科書ができていたということである。

高齢者医療は複数の疾患が合併し、症状も内科以外の各科にわたる複雑な分野であり、複雑性の克服は以前から課題であった。私も困難な上流からようやく一定の境地の中流に辿り着いたと思っていたが、多くの重要なことを見落としていたようだ。川岸に立つ賢人は、老人保健施設でゆっくり逍遙し、高齢者医療の「徒然草」をまとめあげている。専門家以外も一読に値する名著である。

Fall Prevention Using Olfactory Stimulation with Lavender Odor in Elderly Nursing Home Residents: A Randomized Controlled Trial

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OBJECTIVES: To investigate the effects of lavender olfactory stimulation intervention on fall incidence in elderly nursing home residents.

DESIGN: Randomized placebo-controlled trial.

SETTING: Three randomly selected nursing homes in northern Japan.

PARTICIPANTS: One hundred and forty-five nursing home residents aged 65 and older.

INTERVENTION: Participants were randomly assigned to the lavender ($n = 73$) or placebo group ($n = 72$) for a 360-day study period. The lavender group received continuous olfactory stimulation from a lavender patch. The placebo group received an unscented patch.

MEASUREMENT: The primary outcome measure was resident falls. Other measurements taken at baseline and 12 months included functional ability (assessed using the Barthel Index), cognitive function (Mini-Mental State Examination (MMSE)), and behavioral and psychological problems associated with dementia (Cohen-Mansfield Agitation Inventory (CMAI)).

RESULTS: There were fewer fallers in the lavender group ($n = 26$) than in the placebo group ($n = 36$) (hazard ratio (HR)=0.57, 95% confidence interval (CI) = 0.34-0.95) and a lower incidence rate in the lavender group (1.04 per person-year) than in the placebo group (1.40 per person-year) (incidence rate ratio = 0.51, 95% CI = 0.30-0.88).

The lavender group also had a significant decrease in CMAI score ($P = .04$) from baseline to follow-up in a per protocol analysis.

CONCLUSION: Lavender olfactory stimulation may reduce falls and agitation in elderly nursing home residents; further research is necessary to confirm these findings. *J Am Geriatr Soc* 60:1005-1011, 2012.

Key words: fall prevention; lavender; nursing home residents

Falls are recognized as a major problem in community-dwelling elderly adults and even more so in frail elderly adults residing in institutions.^{1,2} Approximately half of nursing home residents fall annually, two to three times that of community residents.³ Falls are associated with morbidity and mortality in nursing home residents and linked to poorer overall functioning. A high risk of falling can considerably compromise the ability to perform activities of daily living (ADLs) and participate in social activities.⁴ Reducing or minimizing the risk of falling can positively affect residents' quality of life.

Important underlying risk factors for falls include lower extremity weakness, gait and balance instability, poor vision, cognitive and functional impairment, and sedating and psychotropic medications.¹ Cognitive impairment is a strong risk factor for falls in nursing homes that may increase the risk of falls in multiple ways through the behavioral and psychological symptoms of dementia (BPSD), as well as gait and balance disturbances.⁵⁻⁷

A systematic review revealed that effective measures to prevent falls in nursing homes are seriously lacking.⁷ Some challenges to incorporating fall prevention into practice include intervention feasibility, staff time constraints, competing demands, and inadequate reimbursement.^{8,9}

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Other barriers include a perceived lack of skills by health-care professionals in managing complex, multifactorial health conditions and a lack of coordination in the nursing home setting. To overcome these difficulties, a new innovative, easy-to-execute intervention is warranted.

It is hypothesized that lavender (*Lavandula angustifolia*), used in aromatherapy as a relaxant, has multiple ameliorating effects on fall-related risk factors in elderly adults. A previous study showed that olfactory stimulation using lavender oil improved balance in elderly people.¹⁰ In addition, another recent study reported that gait performance as measured using the Timed Up and Go test and 10-m walking speed significantly improved after exposure to lavender olfactory stimulation.¹¹ Although these studies demonstrated a transient effect of lavender olfactory stimulation, long-term exposure to continuous lavender olfactory stimulation has not been investigated. It is conceivable that, if individuals were exposed continuously to lavender olfactory stimulation, the stabilizing effects of lavender odor on gait performance might prevent falls in frail elderly people.

Lavender odor has soothing properties affecting anxiety and agitation underlying BPSD.^{12,13} BPSD, such as physically nonaggressive behaviors (including pacing and wandering) and aggressive behaviors (leading to increases in prescription neuroleptic medications), may lead to and increase in fall risk. Because of the difficulty in treating individuals with BPSD, prescription tranquilizers and other psychotropic medications are common,^{14,15} but such medications have shown modest efficacy but can have adverse effects such as confusion, gait disturbance, and falls. Therefore, increasingly more attention is being paid to nonpharmacological interventions specific to agitation. A recent review identified aromatherapy with lavender as a potential treatment for BPSD in nursing home residents.¹⁶

Olfactory stimulation with lavender may prevent falls in nursing home residents by ameliorating behavioral and psychological problems and consequently reducing the need to prescribe psychotropic medications, thereby ameliorating gait and balance disorders. The aim of this study was to test the effects of continuous lavender olfactory stimulation on the incidence and risk of falls in elderly nursing home residents. To this end, a randomized placebo-controlled trial was conducted using a paper patch with or without lavender attached daily by care staff to the inside of the clothes near the neck of nursing home residents.

METHODS

Study Design, Participants, and Setting

The trial was conducted in three nursing homes randomly selected from 24 nursing homes in Aomori city, northern Japan. Inclusion criteria for eligible subjects were aged 65 and older and the ability to transfer independently regardless of assistive devices used. Recruitment occurred between September 10, 2009, and January 27, 2010. Of the 155 residents meeting the eligibility criteria, 10 were excluded; three did not provide informed consent, three moved before the trial began, and four had pica disorder. Residents with pica disorder, the unusual desire to eat

“unnatural” things for food, were excluded because of the risk that they would eat the patch.

In each nursing home, the eligible residents were randomized to the lavender group or placebo group at a 1:1 ratio. An independent statistician performed resident allocations using computer-generated randomization of numbers at each nursing home. Treatment allocation status was delivered to the head nurse at each nursing home, and patches were prepared accordingly. Participants and study staff were blinded to the treatment groups and outcome measurements. One hundred and forty-five residents were randomized: 73 to the lavender group and 72 to the placebo group.

The ethics board of Tohoku University Graduate School of Medicine approved the study protocol, and the study design took into account the principles set out in the Helsinki Declaration (Seoul, 2008). The protocol was registered to UMIN Clinical Trials Registry identifier (UMIN000004222).

Intervention

Lavender olfactory stimulation was provided using a commercially available white patch (1 cm × 2 cm, Aromaseal Lavender; Hakujuji Co., Tokyo, Japan). This patch, attached to the inside of the resident's clothes near the neck, was originally developed to make busy and stressful people relax by providing continuous olfactory exposure to lavender for 24 hours. The odor is so faint that only the person wearing the patch can sense it. The price of one patch is 25 cents U.S. The placebo patch was an Aromaseal that had not been processed and was unscented. Nursing home staff, blinded to which Aromaseal was the placebo, affixed the lavender or placebo patch to the resident's clothing and replaced the patch daily. The head nurse prepared the appropriate patches and distributed them to the nursing home staff accordingly. Residents wore the patch for the whole day. At the time the patch was changed, the nursing home staff confirmed the existence of the prior day's patch; if the patch was missing, it was reported. The intervention finished 360 days after the start unless a resident dropped out. The final participants finished follow-up on January 14, 2011.

Measurements

The primary outcome measure was resident falls. For this study, a fall was defined in accordance with the World Health Organization's definition: “an event which results in a person coming to rest inadvertently on the ground or floor or other lower level.”^{17,18} The nursing home staff, blinded to group allocation, were trained to identify falls according to this definition and recorded falls daily using fall calendar sheets. The head nurse supervised the recording of falls regularly, and the calendar sheets were audited monthly to ensure agreement with incident reports. Individual nursing notes were also cross-checked for duplication and missed falls.

Trained research assistants, blinded to group allocation and information from previous evaluations, collected demographic and behavioral measures at baseline and 12-month follow-up. Behavioral measurements included the Cohen-Mansfield Agitation Inventory (CMAI) to quantify

BPSD,¹⁹ the Barthel Index to assess level of functional ability, the MMSE to assess cognitive function, and the Vitality Index to assess activity of daily living (ADL)-related vitality.²⁰ The resident and caregiver assessed fall history in the previous year, and the staff was consulted and nursing notes and resident charts reviewed. To predict the probability of falling, visual, transfer, and mobility status were assessed using the St. Thomas's Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY).²¹ Medication status was assessed from medical chart reviews.

Statistics

Initial comparisons of outcome measures between groups were performed using chi-square tests or Mann-Whitney tests, as appropriate. Kaplan-Meier plots were used to compare time to first fall between groups.

Analyses for main outcomes, including time to first fall and number of falls per person-year, were based on an intention-to-treat analysis. Kaplan-Meier analyses and log-rank statistics were used to compare the proportion of fallers to non-fallers over time between groups. For consideration of covariance in time to first fall analysis between groups, a multivariate Cox proportional hazards regression was performed. A comparison of the number of falls per person-year between groups was performed using a multivariate Poisson regression model regarding the observation time as the offset variable. To confirm robustness in the Poisson regression model, the standard errors of each coefficient were adjusted by multiplying the unadjusted standard errors by the square root of the multiplicative overdispersion factor.

In multivariate analyses, age category (65–74 vs ≥ 75), sex, history of fall in a previous year (presence vs absence), cognitive function (MMSE score < 24 vs ≥ 24), agitation status (CMAI 22 = not agitated vs ≥ 23 = shows signs of agitation), transfer status (STRATIFY transfer and mobility score 0, 1, 2, 5, 6, or 3, 4), visual status (STRATIFY 1 or 2), number of medications (< 5 vs ≥ 5), and use of tranquilizers (yes vs no) were regarded as possible covariates for the Model 1 multivariate analysis. In the Model 2 analysis, variables that achieved a significance level of $P < .2$ in the univariate analysis were subsequently included in a multivariate analysis using the stepwise forward Cox regression procedure and the Poisson regression procedure, respectively. To elucidate the mechanisms underlying the effects of lavender olfactory stimulation, an analysis for secondary outcomes, such as changes in CMAI, Barthel Index, MMSE, and Vitality Index were performed using a per protocol analysis. Normality of the data was assessed using the Shapiro-Wilk test. Comparisons between groups were performed using the Mann-Whitney test. Comparisons within groups at different time points were performed using the Wilcoxon signed-rank test or the paired Student *t*-test.

The analysis of outcomes for fallers and falls (Table 2) was done on the intention-to-treat analysis set, whereas the comparison of treatment groups at baseline and follow-up (Table 3) used the per protocol analysis set. All *P*-values were two-sided to detect a significance level of $P < .05$. Analyses were performed using SAS software version 9.2 (SAS Institute, Inc., Cary, NC).

Sample Size

To calculate the required sample size, the number of falls per person-year was focused on, based on data from similar nursing homes in Japan.²² When the sample size in each group is 69, with a total number of events required (*E*) of 55, an exponential maximum likelihood test of equality of survival curves with a .05, two-sided significance level will have an 80% power to detect the difference between a placebo exponential parameter (l_1) of 0.8500 and an active exponential parameter (l_2) of 0.4000 (constant hazard ratio (HR) = 2.125); this assumes an accrual period of 0.10, a maximum follow-up time of 1.00, and no dropouts.²³

RESULTS

A flowchart of enrollment, randomization, and follow-up is shown in Figure 1. No significant differences were observed between the lavender and placebo groups in the proportion who withdrew or in their reasons for withdrawal. No participants refused the lavender-scented patch, and there were no adverse effects reported due to exposure to the lavender. The baseline and demographic characteristics of residents allocated to each group are summarized in Table 1. The groups did not differ significantly according to age or risk factors for falls. No participants had missing values on primary outcome measures before death or discharge from nursing homes.

There were 62 falls reported during the follow-up period (Table 2); only two resulted in injury, a subdural hemorrhage in the lavender group and a femoral neck fracture in the placebo group. The percentages of participants who

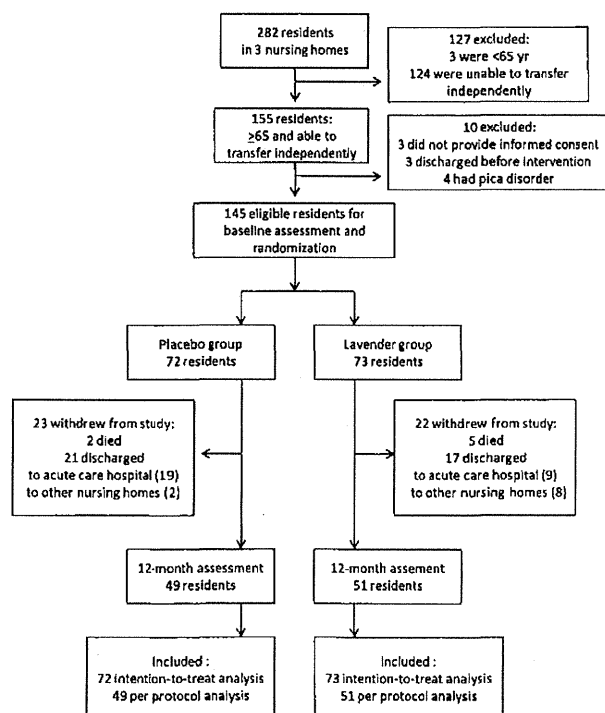


Figure 1. Flowchart for enrollment, randomization, and follow-up of study participants.

Table 1. Baseline Characteristics of Participants (n = 145)

Characteristic	Placebo, n = 72	Lavender, n = 73	P-Value
Age, mean ± SD	84.1 ± 7.7	84.2 ± 7.8	.93 ^a
≥ 75 years, n (%)	62 (86.1)	64 (87.7)	.81 ^b
Female, n (%)	13 (18.1)	14 (19.2)	>.99 ^b
Comorbidity, n (%)			
History of stroke	23 (31.9)	24 (32.9)	>.99 ^b
Diabetes mellitus	12 (16.7)	18 (24.7)	.31 ^b
Osteoarthritis	1 (1.4)	1 (1.4)	>.99 ^c
Parkinson's disease	1 (1.4)	1 (1.4)	>.99 ^c
Visual impairment	6 (8.3)	10 (13.7)	.42 ^b
Barthel Index, mean ± SD	49.6 ± 19.2	50.3 ± 18.5	.82 ^a
Mini-Mental State Examination score, mean ± SD	14.6 ± 8.1	15.3 ± 8.4	.61 ^a
<24, n (%)	59 (81.9)	60 (82.2)	>.99 ^b
Cohen-Mansfield Agitation Inventory score, mean ± SD	24.6 ± 6.9	24.2 ± 5.2	.61 ^a
≥ 23, n (%)	18 (25.0)	23 (31.5)	.46 ^b
Vitality Index, mean ± SD	8.1 ± 1.9	8.1 ± 2.0	.73 ^a
History of falls, n (%)	30 (41.7)	31 (42.5)	>.99 ^b
History of recurrent falls, n (%)	11 (15.3)	10 (13.7)	.49 ^b
Transfer risk, n (%)	34 (47.2)	41 (56.1)	.32 ^b
Mobility status ^d , n (%)			
Walk without aids	52 (72.2)	53 (72.6)	.88 ^b
Walk with aids	16 (22.2)	17 (23.3)	
Use a wheelchair	4 (5.6)	3 (4.1)	
Number of medications, mean ± SD	4.9 (2.7)	5.0 (2.3)	.85 ^a
≥ 5, n (%)	37 (51.4)	37 (9.6)	>.99 ^b
Prescription medications, n (%)			
Tranquilizer	15 (20.8)	10 (13.7)	.28 ^b
Antidepressant	1 (1.4)	2 (2.7)	>.99 ^c
Yokukansan	6 (8.3)	5 (6.8)	.77 ^b
Diuretics	11 (15.3)	15 (20.5)	.52 ^b
Antihypertensive	43 (59.7)	45 (61.6)	.87 ^b
Antidiabetic drugs	7 (9.7)	11 (15.1)	.45 ^b

SD, standard deviation.
^a Mann-Whitney U-test.
^b Chi-square test.
^c Fisher exact test.
^d Moving to the bathroom.

fell at least once during the 12-month study period were 35.6% (lavender group) and 50% (placebo). There were no significant differences observed when examining Kaplan Meier plots of time to first fall between treatment groups ($P = .11$) or in relation to tranquilizer use ($P = .16$).

The crude results of the Cox proportional hazards analysis on the intention-to-treat analysis set were not significant (Table 2), although after adjustment for covariates between the lavender and placebo groups, the differences for first fall were significant for Models 1 ($P = .04$) and 2 ($P = .03$). The HR of the intervention to placebo group was 0.59 (95% confidence interval (CI) = 0.35–0.99) after adjustment for age, sex, fall history, MMSE, CMAI, transfer and visual status, and tranquilizer use (Model 1). The HR decreased to 0.57 (95% CI = 0.34–0.95) after adjustment for MMSE, fall history, and transfer (Model 2).

Table 2. Outcomes for Fallers and Falls

Outcome	Placebo, n = 72	Lavender, n = 73	P-Value
Intervention days, mean ± standard deviation	313.8 ± 76.3	287.6 ± 114.5	.78 ^a
Faller, yes/no	36/36	26/47	.08 ^b
Recurrent faller, yes/no	23/49	14/59	.08 ^b
Total number of falls, n	88	46	
Fall rate per person-year	1.40	1.04	
Hazard ratio for fallers (95% CI)			
Crude	1	0.67 (0.40–1.10)	.11 ^a
Adjusted (Model 1)	1	0.59 (0.35–0.99)	.04 ^c
Adjusted (Model 2)	1	0.57 (0.34–0.95)	.03 ^c
Incidence rate ratio for fallers (95% CI)			
Crude	1	0.57 (0.32–0.99)	.04 ^d
Adjusted (Model 1)	1	0.54 (0.31–0.95)	.03 ^d
Adjusted (Model 2)	1	0.51 (0.30–0.88)	.02 ^d

CI, confidence interval.
 Model 1 adjusted for age, sex, fall history, Mini-Mental State Examination (MMSE) score, Cohen-Mansfield Agitation Inventory, transfer status, visual status, tranquilizer. Model 2 adjusted for MMSE score, fall history, transfer (selected using stepwise variable selection).
^a Mann-Whitney U-test.
^b Chi-square test.
^c Cox proportional hazard regression.
^d Poisson regression model.

The number of falls per person during the follow-up period ranged from zero to five in the lavender group and zero to seven in the placebo group. As shown in Table 2, the incidence rate for the lavender group was significantly lower than for the placebo group even before adjustment for possible covariates ($P = .04$). The incidence rate ratio (IRR) in crude analysis was 0.57 (95% CI = 0.32–0.99). After adjustment for age, sex, fall history, MMSE, CMAI, transfer and visual status, and tranquilizer use (Model 1), the IRR decreased to 0.54 (95% CI = 0.31–0.95). After adjustment for MMSE, fall history, and transfer status (Model 2), the IRR further decreased to 0.51 (95% CI = 0.30–0.88).

Table 3 shows the results of per protocol analyses for changes in functional ability (Barthel Index), cognitive function (MMSE), volition (Vitality Index), and agitation (CMAI) after 12 months of treatment. No differences were observed between groups at baseline or 12 months for any of the indexes analyzed. The lavender and placebo groups showed a significant decrease in cognitive functioning at 12-month follow-up. When comparing CMAI scores at 12-month follow-up, the lavender group showed a significant decrease in agitated status ($P = .04$) from baseline, but the placebo group did not. The Barthel and Vitality indexes did not change significantly from follow-up in either group. The average number of medications at 12-month follow-up was 4.73 ± 2.17 in the lavender group and 4.57 ± 2.17 in the placebo group.

During the study period, one resident from each group was newly prescribed tranquilizers. At 12-month follow-up, six residents in the lavender group and 10 in the placebo group were prescribed tranquilizers. No significant difference was observed in the number of residents

Table 3. Comparison of Groups at Baseline Versus Follow-Up in Per Protocol Analyses

Test	Placebo (n = 49)			Lavender (n = 51)		
	Baseline	Follow-Up	P-Value	Baseline	Follow-Up	P-Value
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Barthel Index	50.0 ± 1.91	47.5 ± 21.0	.09 ^a	49.6 ± 18.3	49.5 ± 18.5	.94 ^b
Mini-Mental State Examination score	14.6 ± 21.0	11.9 ± 8.4	<.001 ^a	15.3 ± 9.2	13.4 ± 9.1	<.001 ^a
Cohen-Mansfield Agitation Inventory score	24.5 ± 6.7	24.0 ± 3.7	.82 ^a	24.3 ± 5.4	22.9 ± 2.3	.04 ^a
Vitality Index	8.2 ± 1.7	8.1 ± 2.3	.76 ^a	8.2 ± 2.0	8.1 ± 2.2	.90 ^a

SD, standard deviation.

No difference was observed between groups at baseline and after 12-month interventions for each index according to the Mann-Whitney *U*-test. *P*-value was comparison between baseline and post intervention according to ^aWilcoxon rank test or ^bpaired Student *t*-test.

prescribed tranquilizers between the groups at baseline ($P = .78$) or the end of the trial ($P = .71$). One resident from the lavender group and one from the placebo group took vitamin D (1 µg) daily; neither of them fell during the study period.

DISCUSSION

This study highlights the beneficial effects of lavender odor on fall prevention in elderly nursing home residents. This multifacility randomized placebo-controlled study showed that daily use of a lavender patch was associated with a lower incidence rate of falls. Although not significant, the number of residents who fell during the observation period ($P = .08$) and those who fell two or more times during the 12-month study ($P = .11$) was less in the lavender group. After adjustment for possible confounding factors, the proportion of residents who were nonfallers over time was significantly lower in the lavender group.

The mechanism by which lavender prevents falls is speculative. Lavender oil is used extensively in aromatherapy and is described as therapeutic for insomnia, headaches, migraines, anxiety, nervousness, and melancholy.²⁴ Lavender has been used as a sleep aid and can be a useful nonpharmacological alternative to traditionally prescribed medications for insomnia, which are strong risk factors for falls in elderly adults.²⁵ Because lavender is thought to have soothing properties, it is logical to assume it may also affect the anxiety and agitation that underlie BPSD. The lavender group showed a significant decrease in agitated status, whereas the placebo group did not, suggesting the involvement of a soothing effect of lavender odor. There was not significant less tranquilizer use in the lavender group than in the placebo group, so tranquilizer use was not viewed as a potential confounding factor in the present study. The frequency of tranquilizer use was lower in the current study than in other studies in nursing homes, probably because of Yokukansan use, a traditional Asian medicine commonly prescribed to treat BPSD.^{26,27} Although there was no difference in Yokukansan use between the lavender and placebo groups, further study is warranted to elucidate the relationship between Yokukansan, tranquilizers, and lavender olfactory stimulation.

Another possible explanation for why lavender prevents falls might be attributed to its stabilizing effects on balance. In previous work, the application of olfactory

stimulation by an essential oil such as lavender and black pepper during quiet standing was associated with less postural sway in frail elderly adults.¹⁰ Multiple sensory and motor mechanisms ranging from peripheral to cortical sensory-motor integration regulate the control of posture and motion.²⁸ In addition to vestibular afferents, visual and proprioceptive inputs contribute to postural stability. Although several multisensory vestibular cortical areas, which process signals provided from multiple thalamic nuclei, were identified using imaging studies, the core vestibular cortical region is thought to be located in the insular cortex.²⁹ Odor is one of the strongest stimuli over a wide area of the cerebral cortex including the insular cortex.³⁰ Olfactory stimulation may stabilize balance by activation of the insular cortex. Unfortunately, a limitation of the present study is the lack of balance data. Further studies are needed to clarify the contribution of the balance-stabilizing effects of lavender on fall prevention.

Only two residents were prescribed vitamin D (1 in each group). Vitamin D supplementation is an easy pharmacotherapy to prevent falls in nursing home residents.^{1,7} The current evidence recommends that vitamin D be prescribed in a dosage of 1,000 IU for nursing home residents. Vitamin D may be effective in reducing falls and increasing muscle strength in persons with severe vitamin D deficits,¹ but current evidence of risk reduction of falls with vitamin D supplementation is inconsistent.⁷

Several current guidelines recommend multifactorial risk assessment of falls and interventions customized to an individual's risk factor profile as a primary treatment strategy in community-dwelling elderly people.^{1,31} Several randomized controlled trials have investigated the effectiveness of this strategy in nursing home residents,³²⁻³⁹ and only some of the trials showed efficacy in reducing falls.³⁶⁻³⁹ It is unclear whether differences in effectiveness may be attributed to a variation in the type of intervention or selection bias. The sample population recruited into trials may not be representative of the general elderly population (e.g., lack of studies that include participants with multiple comorbidities or cognitive decline). It is important to develop a suitable program for multifactorial intervention in each facility setting.

The present study has several limitations. First, it was conducted with nursing home residents, so results cannot be generalized to community-dwelling elderly people. Second, although the study showed that lavender olfactory

stimulation prevents falls in elderly nursing home residents, it was not powered to detect a clinically relevant reduction in injurious falls because the incidence of such events was low. Third, as is the nature of odor application, nursing home residents and staff may not have been completely blinded, which may have resulted in reporting bias. Finally, the olfactory functioning of the participants was not tested. Difficulty in identifying odor has been reported not only in individuals with Alzheimer's and Parkinson's diseases,⁴⁰ but also in elderly persons without cognitive impairment.⁴¹ Therefore, it was possible there were residents who could not sense the lavender odor.

A meta-analysis showed that a multifactorial intervention including exercise training for balance stability reduced the risk and rate of falls in community-dwelling elderly adults.²⁵ Moreover, gradual withdrawal of some types of drugs for improving sleep, reducing anxiety, and treating depression have been shown to reduce the rate of falls.²⁵ Lavender olfactory stimulation acts on balance and psychological status, suggesting that it may have the ability to reduce falls in nursing home residents and community dwelling-elderly adults.

CONCLUSION

Daily olfactory stimulation with lavender may prevent falls in elderly nursing home residents. Further studies with large sample sizes comprising multiple ethnic groups are warranted to confirm these findings.

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REFERENCES

- Perry BC. Falls among the elderly: A review of the methods and conclusions of epidemiologic studies. *J Am Geriatr Soc* 1982;30:367-371.
- Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. *Ann Intern Med* 1994;121:442-451.
- Quigley P, Bulat T, Kurtzman E et al. Fall prevention and injury protection for nursing home residents. *J Am Med Dir Assoc* 2010;11:284-293.
- Becker C, Rapp K. Fall prevention in nursing homes. *Clin Geriatr Med* 2010;26:693-704.
- van Doorn C, Gruber-Baldini AL, Zimmerman S et al. Epidemiology of dementia in nursing homes research group. Dementia as a risk factor for falls and fall injuries among nursing home residents. *J Am Geriatr Soc* 2003;51:1213-1218.
- Axer H, Axer M, Sauer H et al. Falls and gait disorders in geriatric neurology. *Clin Neurol Neurosurg* 2010;112:265-274.
- Cameron ID, Murray GR, Gillespie LD et al. Interventions for preventing falls in older people in nursing care facilities and hospitals. *Cochrane Database Syst Rev* 2010;1:CD005465.
- Baker DI, King MB, Fortinsky RH et al. Dissemination of an evidence-based multicomponent fall risk-assessment and -management strategy throughout a geographic area. *J Am Geriatr Soc* 2005;53:675-680.
- Tinetti ME, Gordon C, Sogolow E et al. Fall-risk evaluation and management: Challenges in adopting geriatric care practices. *Gerontologist* 2006;46:717-725.
- Freeman S, Ebihara S, Ebihara T et al. Olfactory stimuli and enhanced postural stability in older adults. *Gait Posture* 2009;29:658-660.
- Ebihara S, Nikkuni E, Ebihara T et al. Effects of olfactory stimulation on gait performance in frail older adults. *Geriatr Gerontol Int*, in press.
- Snow LA, Hovanec L, Brandt J. A controlled trial of aromatherapy for agitation in nursing home patients with dementia. *J Altern Complement Med* 2004;10:431-437.
- Fujii M, Hatakeyama R, Fukuoka Y et al. Lavender aroma therapy for behavioral and psychological symptoms in dementia patients. *Geriatr Gerontol Int* 2008;8:136-138.
- Opie J, Doyle C, O'Connor DW. Challenging behaviours in nursing home residents with dementia: A randomized controlled trial of multidisciplinary interventions. *Int J Geriatr Psychiatry* 2002;17:6-13.
- Schneider LS, Dagerman K, Insel PS. Efficacy and adverse effects of atypical antipsychotics for dementia: Meta-analysis of randomized, placebo-controlled trials. *Am J Geriatr Psychiatry* 2006;14:191-210.
- O'Connor DW, Ames D, Gardner B et al. Psychosocial treatments of behavior symptoms in dementia: A systematic review of reports meeting quality standards. *Int Psychogeriatr* 2009;21:225-240.
- World Health Organization. WHO Global Report on Falls Prevention in Older Age [on-line]. Available at http://www.who.int/ageing/publications/falls_prevention7March.pdf Accessed February 20, 2010.
- Haines TP, Hill AM, Hill KD et al. Patient education to prevent falls among older hospital inpatients: A randomized controlled trial. *Arch Intern Med* 2011;171:516-524.
- Cohen-Mansfield J, Marx MS, Rosenthal AS. A description of agitation in a nursing home. *J Gerontol* 1989;44:M77-M84.
- Toba K, Nakai R, Akishita M et al. Vitality Index as a useful tool to assess elderly with dementia. *Geriatr Gerontol Int* 2002;2:23-29.
- Oliver D, Britton M, Seed P et al. Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: Case-control and cohort studies. *BMJ* 1997;315:1049-1053.
- Harada A, Mizuno M, Takemura M et al. Hip fracture prevention trial using hip protectors in Japanese nursing homes. *Osteoporos Int* 2001;12:215-221.
- Lakatos E, Lan KKG. A comparison of sample size methods for the log-rank statistic. *Stat Med* 1992;11:179-191.
- Collett D. *Modelling Survival Data in Medical Research*. London: Chapman & Hall, 1994.
- Woronuk G, Demissie Z, Rheault M et al. Biosynthesis and therapeutic properties of Lavandula essential oil constituents. *Planta Med* 2011;77:7-15.
- Gillespie LD, Robertson MC, Gillespie WJ et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2009;2:CD007146.
- Iwasaki K, Satoh-Nakagawa T, Maruyama M et al. A randomized, observer-blind, controlled trial of the traditional Chinese medicine Yi-Gan San

- for improvement of behavioral and psychological symptoms and activities of daily living in dementia patients. *J Clin Psychiatry* 2005;66:248-252.
28. Iwasaki K, Kosaka K, Mori H et al. Open label trial to evaluate the efficacy and safety of Yokukansan, a traditional Asian medicine, in dementia with Lewy bodies. *J Am Geriatr Soc* 2011;59:936-938.
 29. Lackner JR, DiZio P. Vestibular, proprioceptive, and haptic contributions to spatial orientation. *Annu Rev Psychol* 2005;56:115-147.
 30. Lopez C, Blanke O. The thalamocortical vestibular system in animals and humans. *Brain Res Rev* 2011;67:119-146.
 31. Soudry Y, Lemogne C, Malinvaud D et al. Olfactory system and emotion: Common substrates. *Eur Ann Otorhinolaryngol Head Neck Dis* 2011;128:18-23.
 32. The NICE guideline on assessing and preventing falls in elderly people [online]. Available at www.nice.org.uk/CG021NICEguideline Accessed December 20, 2010.
 33. McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. *Gerontology* 2000;46:83-87.
 34. Nowalk MP, Prendergast JM, Bayles CM et al. A randomized trial of exercise programs among older individuals living in two long-term care facilities: The Falls FREE program. *J Am Geriatr Soc* 2001;49:859-865.
 35. Dyer CA, Taylor GJ, Reed M et al. Falls prevention in residential care homes: A randomised controlled trial. *Age Ageing* 2004;33:596-602.
 36. Kerse N, Butler M, Robinson E et al. Fall prevention in residential care: A cluster, randomized, controlled trial. *J Am Geriatr Soc* 2004;52:524-531.
 37. Ray WA, Taylor JA, Meador KG et al. A randomized trial of a consultation service to reduce falls in nursing homes. *JAMA* 1997;278:557-562.
 38. Jensen J, Lundin-Olsson L, Nyberg L et al. Fall and injury prevention in older people living in residential care facilities. A cluster randomized trial. *Ann Intern Med* 2002;136:733-741.
 39. Becker C, Kron M, Lindemann U et al. Effectiveness of a multifaceted intervention on falls in nursing home residents. *J Am Geriatr Soc* 2003;51:306-313.
 40. Meshulam RI, Moberg PJ, Mahr RN et al. Olfaction in neurodegenerative disease: A meta-analysis of olfactory functioning in Alzheimer's and Parkinson's diseases. *Arch Neurol* 1998;55:84-90.
 41. Wilson RS, Schneider JA, Arnold SF et al. Olfactory identification and incidence of mild cognitive impairment in older age. *Arch Gen Psychiatry* 2007;64:802-808.

RELATIONSHIP BETWEEN TESTOSTERONE AND COGNITIVE FUNCTION IN ELDERLY MEN WITH DEMENTIA

To the Editor: A decrease in sex hormones with aging has been reported to be related to psychosomatic disorders such as late-onset hypogonadism syndrome, frailty, and cognitive impairment in adult men.¹ For example, a community-based cross-sectional study has shown that elderly men with a lower blood concentration of bioavailable testosterone have more-severe impairment of cognitive function.² Moreover, a longitudinal study indicated that serum free testosterone (FT) concentration could predict memory performance and cognitive status in elderly men,³ but it is unknown whether lower testosterone concentration is related to cognitive impairment in individuals with dementia, because the previous studies primarily focused on a healthy community-based population. Also, few studies have addressed the relationship between testosterone and cognitive function in elderly Japanese men.

One recent cross-sectional study showed that total testosterone and FT concentration were associated with activities of daily living (ADLs) in institutionalized elderly men.⁴ This study also revealed that a relationship between testosterone and cognitive function could be found even in institutionalized elderly men with physical or neuropsychiatric dysfunction. Thus, whether lower testosterone concentration is related to deterioration of ADL in elderly men with cognitive impairment was longitudinally investigated.

Fifty-two male outpatients attending the Center for Comprehensive Care on Memory Disorders at Kyorin University Hospital were recruited (mean age 77.0 ± 5.5 , range 65–87). Participants' clinical backgrounds were hypertension, 48.9%; diabetes mellitus, 12.2%; and dyslipidemia, 38.1%. None had a history of stroke. Comprehensive geriatric assessment was performed based on basic ADLs (Barthel Index),⁵ instrumental ADLs (Lawton and Brody IADLs, 0–5 points in men),⁶ cognitive function (Mini-Mental State Examination (MMSE)),⁷ mood (Geriatric Depression Scale (GDS), 15 items),⁸ and vitality (Vitality Index, 10-point scale).⁹ This assessment was repeated 1, 2, and 3 years after baseline assessment at the first visit to the clinic. At the first visit, blood was drawn after an overnight fast and FT concentration was measured using radioimmunoassay. FT values ranged from 1.0 to 53.0 pmol/L (mean \pm SD 30.4 ± 11.0 pmol/L). Participants were classified into three groups according to tertile according to the baseline FT value (Figure 1), and the parameters from the comprehensive geriatric assessment were compared between groups and visits. Statistical data were analyzed using SPSS version 17.0 (SPSS, Inc., Chicago, IL). One-way analysis of variance (ANOVA) was applied for comparisons between groups, and the Fisher post hoc test was applied when significant ($P < .05$). One-way repeated ANOVA was used for comparisons between baseline and the 1-, 2-, and 3-year visits, and the Fisher post hoc test was applied when significant ($P < .05$).

There were no significant differences between groups in age (high, 75.3; middle, 76.6; low, 79.0), basic ADLs (high, 96.9; middle, 99.1; low, 95.3 points), MMSE (high, 23.2; middle, 25.1; low, 23.1 points), GDS-15 (high, 5.1; middle,

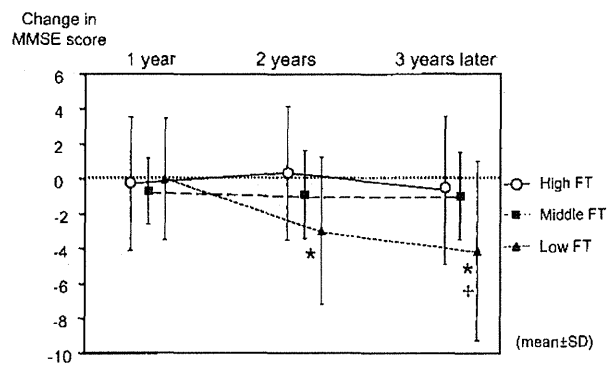


Figure 1. Change in Mini-Mental State Examination (MMSE) score according to tertile of serum free testosterone (FT) level in men. FT tertile: high, >36.1 pmol/L, $n = 17$; middle, 29.1 – 35.4 pmol/L, $n = 17$; low, <28.8 pmol/L, $n = 18$. * $P < 0.05$ vs highest FT group, + $P < 0.05$ vs middle FT group.

4.1; low, 4.6 points), and Vitality Index (high, 9.1; middle, 9.1; low, 8.8 points) at baseline, whereas IADLs tended to be lower (high, 4.1; middle, 4.1; low, 3.4 points, $P = .06$) in the low FT tertile group than in the other groups.

At the 1-year visit, there was no difference in change in MMSE score from baseline between the groups, although the decrease in MMSE score was larger in the low FT tertile group than in the middle and high tertile groups at the 2- and 3-year visits (Figure 1). Also, MMSE scores were lower in the low FT tertile group at the 2- ($P = .009$) and 3-year ($P < 0.001$) visits than at baseline, whereas they were not lower in the middle and high tertile groups. In contrast, there was no such trend in basic ADLs, IADLs, GDS scores, and Vitality Index.

Multiple regression analysis was performed with a decrease in MMSE score as a dependent variable and age; ADLs; body mass index; presence of hypertension, diabetes mellitus, or hyperlipidemia; and FT concentration as independent variables to consider factors affecting cognitive impairment, according to a previous report.⁴ Blood FT concentration was found to be an independent predictor of decrease in MMSE score at the 3-year visit ($\beta = 0.492$, $P = .02$).

A number of investigations support the biological plausibility of a protective effect of testosterone against cognitive dysfunction. The present findings from memory clinic outpatients are consistent with previous findings observed in elderly community-based men, showing a relationship between FT concentration and cognitive performance.³ Furthermore, the present findings indicate that a lower FT concentration could lead to a faster decline in cognitive function in elderly Japanese men who already show cognitive impairment. This study provides fundamental data for the future study of hormone replacement therapy for cognitive decline in elderly adults with low FT.

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REFERENCES

1. Ulubaev A, Lee DM, Purandare N et al. Activation effects of sex hormones on cognition in men. *Clin Endocrinol* 2009;71:607-623.
2. Yaffe K, Lui LY, Zmuda J et al. Sex hormones and cognitive function in older men. *J Am Geriatr Soc* 2002;50:707-712.
3. Muffar SD, Zonderman AB, Metter EJ et al. Longitudinal assessment of serum free testosterone concentration predicts memory performance and cognitive status in elderly men. *J Clin Endocrinol Metab* 2002;87:5001-5007.
4. Fukai S, Akishita M, Yamada S et al. Association of plasma sex hormone levels with functional decline in elderly men and women. *Geriatr Gerontol Int* 2009;9:282-289.
5. Mahoney FI, Barthel DW. Functional evaluation: Barthel Index. *Md State Med J* 1965;14:61-65.
6. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist* 1969;9:179-186.
7. Folstein MF, Folstein SE, McHugh PR. 'Mini-Mental State'. A practical method for grading the cognitive state of patients for clinician. *J Psychiatr Res* 1975;12:189-198.
8. Yesavage JA. Geriatric Depression Scale. *Psychopharmacol Bull* 1988;24:709-711.
9. Toba K, Nakai R, Akishita M et al. Vitality Index as a useful tool to assess elderly with dementia. *Geriatr Gerontol Int* 2002;2:23-29.

BASELINE INSTRUMENTAL ACTIVITIES OF DAILY LIVING AND INCIDENT DEMENTIA

To the Editor: Sikkes et al.¹ have written an important paper showing that individuals without dementia with impairment in at least one of nine instrumental activities of daily living (IADLs) at baseline had a significantly higher incidence of dementia at 12 months (24.4%) than individuals without IADL impairment at baseline (16.7%) ($P = .04$). Their 531 participants who were followed for 12 months were relatively young (mean age 69.6), so it was decided to duplicate their study from prospective data from the Wyong Hospital Memory Clinic, 100 km north of Sydney. From 415 individu-

als attending a memory clinic, community-dwelling individuals aged 60 and older who were free of dementia at baseline and had a Mini-Mental State Examination score (MMSE²) of 25 to 30 and a follow-up MMSE and Montreal Cognitive Assessment (MoCA), range 0 (worst) to 30 (best)³ at 12 months were selected in a consensus conference of a geriatrician (PJ) and a clinical nurse consultant (EH). Each individual's family rated IADLs on the Nottingham scale,⁴ which ranged from 0 (worst) to 22 (best). Twenty-two of 82 (27%) converted to dementia at 12 months, compared with Sikkes conversion rate of 20.8% at 24 months—the most likely reason for this difference was that mean age (79.1) was 9.5 years older than theirs (69.6). Stats Direct Version 2.7.8b (StatsDirect Ltd, Altrincham, UK) from November 2011 was used to compare converters and nonconverters. Mean age of the 22 converters at baseline was significantly higher than that of the 60 nonconverters (82.0 ± 5.8 vs 78.0 ± 6.8 , $P < .01$), mean IADL score at baseline was significantly lower (13.1 ± 5.3 vs 16.1 ± 4.0 , $P = .0236$), MMSE score at baseline was by definition lower (25.6 ± 0.73 vs 27.5 ± 1.50 , $P < .001$), and MoCA score at baseline was lower (19.2 ± 3.5 vs 22.8 ± 3.9 , $P < .001$). At 12 months, IADL (11.4 ± 5.6 vs 15.4 ± 4.5 , $P = .004$), MMSE score (21.6 ± 4.5 vs 27.4 ± 1.6 , $P < .001$), MoCA (16.8 ± 3.6 vs 22.8 ± 4.2 , $P < .001$) remained significantly lower in converters.

The Nottingham IADL covers seven of the nine IADL items that Sikkes used, excluding medications and finances. Women are more likely than men to perform five of the Nottingham IADL items unless the men live alone with no home care services: cleaning the kitchen, making a hot snack, washing small items of clothing, doing a full clothes wash, and doing housework.

Although the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, criteria for dementia include a decline in social and occupational function, there is a surprising lack of research into IADLs as a predictor of incident dementia. This is an important topic for future research and ongoing studies are being conducted in three cohorts: Wyong Memory Clinic; general medical inpatients with delirium or subsyndromal delirium—a prospective randomized controlled trial, Central Coast Australia Delirium Intervention Study; and PhD study, PR DEFEAT DELIRIUM, in outpatients at high risk for incident delirium. One study⁵ with 255 community-dwelling individuals attending a memory clinic who were followed an average of 13 months has been published. The 11.4% of participants with antithyroid antibodies had similar outcomes at 12 months with respect to IADLs, decline in IADLs, MMSE and MoCA scores, and transfer to residential care.

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LETTERS TO THE EDITOR

New dorsiflexion measure device: A simple method to assess fall risks in the elderly

Dear Editor,

Hip fracture is the third leading cause yielding bedridden status in Japan, and more than 80% of hip fractures are reported to be caused by falling. There are a variety of causes for falls in the elderly, and one of the significant causes is the inability to lift their toes when they walk. Here, we show a new device to measure dorsiflexion angle, an instrument that we developed to assess fall risks in the elderly.

Participants were requested to stand up straight and step back until the hip leaned on the wall (Fig. 1a). The fulcrum of the instrument was adjusted to the center of the external malleolus (Fig. 1b). The arm of the instrument was set to stay level, adjusting the branching thin arm placed on the ridge of the dorsum of the foot. Then, participants were asked to dorsiflex as much as possible. The mean time to measure bilateral dorsiflexion angles was within 5 min.

We measured dorsiflexion and Fall Risk Index (FRI),^{1,2} including the history of falls within the past year, in 131 women (46–89 years, mean age 78.0 ± 7.1 years) and 88 men (46–93 years, mean age 76.2 ± 8.6 years) who visited the fall prevention clinic in Kyorin University Hospital. The occurrence of falls within the past year was 35.6%. Falls occurred 2.0 ± 0.1 times in fallers within 1 year, and women fell more frequently than men (42.7% vs 25.0%, $\chi^2 = 7.2$, $P \leq 0.01$). The average FRI score was 6.7 ± 3.4 in non-fallers and 10.6 ± 3.0 in fallers ($P < 0.0001$). Women showed a higher FRI score than men (8.8 ± 3.6 vs 7.0 ± 3.8, $P = 0.003$).

This new device appears promising in detecting the high-risk group of fallers, because the dorsiflexion angle was significantly smaller in fallers than non-fallers (right 9.6 ± 8.4 vs 13.7 ± 9.6 degrees, $P = 0.012$; left 10.0 ± 8.5 vs 14.2 ± 9.8 degrees, $P = 0.014$). Furthermore, the occurrence of falls was more frequent as the dorsiflexion angle decreased in women ($\chi^2 = 6.4$, $P = 0.042$; Fig. 1c), and half of the subjects, whose dorsiflexion angle was less than 10 degrees, experienced falls within a year.

Previously, it was reported that hip fractures occur more frequently in women than men, even though the incidence rate of falls was comparable until the age of 90 years. This is considered to be a result of the higher prevalence of osteoporosis in women.³ In contrast, the present study found that women less than 90 years-of-age fell more frequently than men in the Japanese population of this age group. We also found that the FRI score was higher in women than men, as has been shown previously.⁴ In addition, dorsiflexion angle was

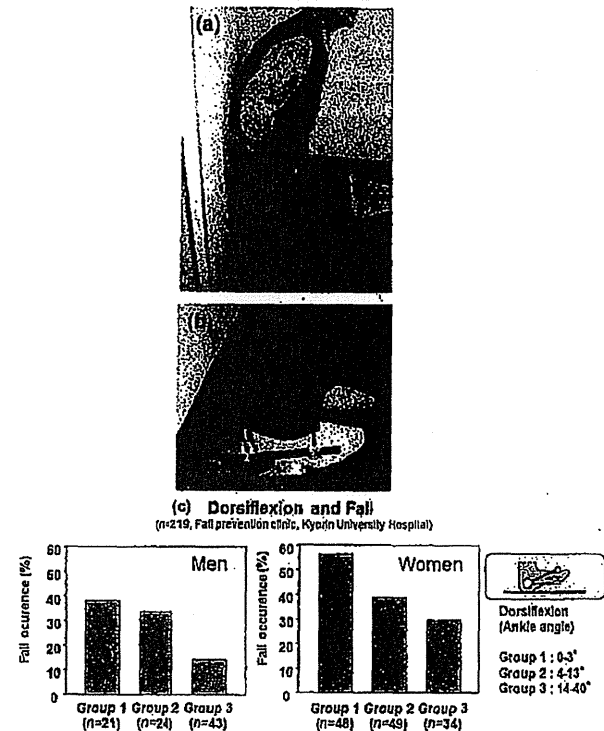


Figure 1 (a,b) How to measure dorsiflexion angle using a dorsiflexion measure device. (c) The relationship between dorsiflexion angle and the occurrence of falls within the past year. In men and women respectively, participants were grouped by tertile according to the dorsiflexion angle.

smaller in women than men (right 10.3 ± 8.4 vs 15.2 ± 10.1 degrees, $P = 0.0001$; left 11.0 ± 8.5 vs 15.2 ± 10.4 degrees, $P = 0.0013$), and a stepwise increase in the fall occurrence rate according to the level of dorsiflexion angle was evident in women (not significant in men). These results show that less ability to dorsiflex would partly explain the sex difference in the occurrence of falls and ensuing hip fracture.

The new dorsiflexion measure device we report here is easy and less time-consuming to use, and will be sure to help identify a high-risk group of fallers in the elderly.

Disclosure statement

This study was approved by the Ethics Committee of Kyorin University School of Medicine. Accordingly, written informed consent was obtained from all patients. All authors contributed significantly to this work and are

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References

- 1 Okochi J, Toba K, Takahashi T. Simple screening test for risk of falls in the elderly. *Geriatr Gerontol Int* 2006; 6: 223-227.
- 2 Wada T, Ishimoto Y, Matsubayashi K. Twenty-one-item fall risk index predicts falls in elderly community-dwelling Japanese. *J Am Geriatr Soc* 2009; 57: 2369-2371.
- 3 Campbell AJ, Borrie MJ, Spears GF, Jackson SL, Brown JS, Fitzgerald JL. Circumstances and consequences of falls experienced by a community population 70 years and over during a prospective study. *Age Ageing* 1990; 19: 136-141.
- 4 Ishimoto Y, Wada T, Matsubayashi K. Age and sex significantly influence fall risk in community-dwelling elderly people in Japan. *J Am Geriatr Soc* 2009; 57: 930-932.

認知症の包括的アプローチ

Comprehensive care and research on memory disorders

国立長寿医療研究センター 病院長

鳥羽 研二

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高齢者医療の目標は医師の調査で、認知症に限らず、QOLの重視が最重点課題で、延命が最下位に位置づけられているのと対照的である。

平成20年5月1日に、今後の認知症対策をさらに効果的に推進し、「たとえ認知症になっても安心して生活できる社会を早期に構築する」ための「認知症の医療と生活の質を高める緊急プロジェクト」が発表された。骨子は、早期の確定診断を出発点とした適切な対応の促進であり、具体的には、

- (1) 実態の把握
- (2) 研究開発の加速
- (3) 早期診断の推進と適切な医療の提供
- (4) 適切なケアの普及及び本人・家族支援
- (5) 若年性認知症対策

の五つの柱が掲げられている。

長寿科学研究朝田班による、認知症高齢者の実態調査の結果は、国民を震撼させる結果であった。高齢者の14.4%が認知症であるという罹患率は、高齢者人口に当てはめると400万人を超え、予備軍である軽度認知障害(Mild Cognitive Impairment; MCI)も同数存在することが初めて明らかになった。この結果は、認知症があらたな「国民病」であることを明確に示している。90歳以上では3/4以上が罹患する疾患に国民の不安は大きい。早期の予防戦略の充実、悪化阻止の新薬の開発の促進も重要であることは言をまたないが、開発に要する時間軸を考えると、発症した認知症患者に対する、医療関係者の根本的意識改革と、社会が認知症を「ありふれた疾患」として受け入れる準備が必要だろう。

全国に認知症疾患医療センターは170箇所以上整備されたが、この危機意識を共有してどこまで、面

展開が出来ているかははなはだ疑問である。

認知症に関する不安と課題を以下に列挙した。

- 1) だんだん悪くなり、自分が自分でなくなっていく不安(認知機能)
- 2) 気分が荒れたり、落ち込んだりして、家族に迷惑がかかる(周辺症状)
- 3) 身の回りの世話ができなくなり、炊事や通院も人手を借りる(生活機能)
- 4) 尿を漏らしたり、転んだり、むせたりして入院するのは(老年症候群)
- 5) 家族に迷惑をかけたくない(介護負担)
- 6) 家族以外に助けてくれるところはあるの?(介護保険、サービス利用)
- 7) 急に悪くなったとき、入院できる場所はあるの(緊急対応)
- 8) 寝たきりになって施設で、胃瘻で生かされるの?(エンドオブライフケア)
- 9) 最初から最後まで親身になってみてくれるお医者さんは(かかりつけ医)
- 10) 国全体でもっと真剣にとりくんでくれないのか(医療、介護政策)

これらの要素に丁寧に答えることが、認知症に対する包括的アプローチであり、認知症疾患医療センターに国民が求めていることであろう。

平成24年6月18日、厚生労働省は副大臣のもと局横断的に「今後の認知症政策」について骨子を発表した。

- 1) 平易なスケールによる早期診断、患者の把握
- 2) 多職種チームによる早期相談ケア
- 3) かかりつけ医教育の充実
- 4) 家族教室の拡充

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- 5) 精神病院入院基準の明確化と早期在宅復帰
- 6) 精神薬の使用ガイドライン策定
- 7) 認知症疾患医療センターの基準を緩め（身近型）
6万人に一箇所整備

などとなっている。2) 新聞報道されたが、英国の制度を翻訳輸入しようとしていて、実証のないアイデアで実効性の検証はこれからである。

身近型認知症疾患医療センターの創設は、なにより現在の認知症疾患医療センターの実態調査で活動性が担保されていなければ、税金を用いた意味が問

われよう。制度を充実させるのは、「人」であり、人を育てるには教育カリキュラムが必要である。サポート医—かかりつけ医対応力向上研修システムの成功に何を学ばいいのか？ 残された少ない時間のなかで、早急にすべきことは明確であり、認知症の包括的アプローチに、産官学は「国民病」にどう連携して立ち向かうのかが問われている。

この論文は、平成24年7月28日（土）第26回老年期認知症研究会で発表された内容です。

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第7回

国立長寿医療研究センター 「もの忘れセンター」と 認知症診療ネットワーク

国立長寿医療研究センター病院もの忘れセンター外来部長

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国立長寿医療研究センターの 「もの忘れセンター」

2011年は新たな抗認知症薬が使用可能となり、認知症医療も新たな時代に入った。これまで「もの忘れ外来」では、認知症の鑑別診断を行い、薬物療法を始めることで完結することが多かった。しかし認知症高齢者の療養はそこから始まるのであり、多くの身体合併症や行動・心理症状(behavioral and psychological symptoms of dementia: BPSD)に苦しみながら療養を続けている。

わが国における認知症高齢者数はすでに14%とも推計され¹⁾、認知症は「ありふれた病気」である。厚生労働省は認知症医療における地域の拠点として、認知症疾患医療センターを全国に整備することを提言した。しかし精神科中心の施設が申請しているケースが多く、身体疾患が認知症の経過中に発症した場合の対応では、患者・家族のニーズ

に応えられているとは言い難い。一般病院の中で、認知症の専門外来と入院設備を有する認知症疾患医療センターをいかに機能させるかがキーとなる。

そこで認知症疾患医療センターの新たなモデルとなる「もの忘れセンター」を、国立長寿医療研究センター病院に開設した。私たちは診療目標を、患者・家族の目線から表1のように設定した。これらの機能をすべて有するもの忘れセンターを構築し実践することで、認知症の予防から終末期までを見据えた、切れ目のない医療サービスを提供する。患者・家族のあらゆる要望に応えられる「もの忘れセンター」である。本稿では私たちの試みを概説する。

1. もの忘れセンターの設備と人員

もの忘れセンターは外来部門、入院部門からなり、外来初診を担当する医師は17名(老年科7名、神経内科7名、精神科2名、脳外科1名；認知症学会および老年精神医学会の専門医は7

名)である。神経放射線科、リハビリテーション科、循環器科、消化器科、骨代謝・整形外科が加わる。認知症専門看護師、心理士、作業療法士、精神保健福祉士(PSW)、薬剤師が専属で配置されている(図1)。これらのスタッフが同じ土俵上で総合的に診療する。検査機器としては、CT、MRI、脳血流シンチグラフィ、PET[FDG (fluorodeoxyglucose)、アミロイドイメージング]、近赤外分光法(near-infrared spectroscopy: NIRS)を用いた脳活動計測器、磁気刺激装置が設置されている。また脳脊髄液のアミロイドβ(Aβ)₁₋₄₂、リン酸化タウの測定を行っている。

入院部門は、個室が10室、大部屋(4人床)が5室である。上記診療科のほか、すべての診療科の認知症患者が利用することが可能である。

2. 認知症の診断と入院治療

もの忘れセンター外来には、1カ月に100名以上の新患患者が来院する(全予約制)。かかりつけ医からの紹介は約50%で、近隣の市町村をはじめ愛知県、東海全域から受診する。初診患者は心理士が総合機能評価を用いた問診・身体機能評価を行う(約1時間)。引き続き医師が診察を行う(30~60分)。血液検査、画像検査を行い、次回の再診日で検査結果と治療方針について担当医が説明する。初診時診断はすべてカンファレンスで決定される。入院部門では、認知症に合併した身体疾患、BPSDの治療、認知症の診断パス入院、レスパイト入院などに対応している。



表1 もの忘れセンターの診療目標

1. 認知機能を維持するための医療・サービスの提供
2. 認知症の周辺症状の速やかな改善
3. 生活機能の維持
4. 老年症候群(転倒, 誤嚥, 失禁など)の予防
5. 介護負担感の軽減
6. 身近な場所での認知症介護サービス利用の情報提供
7. 緊急時の入院対応



図1 発足時の主な診療スタッフ

3. 認知症診療における高齢者総合機能評価

高齢者総合機能評価(Comprehensive Geriatric Assessment; CGA)は、高齢者の身体疾患のみならず精神的、社会的・経済的側面を含め、多角的に評価するツールである。認知症診療でCGAを導入することにはメリットが多い。

- ①患者本人・介護者から得られる情報を漏れなく系統的に得られる。
- ②被験者間・時系列の比較が容易。
- ③診断およびカンファレンスなどの資料として役立つ。
- ④多職種・かかりつけ医との情報共有。
- ⑤認知症療養計画書(平成24年度診療報酬改定)や介護保険意見書な

どの作成に利用。

- ⑥ファイルメーカーを用いており参照操作は簡単・迅速。

もの忘れセンターでは、すべての患者でCGAによる評価を行っている。診療情報の収集・管理は心理士が行い、データは電子カルテに組み込まれたファイルメーカーで管理している。

CGAの評価項目は、認知機能(Mini-Mental State Examination; MMSE)、生活障害(Barthel Index・Lawton Index)、うつ傾向(Geriatric Depression Scale 15)、認知症行動障害尺度(Dementia Behavior Disturbance Scale)、意欲の指標(Vitality Index)、Zarit介護負担尺度日本語版(J-ZBI)、栄養(Mini Nutritional Assessment)、社会・ライフスタイル、転倒リスク(Fall Risk

Index)、老年症候群について調べる²⁾。

4. 初診時診断を決めるカンファレンス
もの忘れセンターでは初診時診断はカンファレンスで決定される。カンファレンスにはすべての外来担当医師、心理士が参加する。担当医が症例を提示し、参加者と問題点を討論する。毎回、多くの症例が提示され診断に苦慮する例も少なくない。カンファレンスには時間と労力を要するが、診断精度が高まり参加者は多くの症例を学ぶことができ、各診療科の見方を聞くことには利点が多い²⁾。

診断後の治療・ケアについても議論される。薬物療法の選択や中止、栄養、認知リハビリテーションの適応、介護サービス利用などについて、看護師、PSWなどの多職種が参加する。結果として認知症のチーム医療が実現されている。カンファレンスは院内でオープンとしており、研修医や看護師、放射線技師の研修の場としても使われている。

私たちのもの忘れセンターは認知症を診る医師が多い。全国的には例外的な施設かもしれない。ここで強調したいことは、認知症は高齢者の「ありふれた病気」であり、裾野の広い領域である点である。つまり従来の縦割り診療ではなく、認知症に関わるすべての医師が協調して診療することが重要である。さらに多職種のコメディカルとチームを組んで診療する体制を築くことがキーであり、その意味でカンファレンスの意義は大きい(図2)。

5. 認知症の再診で考慮すべきこと

認知症高齢者の再診をどのように行うかは、もの忘れ外来の活動を左右す

・豊富な知識をもつ老年科医をコーディネーターとして、認知症の専門医と地域一般医のネットワークを構築する。

(*特に診断にたけた神経内科医・放射線科医, 周辺症状の薬物療法に長ずる精神科医, 手術の適応にたけた脳神経外科医)

・コメディカルだけでなく患者・家族も治療チームに加わる。

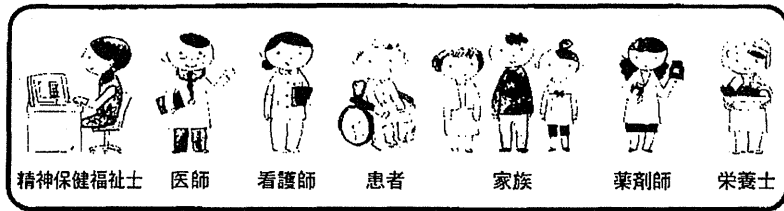


図2 新しいチーム医療

るポイントである。かかりつけ医からの紹介の場合は戻っていただく。かかりつけ医がない場合でも、地域連携室を介して逆紹介を行うことが多い。いずれの場合でも6ヵ月～1年で再診することにしている。この間に身体疾患やBPSDが悪化して再診あるいは入院する例もあり、認知症疾患医療センターに求められる機能の1つである³⁾。

2011年より新たな認知症治療薬が3種類加わった。今後、薬剤の効果、副作用を確認しつつ処方を見直すことがルーチンとなろう。このため簡易な認知能や生活機能を随時評価し、生活機能を維持する視点が重要である。早期の認知症でも薬物管理、買い物などの高度の日常生活動作(ADL)に障害がみられる。認知症の進行とともに生活障害はより広範となり、家族への指導、また介護保険のサービス利用を含めた支援を考慮する。

認知症に併発する身体疾患では、転倒・骨折、失禁、嚥下障害、脱水、低栄養などが多い²⁾。認知症の進行により発症頻度が高まる疾患を知り、早期発見・治療を行う。また認知症の進展

予防に、生活習慣病の管理や運動習慣が重要な意味をもつことが明らかになってきた。軽度認知障害(mild cognitive impairment; MCI)から認知症へのコンバージョンが抑制できるとのエビデンスも報告されている⁴⁾。

BPSDは認知症の中期～進行期のみならず、初期からみられることを忘れてはならない。怒りっぽい、うつなどの症状は、MCIの段階から始まっている。周囲が気づかないうちから患者自身はもの忘れに気づいており、不安になり、焦燥感が募って怒りっぽくなったりする。BPSDの芽を早くから摘み取り、重症化を防ぐことが重要である。BPSDへの対応、介護サービスの利用、認知リハビリテーションなどについて、看護師またはPSWが個別の相談に当たっている。

6. 家族教室

認知症は適切な治療やケアがあると、その予後や生活の質(quality of life; QOL)が大きく改善し、それにより介護者のQOLも改善する。逆に適切なケアがないと、状況は悪化の一途をた

どる。認知症の早期には家族も認知症を受け止められず、将来についての不安が漠然と拡大して、家族もしばしば抑うつとなる。この悪循環を断つために、家族教室で認知症についての正しい理解を促している。家族教室では、①認知症の診断と治療、②心理・行動症状、③栄養、④予防法、⑤対応とケア、⑥地域連携と介護サービス利用、⑦総括を、1回1時間程度、7回1セットとして定期的に行っている。参加者からは多くの質問があり、白熱することもある。患者本人を加えた家族教室への参加を推奨している。

地域連携ネットワーク

地域連携業務は認知症診療の花形である。もの忘れ外来にはどこも診察依頼が殺到しており、前方連携の課題は、予約を受けてから診察までの待機期間をいかに短縮するかにある。私たちのもの忘れセンターでも、いまだ約3ヵ月前後である。かかりつけ医からの紹介には地域連携枠(週に3～4枠)を設定しており、1ヵ月以内に対応している。

後方連携の確立にはさまざまな工夫と時間を要する。全国的には大学病院、医師会、行政が中心となるなど、多様なモデルがみられるが、地域の実情にあった連携システムを構築することが肝要である⁵⁾。かかりつけ医でも認知症診療に対する温度差は大きい。認知症の診療には時間と手間を要するなど、浸透には障壁が多い。しかし平成24年度の診療報酬改定では、かかりつけ医が認知症患者を管理すると350点の加算(6ヵ月に限る)が認められた³⁾。この好機を逸さず、認知症疾患医療センターとかかりつけ医とのネットワーク