

図2-2 認知症患者の施設別割合(平成22年9月末現在)※(290万人)

域連携バスが^{3, 4)}、大腿骨近位部骨折地域連携バスがそれぞれ実施されており^{5, 6)}、これらには診療所主体型や病院主体型、インターネットの利用や遠隔操作など、地域の特質により各地域でいろいろな工夫がされている。しかしこれらの地域連携バスは、病院→リハビリテーション施設→在宅と一方向であることが多い。また、がん地域医療連携バスは術後の経過フォローや治療主体のバスと考えられ、外来化学療法の増加に伴い増加している^{7, 9)}。

果たして認知症は、このような既存の病診連携方式で患者、家族、医師が満足する連携が取れるのであろうか？

背景

厚生労働省の発表で平成25年の時点で、すでに国民のうち420万人が認知症に罹患しているとされている。またこのうち半数は在宅患者である(図2-2)。言い換えれば、認知症は認知症を専門としない医師も診なければならぬcommon diseaseになってきている。しかし、通常の一般医は認知症の診療に慣れておらず、高血圧や糖尿病、風邪などの通常疾患の合間に、中等度から重度の認知症患者を診察することになる。これらの認知症診療には非常に労力・時間が取られ、ともすると診断・治療に難渋する。場合によっては患者や家族、診察した医師すらも満足のいかない結果となり、“認知症診療はもうこりごり！”ということになってしまうかもしれない。しかし、以前から高血圧や糖尿病などで診ていたかかりつけの患者も高齢化により認知機能が低下しはじめる。かといってこの患者の診療をいきなり止めることもできないため、非常に困っ

認知症高齢者の長期予約待ちが恒常化

① 認知症高齢者の長期予約待ちが恒常化

- かかりつけ医でも対応してほしい
- ② 高齢者の在宅での生活実態がわからない
- ③ 在宅相談機関との連携が不十分

かかりつけ医の負担

① 認知症を専門としていないため、診断・治療が難しいと感じる

- ② 外来診療時間を圧迫される
- ③ 高齢者の在宅での生活実態がわからない
- ④ 在宅相談機関との連携が不十分

家族の負担

- ① 認知症に気づかない
- ② 認知症のことがわからない→不安が大きい
- ③ 適切な介護がないと家族の負担が増える

在宅相談機関の課題

- ① 病識がない認知症高齢者、家族をどのように医療につなげたらよいかわからない
- ② 病状・診察状況がわからない
- ③ どう対応すればよいかわからない

て認知症の専門病院へあわてて紹介することになる。病診連携がうまくいっていない場合、紹介を受けた認知症専門病院はすでに既存の患者であふれており、新患を診るまでに時間がかかり、これ以上の再診患者を受け入れられなくなっていることも多い。こうなると、紹介する側の診療所は“いつになったら専門病院は診てくれるのか！診てくれるまでに時間がかかりすぎる！中途半端な状態でこちらに返されても困る！”となってしまう。反対に紹介を受けた認知症専門病院は“軽症の認知症を送られても困る！かかりつけ医に戻そうとしても受けてくれない！これ以上再診患者は診きれない！”といった悪循環に陥る危険性がある(図2-3)。このような課題を解決するには、果たして、どのような連携が必要なのであろうか？

認知症では、治療とケアを同時に行い患者や家族が在宅で地域コミュニティと協力しながら生活していくことが最大の目標である。このため、認知症地域連携バスと他の地域連携バスとでは、その方向性が大きく異なると考えられる。

脳卒中地域連携バス、大腿骨近位部骨折地域連携バス、がん地域連携バスはとくに中核病院とリハビリテーション施設、地域の診療所との“医療情報連携”が主体となっている。一方、介護やケアがより重要である認知症地域連携においてはこのような“医療情報主体型地域連携バス”では不十分な側面が出てくると考えられる。最近さまざまな地域で認知症の連携やバスについての報告がある¹⁰⁻¹²⁾。

認知症の多職種連携に関しては次章に譲るが、きちん

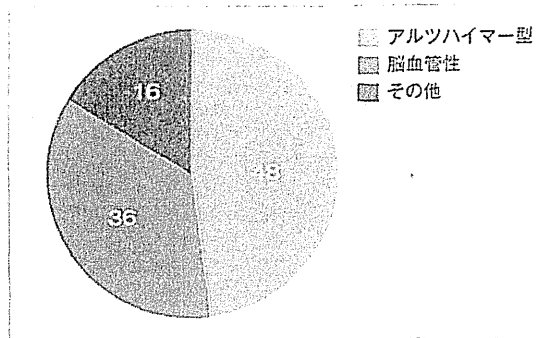


図13 認知症の病型別割合 (2009年) (総人数: 1,224名) 数字は%.

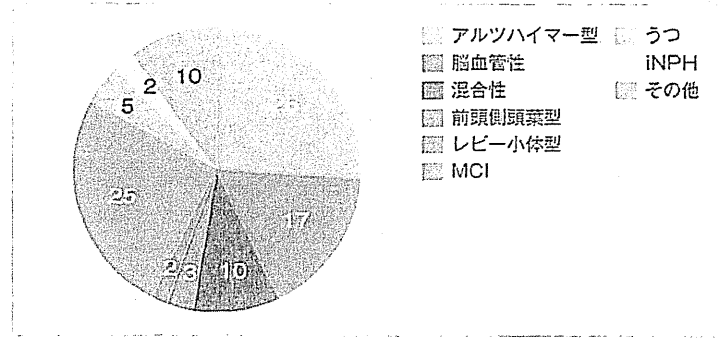


図15 認知症の病型別割合 (2014年) (総人数: 700名) (再診: 500名) 数字は%.

と確立した病診連携が地域連携の大きな柱のひとつであることは論を待たない。では、どのようにして利用しやすく有用な病診連携を構築すればよいのであろうか。

認知症連携におけるかかりつけ医の立場

図2に示すように、認知症は在宅の患者が一番多い。また、認知症は軽いうちは見過ごされる傾向があり(図3)、また認知症が疑われてから受診するまでの期間は平均2年間という報告もある¹³⁾。しかし、これらの患者はすでに高血圧や糖尿病などのcommon diseaseでかかりつけ医を定期的に受診していることが多い。また、かかりつけ医は患者の家族との関係が構築できていることが多く、早めに患者の認知機能低下の情報を得られることも多い。こうなると、かかりつけ医がその患者の認知機能のある程度の確に評価し経過を追っていけば、認知症の中核症状や徘徊などの周辺症状が悪化してからあわてて専門病院へ紹介するといった事態を避けることができる可能性が高い。

専門医に紹介するタイミングは前章で述べられているが、現実的には困ったら一度は専門医の意見を求めたいと考えるのは自然な流れである。ここで重要なのは、多くのかかりつけ医は認知症患者の診療を必ずしも拒否しているわけではなく、情報や状況が整えば、軽度から中等度の認知症患者を診る覚悟がある医師も多いということである。実際に筆者が参加している三鷹・武蔵野市認知症連携では、当初はかかりつけ医から当もの忘れセンターへの、やや一方向に傾いた紹介が多かったが、最近では診断を行い、治療方針を立てた軽度から中等度の認知症患者の相

当数をかかりつけ医で診ていただいているのが現状である(図13・図15)。

最初から述べているように、重度の認知症患者や周辺症状の強い認知症患者をいきなりかかりつけ医が診ることはかなり困難である。かかりつけ医が医師会の勉強会や書籍などでセルフトレーニングを積んだり、認知症サポート医講習を積極的に受けることや、実際に診療し経験を積むことで軽度から中等度の認知症は対処可能になることが多い。また、当初は重度であったり周辺症状が強かったりした患者も、投薬や介護環境の改善により症状が改善し、かかりつけ医で診ることが可能になることもある。

認知症連携における専門医療機関の立場

認知症専門病院は地域のかかりつけ医からの依頼に誠実に対応し、軽度から中等度の患者は診断と治療方針を決定した後にかかりつけ医に戻ってもらうコミュニケーションを取るべきである。専門病院はできるだけ地域で診ることが難しい重度や周辺症状の強い患者の診療を行うよう努めるべきであろう。しかし認知症は疾患の性格上、進行することが多いため、一度かかりつけ医に戻した患者でも症状が増悪することがある。この場合は可能なかぎりすみやかに再診できるように工夫すべきである。また、その認知症専門病院が認知症入院病床を持っているか否かで入院に対するアクセスは大きく異なってくる。入院病床を持っている認知症専門病院は比較的容易に入院治療を行えることも多いが、認知症入院病床を持たない専門病院は、BPSD(周辺症状)が増悪した際に入院先を探すために多大な労力を必要と

することがある。これらの問題は入院治療後も存在する。平成22年度の厚生労働省人口統計では入院中の認知症患者数は7万7400人（血管性および詳細不明の認知症患者4万4400人+アルツハイマー病患者3万3000人）とされている。認知症の入院病床は各地域ともきわめて限られており、近くに精神科の病院があっても認知症の入院治療を行っていないことも多い。また、認知症患者の入院期間自体が長期化している（平成22年度厚生労働省人口統計）という問題もあり、これらの問題に対する解決が求められている。

また、もともと認知症患者は高齢者が多く、すでに複数の身体疾患を抱えていることが多い。これらが増悪したり、肺炎、心不全、虚血性心疾患、脳血管障害などを発症することも多い。認知症患者の場合、入院後の管理の難しさから一般の病院での入院を断られることがあり、大きな問題となっている。

認知症疾患医療センター

これらの問題を解決するために、平成20年厚生労働省の主導で、従来の老人性認知症疾患センターに代わり全国に認知症疾患医療センターの設置が決定された。

認知症疾患医療センターとは、都道府県および指定都市により認知症専門医療の提供と介護サービス事業者との連携を担う中核機関として指定を受けた医療機関のことである。全国に約175ヵ所の整備を目的としており、平成25年4月1日現在において195ヵ所が設置されている。

認知症疾患医療センターの役割としては、以下のようなものが挙げられる。

専門医療相談の実施

認知症疾患医療センターには医療相談室を設置し、認知症に関する専門知識を有する精神保健福祉士などを配置する。この医療相談室では、本人、家族、関係機関（地域包括

支援センター、区市町村、保健所・保健センター、介護保険事業所など）からの認知症に関する医療相談に対応するとともに、状況に応じて、適切な医療機関などへの紹介を行う。

認知症の診断と対応

認知症疾患医療センターでは、認知症の診断を行うが、医学的な診断だけでなく、日常生活の状況や、他の身体疾患などの状況なども踏まえ、総合的に評価を行う。また、関係機関と情報の共有化を図り、医療・福祉・介護の支援に結びつけていく。

診断後は、患者のかかりつけ医と連携を図り、日常の診療はかかりつけ医が担当することが基本となる。

身体合併症・周辺症状への対応

身体合併症および周辺症状を有する認知症患者は、認知症疾患医療センターで受け入れるほか、地域の認知症に係る専門医療機関、一般病院や精神科病院などと緊密な連携を図り、地域全体で受け入れる体制をつくっていく。

地域連携の推進

地域の医療機関、地域包括支援センター、区市町村、保健所・保健センターなどの関係機関、家族介護者の会などとの連携を図るため、協議会などを開催し、地域において関係者が密接に連携するネットワークづくりに向けた検討を行っていく。

専門医療・地域連携を支える人材の育成

認知症疾患医療センターの院内においては、専門的な知識・経験を有する医師・看護師の育成に努めていくとともに、地域においては、かかりつけ医の認知症患者への対応力を向上させるための研修などに取り組んでいく。

情報発信

認知症に関する正しい知識を理解してもらうための情報発信を行う。

要約すると、認知症疾患医療センターは地域医療と連

携し、診断や治療が難しい認知症高齢者を受け入れる切り札的な施設と位置づけられる。ごく早期の認知症は、かかりつけ医では判断が難しいが、センターでは専門医が適切に診断し、医療や介護支援につなげる。認知症に伴う徘徊や幻覚・妄想などがある患者が、糖尿病や肺炎といった体の病気が悪化した場合、一般の医療機関では治療が難しいことがある。センターは地域の病院や診療所と連携して、こうした患者にも対応することとなっている。

しかし、各認知症疾患医療センターはすべての地域に設置されているわけではなく、また膨大な数の地域患者を対象にしているため、すべてのケースに迅速に対応できているとはいえない場合もある。

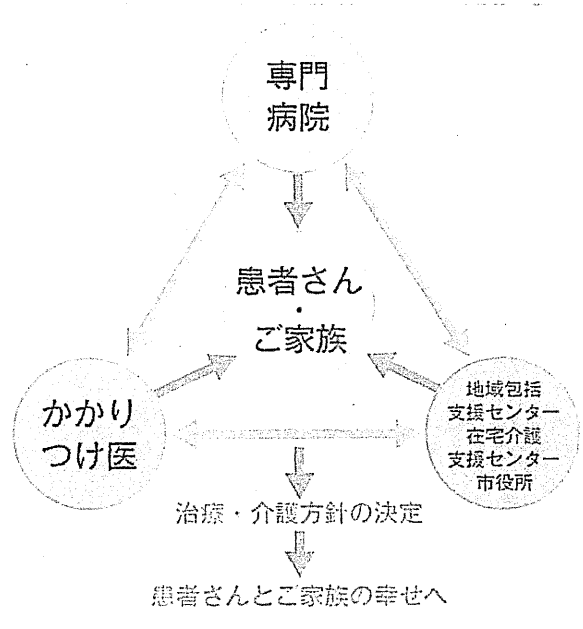


図1 認知症高齢者の在宅医療と介護

おわりに

一番重要なことは、最初に述べたように病診連携は地域や多職種を交えた大きな認知症連携の一部であることを常に考え診療にあたることである。このなかで病診連携

はその根幹をなすものであるため、各病院、各診療所は認知症に対し可能である医療資源を最大限提供し、互いの立場を理解しながら良好なコミュニケーションを取り合い、地域包括センターや行政のサービスをよく理解したうえで、患者、家族、ひいては診療する医師自身が満足する形を構築できるよう努力すべきである(図1)。

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ORIGINAL ARTICLE

Developing an interdisciplinary program of educational support for early-stage dementia patients and their family members: An investigation based on learning needs and attitude changes

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Aim: The National Center for Geriatrics and Gerontology has begun to provide educational support for family caregivers through interdisciplinary programs focusing on patients in the early stage of dementia. These interdisciplinary programs have established two domains for the purpose of “educational support”: cure domains (medical care, medication) and care domains (nursing care, welfare). In the present study, we examined the learning needs and post-learning attitude changes of patients and their families who participated in these programs in order to assess the effectiveness of an interdisciplinary program of educational support in each of these domains.

Methods: A total of 170 participants (51 dementia patients, 119 family members) were included in the study. Data were obtained from electronic health records, and through a written survey administered before and immediately after each program.

Results: A high percentage of patients and family members desired knowledge about the progression and symptoms of dementia, as well as measures to prevent progression, both of which fall under the medical care content. For patients, education in the medical care content increased their motivation to live. For families, education in the medical and nursing care contents promoted their understanding of dementia, while education in medication and welfare contents improved their skills for handling dementia patients and their symptoms.

Conclusion: Both patients and family members expressed a need to learn medical care content, including the progression and disease symptoms of dementia, and methods to prevent the progression of dementia symptoms. Their responses showed that learning medical care was effective for understanding dementia. We suggested that medical care content was the core of interdisciplinary educational support for early-stage dementia patients and their family members. *Geriatr Gerontol Int* 2014; 14 (Suppl. 2): 28–34.

Keywords: attitude changes, early-stage-dementia, educational support, interdisciplinary, learning needs, medical care content.

Introduction

The number of dementia patients in Japan is steadily increasing. In response to this situation, the “Future Direction of Dementia Policy –June 2012–” highlighted “early diagnosis and early care” as the foundation of

care.¹ The Japanese Ministry of Health, Labor and Welfare advocates the strengthening of day-to-day family support in the community, irrespective of the stage of dementia.² Previous studies have shown that providing family caregivers of dementia patients with a psycho-educational program for a fixed period improves the trust between caregivers and patients, and provides caregivers with an understanding of the disease and coping ability for caregiving.^{3,4} Chien *et al.* stated that when care managers provided sessions on self-care and restoring or building family relationships, the patients’ symptoms stabilized, caregivers felt their care to be less burdensome, and the admission rates and periods of admission to medical institutions decreased.⁵ In

Accepted for publication 10 January 2014.

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addition, counseling for dementia patients' family members enabled prolonged home care.^{6,7} However, all of these studies have methodological shortcomings. For example, when selecting study subjects from the population of dementia patients requiring care, these studies categorized symptoms too broadly, ranging from slight to severe. In addition, study program providers (interveners) were only chosen from the paramedic profession rather than from an interdisciplinary group.

In order to address some of these issues, the Center for Comprehensive Care and Research on Memory Disorders (Monowasure-Center) of the National Center for Geriatrics and Gerontology (NCGG) embarked on an interdisciplinary program of educational support for dementia patients and their families immediately after the definitive diagnosis of dementia. We examined the learning needs and post-learning attitude changes of patients and their families in order to assess the effectiveness of this interdisciplinary program of educational support.

Methods

Operational definition

First, the interdisciplinary research team set up two operational definitions. We defined the first few months after a definitive dementia diagnosis as the "early stage." Next, we set up a program offered through an interdisciplinary collaboration as "early-stage educational support."

Psycho-educational program

We divided the program structure broadly into two domains: the "cure domain" concerned with diagnosis,

treatment and medication for dementia, and the "care domain" concerned with care methods and social support for dementia patients. Furthermore, the cure domain consisted of medical care content and medication content, the care domain consisted of nursing care content and welfare content. We then set up four content categories for each domain (Table 1), and assigned physicians, pharmacists, nurses and psychiatric social workers as interveners.

Participants

The study protocol was approved by the institutional review board of the NCGG of Japan. Candidate patients and their family caregivers submitted informed consent before participating in the study. The total number of participants was 170. This research included several cases in which there were two or more family participants to one patient. In these cases, all participating family members in the household were counted in the number of participants. Following are the details of the 170 study participants (Fig. S1).

The study participants were 51 dementia patients (henceforth referred to as "patients") who had been given a definitive dementia diagnosis only a few months before participation in the program (August 2012 to August 2013). The 51 patients targeted in the study comprised 41 patients who participated in both the cure and the care domains, and 10 patients who participated in only the care domain. Furthermore, the study also targeted 119 family members of patients, raising the total number of participants to 170. These 119 family members comprised 53 who participated in both the cure and the care domains, and 66 who participated in only one domain. Of these 66 single-domain participants, 27 participated in the cure domain, and 39

Table 1 Structure of educational program

Domain	Program content	Intervener	Time provided (min)	No. times	Theme
Cure	Medical care	Physician	15	One time/one month	Basic knowledge about dementia
	Medication	Pharmacist	15	One time/one month	Pharmacological treatment and management through medication
Care	Nursing care	Nurse	15	One time/one month	Understanding dementia patients as "people with dementia" and coping methods
	Welfare	Psychiatric social worker	15	One time/one month	Provision of information concerning social resources that help patients and their caregivers in the community

participated in the care domain. Participation in each domain was based on request rather than random allocation.

Assessment and questionnaires

The items of type of dementia, Barthel Index (BI),⁸ Mini-Mental State Examination (MMSE),⁹ Dementia Behavior Disturbance Scale (DBD)¹⁰ and Zarit Burden Interview (ZBI)¹¹ were collected through patients' electronic health records, and descriptive questionnaires issued before and after each program. The questionnaire items administered before attending the program inquired about personal attributes and what the participant desired to learn. After completion of the program, we examined participants' learning needs and attitude changes for each domain, using four items: (i) degree of usefulness for future life and caregiving; (ii) degree to which anxieties about life and care are resolved; (iii) degree of improvement in future life and increase in incentive for care; and (iv) degree to which understanding of dementia is promoted. For the responses, we used a five-point Likert scale with possible answers to each question being: (i) completely disagree; (ii) disagree somewhat; (iii) cannot say either way; (iv) agree considerably; and (v) agree very much.

Statistical analysis

We carried out a statistical analysis of the quantitative data and categorized the qualitative data. For the data

analysis of χ^2 -test, we used the SPSS windows version 21.0 program (SPSS, Chicago, IL, USA).

Results

Characteristics of patients and family members

Characteristics of both patients and family member participants were analyzed (Table 2). Patients' clinical characteristics were analyzed according to sex, age, type of dementia, the BI, the MMSE score and the DBD. Among the clinical characteristics, Alzheimer's disease was the most common type of dementia (88.2%). In addition, some participating patients showed early-stage dementia with MMSE (mean \pm SD) scores of 19.9 ± 4.5 .

The family member characteristics analyzed were sex, age group, family relationship to patient, living with patients and the ZBI. Approximately 70.0% of family member participants were females, and approximately 50.0% of family member participants were in the old age group. In the family member's relationship to patient group, "spouse" accounted for the highest proportion of responses (47.9%).

Learning needs according to program contents and change in participant attitude

Cure domain (program content: Medical care/ Medication).

Table 2 Baseline characteristics of patients and family members

The items	n (%)	Mean \pm SD
Patients characteristics (n = 51)		
Sex (female)	30 (58.8)	
Age (years)		78.8 \pm 6.6
Types of dementia		
Alzheimer's disease	45 (88.2)	
Vascular dementia	5 (9.8)	
Dementia with Lewy bodies	1 (2.0)	
Barthel Index		94.5 \pm 15.9
MMSE (total score)		19.9 \pm 4.5
DBD scale (total score)		13.1 \pm 8.1
Living with family members (at home)	47 (92.1)	
Family members' characteristics (n = 119)		
Sex (female)	83 (69.7)	
Older age group (from 60s to 80s)	59 (49.5)	
Patient's spouse	57 (47.9)	
Patient's daughter or son	41 (34.5)	
Patient's daughter or son-in-law	14 (11.8)	
Living with patients (at home)	114 (95.8)	
ZBI (total score)		19.6 \pm 4.5

DBD, Dementia Behavior Disturbance Scale; MMSE, Mini-Mental State Examination; ZBI, Zarit Burden Interview.

Learning needs

A total of 27 patients and 80 family members gave complete answers regarding learning needs (Table 3). The majority of the patients' answers were categorized as "Understand how the advance of dementia can be prevented" and "Gained a general understanding of dementia." Many patients expressed a desire to know how to slow down the progress of dementia, as well as general things to keep in mind when going about their daily lives. Patients also stated their desire to confirm whether their current disease and symptoms were real.

With regard to family members, the majority of answers were in the categories "Gain understanding about dementia" and "How to cope with dementia and the patient."

Attitude change

With regard to program 1, "Leads to understanding of dementia" and "Useful for future care and living methods" had high values of more than 80.0% for patients, and more than 70.0% for family members

(Table 4). We did not find a statistical difference, but more than 70.0% of the patients answered "Leads to increased motivation to live," and similarly, more than 70.0% of family members answered that it "Leads to a resolution of anxiety about life and care."

For program 2, results for "Led to a resolution of anxiety about life and care" were approximately 70.0% for both patients and family members. In this program, family members' attitudes appeared to change, with 72.5% of family members, a markedly high result, answering that the program is "Useful for future care and living methods" and "Leads to increased motivation to live."

Care domain (Program content: Nursing care/Welfare).

Learning needs

On the topic of learning needs, 30 patients and 92 family members gave complete answers (Table 3). An extremely high proportion of patients (90.0%) answered that the program helped them to "Gain a general understanding of dementia." This result showed patients'

Table 3 Learning needs according to program contents

Domain	Content	Category	Patients	Family members
			n = 27	n = 80
Cure	Medical care/Medication	†Gain a general understanding of dementia	8 (29.6%)	35 (43.8%)
		†Learn how to prevent dementia from progressing	10 (37.0%)	5 (6.3%)
		Gain knowledge on the treatment methods for dementia	5 (18.5%)	16 (20.0%)
		Learn how to approach dementia	0 (0.0%)	18 (22.5%)
		†Resolution of psychological anxiety and conflict	4 (14.8%)	3 (3.8%)
		Find fellow dementia patients and caregivers	0 (0.0%)	2 (2.5%)
		Examine ways in which to announce dementia	0 (0.0%)	1 (1.3%)
			Patients	Family members
			n = 30	n = 92
Care	Nursing care/Welfare	Learn care methods	0 (0.0%)	56 (60.8%)
		†Gain a general understanding of dementia	27 (90.0%)	17 (18.5%)
		†Learn how to prevent dementia from progressing	12 (40.0%)	0 (0.0%)
		Learn living methods	0 (0.0%)	5 (5.4%)
		Learn theories of coping with dementia patients	1 (3.3%)	6 (6.5%)
		Acquire information on the various types of social support	0 (0.0%)	4 (4.3%)
		Connection with community and whether or not to announce dementia	0 (0.0%)	2 (2.2%)
		†Resolution of psychological anxiety and conflict	1 (3.3%)	2 (2.2%)
		Learn ways to make use of social resources	0 (0.0%)	1 (1.1%)
		Other	4 (13.3%)	0 (0.0%)

†Categories raised (as needs) in both categories.

Table 4 Cure domain: Change in participants' attitude according to program contents

Program content	Questions inquiring about	Responses [†]	Patients (n = 27)	Family members (n = 80)	P-value (χ^2 -test)
1. Medical care	Q1: Program content is useful for future care and living methods	Agree	21 (77.7%)	60 (75.0%)	P = 0.97
		Disagree	6 (22.3%)	20 (25.0%)	
	Q2: Program content linked to a resolution of anxiety concerning life and care	Agree	19 (70.3%)	58 (72.5%)	P = 0.85
		Disagree	8 (29.7%)	22 (27.5%)	
Q3: Program content linked to improvement in future life and increase in motivation to live	Agree	19 (70.4%)	54 (67.5%)	P = 0.95	
	Disagree	8 (29.6%)	26 (32.5%)		
2. Medication	Q4: Program content linked to understanding of dementia	Agree	22 (81.5%)	66 (82.5%)	P = 0.78
		Disagree	5 (18.5%)	14 (17.5%)	
	Q1: Program content is useful for future care and living methods	Agree	17 (62.9%)	58 (72.5%)	P = 0.09
		Disagree	10 (37.1%)	22 (27.5%)	
	Q2: Program content linked to a resolution of anxiety concerning life and care	Agree	18 (66.6%)	59 (73.7%)	P = 0.42
		Disagree	9 (33.4%)	21 (26.3%)	
	Q3: Program content linked to improvement in future life and increase in motivation to live	Agree	16 (59.2%)	58 (72.5%)	P = 0.06
		Disagree	11 (40.8%)	22 (27.5%)	
Q4: Program content linked to understanding of dementia	Agree	16 (59.2%)	55 (68.7%)	P = 0.30	
	Disagree	11 (40.8%)	25 (31.3%)		

[†]For each question, we calculated the answers by using a five-point Likert scale whereby we combined the number of participants who selected "Agree very much" and "Agree considerably" as those who selected "Agree"; we counted those who selected "Completely disagree," "Disagree somewhat" and "Cannot say either way" as "Disagree." We additionally used a χ^2 -test.

desires to learn the means to prevent their dementia from worsening. In other words, patients wanted to learn about treatments and living methods that could stop the progression of their dementia.

As for family members, 60.8% showed a desire to "Learn care methods." Family members desired to know more about the ways to approach problem behaviors in dementia patients.

Attitude change

In program 3, the degree of attitude change among patients was polarized at approximately 60.0% (Table 5). Those whose degree of attitude change was 60.0% or above answered that it was "Useful for future living methods" and "Leads to increased motivation to live." As for the degree of attitude change among family members, the results were high (70.0%) on all four items. The highest items were "Leads to a resolution of anxiety about life and care," and "Leads to understanding of dementia," at 76.1% and 78.3% respectively. A significant difference was observed in the latter (χ^2 -test, $P < 0.05$).

With regard to program 4, the degree of attitude change among patients remained at approximately 60.0% for all four items, with the highest of these, at 66.6%, being "Leads to increased motivation to live."

As for family members, no significant difference was observed, but "Useful for future life and care" and "Leads to a resolution of anxiety about life and care" were high at 72.8% and 71.7%, respectively.

Discussion

Although educational support programs typically target family caregivers,¹² the present study was unique in that it targeted patients as well. As very little time had passed since the definitive dementia diagnosis, both patients and family members might have been confused or anxious,^{13,14} but they showed high expectations for learning. In considering these concerns and expectations, it is important to examine the learning needs and attitude changes throughout the program.

As shown in Table 2, both patients and family members were aging. We reasoned that there was elderly care by the elderly because of the high rate of "spouse" in the family relationship to patient. Dementia conditions will worsen little by little from diagnosis, even if patients have early-stage dementia. Therefore, the necessity for learning about the cure and care of dementia was suggested as preparation for preventing care burden and care breakdown.

Many patients and their family members showed learning needs for medical care content in the cure

Table 5 Care domain: Change in participants' attitude according to program contents

Program content	Questions inquiring about	Responses [†]	Patients (n = 30)	Family members (n = 92)	P-value (χ^2 -test)
3. Nursing care	Q1: Program content is useful for future care and living methods	Agree	19 (63.3%)	65 (70.7%)	P = 0.82
		Disagree	11 (36.7%)	27 (29.3%)	
	Q2: Program content linked to a resolution of anxiety concerning life and care	Agree	18 (60.0%)	70 (76.1%)	P = 0.17
		Disagree	12 (40.0%)	22 (23.9%)	
4. Welfare	Q3: Program content linked to improvement in future life and increase in motivation to live	Agree	19 (63.3%)	67 (72.8%)	P = 0.59
		Disagree	11 (36.7%)	25 (27.2%)	
	Q4: Program content linked to understanding of dementia	Agree	17 (56.6%)	72 (78.3%)	P = 0.40
		Disagree	13 (43.4%)	20 (21.7%)	
	Q1: Program content is useful for future care and living methods	Agree	19 (63.3%)	67 (72.8%)	P = 0.21
		Disagree	11 (36.7%)	25 (27.2%)	
	Q2: Program content linked to a resolution of anxiety concerning life and care	Agree	19 (63.3%)	66 (71.7%)	P = 0.73
		Disagree	11 (36.7%)	26 (28.3%)	
	Q3: Program content linked to improvement in future life and increase in motivation to live	Agree	20 (66.6%)	62 (67.4%)	P = 0.72
		Disagree	10 (33.4%)	30 (32.6%)	
	Q4: Program content linked to understanding of dementia	Agree	19 (63.3%)	63 (68.4%)	P = 0.96
		Disagree	11 (36.7%)	29 (31.6%)	

[†]For each question, we calculated the answers by using a five-point Likert scale whereby we combined the number of participants who selected "Agree very much" and "Agree considerably" as those who selected "Agree"; we counted those who selected "Completely disagree," "Disagree somewhat" and "Cannot say either way" as "Disagree." We additionally used a χ^2 -test.

domain, including dementia progression, symptoms and ways to prevent progression. Family members tended to desire information about the progression of dementia and treatment methods appropriate for stopping it, as well as the symptoms that appear. Such results support the demand for a program with continuity between cure and care.

When we attempted to verify the efficacy of each program according to attitudinal change, we found that the results were different depending on participants' attributes. The most notable results among patients were in the medical care content (program 1) "Degree of usefulness for future life," "Degree of increased motivation to live" and "Degree to which the program helped participants understand dementia." Many patients felt this program helped to them seek a way of life that prevents dementia from worsening.

With regard to family members, "Degree of resolution of anxiety about life and care" was markedly high across all the programs. Examining the programs individually, "Degree to which understanding of dementia was promoted" was markedly high for medical care content (program 1) and nursing care content (program 3), and "Degree of usefulness for future life and care" was markedly high for medication content (program 2) and welfare content (program 4). We could infer that, in

each case, cure and care were shown to be effective as one unit, with "gaining understanding of dementia patients and their symptoms" in the former, and "learning methods for sustainable care" in the latter. Interdisciplinary educational support, consisting of both cure and care content, can provide appropriate psychological care. Another benefit of interdisciplinary educational support is that, through learning the knowledge and skills necessary for living with dementia, patients and their family members spontaneously involved themselves in medical consultations and treatment. This benefits healthcare providers by facilitating medical consultations, and empowers patients and family members about cure and care.

The present study provides evidence for three assertions:

- 1 Both patients and family members feel a need to learn medical care content including dementia progression, symptoms and methods to prevent progression.
- 2 Learning medical care content would lead to their use of knowledge and an increased motivation to live.
- 3 Learning medical care content is effective in helping family members understand dementia, and leads to the acquisition of skills for coping with dementia patients and their symptoms.

Following these three points, we suggest that medical care content was the core of interdisciplinary educational support for early-stage dementia patients and their family members. Finally, there is a need to continue research to verify this program's effectiveness.

Acknowledgments

We express our gratitude to the NCGG, the Uehiro Foundation on Ethics and Education, Professor Carl Becker and fellow researcher Jason Danely, research assistants Yoko Kajino and Sakie Miyamoto, participating patients, and family members. This study could not have been carried out without the NCGG's research and development fund (24–24), and we hereby express our gratitude. Finally, we also thank the Bio-Bank at NCGG for quality control of the clinical data.

Disclosure statement

The authors declare no conflict of interest.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1 Flow chart of the study protocol.



REVIEW ARTICLE

Educational program in Japan for Dementia Support Doctors who support medical and care systems as liaisons for demented older adults in the community

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Now that the number of elderly people has increased and the number of dementia patients is rapidly increasing, dementia might be regarded as a common disease. Under these circumstances, the establishment of systems to support the elderly with dementia from the early stages, and to provide primary care doctors and care workers with necessary education is an urgent issue. Up to the end of 2012, a total of 2680 doctors had been certified as Dementia Support Doctors (DSD). The DSD's function and roles are: (i) to support primary care doctors and care specialists involved in the medical care, and general care of dementia patients; (ii) to facilitate multidisciplinary cooperation led by a Community General Support Center; and (iii) to give lectures about dementia to primary care doctors and educate people in the community. DSD are more skilled than primary care doctors in the following functions: differential diagnosis; outpatient services to deal with behavioral and psychological symptoms of dementia; community liaison; and home care. *Geriatr Gerontol Int* 2014; 14 (Suppl. 2): 11–16.

Keywords: community liaison, Dementia Support Doctor, educational program for Dementia Support Doctors.

Introduction

Now that the number of patients with dementia is rapidly increasing with the increase of the number of elderly people, dementia might be regarded as a common disease. In fact, primary care doctors are now more frequently engaged in the care of patients with dementia, regardless of their specialty, and, consequently, it has become necessary for all of them to have a certain level of ability to treat the disease. Furthermore, in dementia care, appropriate role-sharing among medical professionals is important, while it is necessary to cooperate with care workers and administrative institutions.¹ Under these circumstances, the establishment of systems to support the elderly with dementia from the early stages, and provide primary care doctors and care workers with the necessary education is an urgent issue. To address this, the Ministry of Health, Labor, and Welfare launched a plan in 2005 to train Dementia Support Doctors (DSD), playing a central

role in community-based activities to support dementia patients. Subsequently, in 2006, another plan called the Skill-up Program of Dementia Medicine for Primary Care Doctors was initiated mainly by DSD, and, up to the end of 2012, a total of 2680 doctors had been certified as DSD. The total number of doctors who had completed the Skill-up Program of Dementia Medicine for Primary Care Doctors by the end of 2011 was 28 024. The government aims to increase the number of DSD to 4000, and that of doctors who have completed the Skill-up Program of Dementia Medicine for Primary Care Doctors to 50 000 by 2017.² The present article reports appropriate DSD training systems, while discussing the roles and activities of DSD. It also provides an outline of training programs focusing on long-term care services.

Educational program for DSD

With a Grant for Plans to Promote Health and Medical Services for the Elderly, the Ministry of Health, Labor, and Welfare launched the Research Project on Community Systems to Provide Early Identification and Appropriate Care for the Elderly with Dementia in 2004. In line with this, a working group was organized to examine methods to provide the Skill-up Program of Dementia Medicine for Primary Care Doctors,³ with a

Accepted for publication 17 December 2013.

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view to discussing the content of such training, as well as methods and systems to cooperate with doctors specializing in dementia care, who support Primary Care Doctors' medical practice and roles in the community. The DSD Training Program was initiated in 2005, and the Skill-up Program of Dementia Medicine for Primary Care Doctors in 2006. The former, aiming to train DSD who provide primary care doctors with advice regarding the early diagnosis of dementia, and play a central role in dementia care, was initially led by the National Center for Geriatrics and Gerontology as a commissioned business. In 2005, training materials, such as texts and DVDs, were developed, and, in 2006, training seminar sessions took place in Sapporo, Tokyo, Fukuoka and Obu (twice), producing a total of 318 DSD (covering 44 prefectures and 13 ordinance-designated cities). Following this, five seminar sessions a year have been held mainly in Tokyo, Nagoya, Osaka or Kyoto, and Fukuoka. Those who want to participate in these sessions should be recommended by the medical associations located in relevant ordinance-designated cities or their prefectures. Although those with medical associations' recommendation initially accounted for the majority, an increasing number of participants in recent years have made requests for participation to the medical associations located in ordinance-designated cities or their prefectures. To follow changes in clinical trial methods and systems, and reflect participants' opinions, training texts have been revised every year; up to 2012, four versions had been published. A major revision took place in 2012, and, in 2013, new texts have been adopted. The purposes of such revisions include: to focus on DSD-specific issues more closely, rather than conventional primary care doctor training; to provide the latest information regarding diagnosis and treatment; to increase sections related to medical liaison

systems in order to enhance participants' understanding of the importance of cooperation between medical and care professionals when supporting the elderly with dementia requiring long-term care; and to promote case studies and discussions. Each training session takes place from a Saturday afternoon to the following Sunday morning. In addition to learning methods to teach primary care doctors the content of each domain, participants are provided with lectures regarding the importance of DSD and primary care doctor training programs by an officer invited from the Office for Dementia and Elder Abuse Prevention, the Ministry of Health, Labor, and Welfare, and officers invited from the Japan Medical Association. Participants also freely discuss challenges for DSD in the establishment of systems to facilitate the early diagnosis and treatment of dementia in the community. By promoting discussions among doctors based in different areas, it is possible to clarify the status of each area's approach and points for improvement.

Current status and challenges of DSD

The roles of DSD include: (i) supporting primary care doctors and care professionals engaged in dementia care; (ii) establishing multiprofessional liaison systems led by the Community General Support Center; and (iii) giving lectures about dementia-specific training for primary care doctors and education for residents. In short, it is expected that DSD will promote cooperation between different medical professions, and between medical and care professions. (Fig. 1) As previously mentioned, the current total number of DSD is 2680; those specialized in fields generally related to dementia, such as psychiatry, neurology, geriatric medicine and neurosurgery, account for 42%, and those specialized in

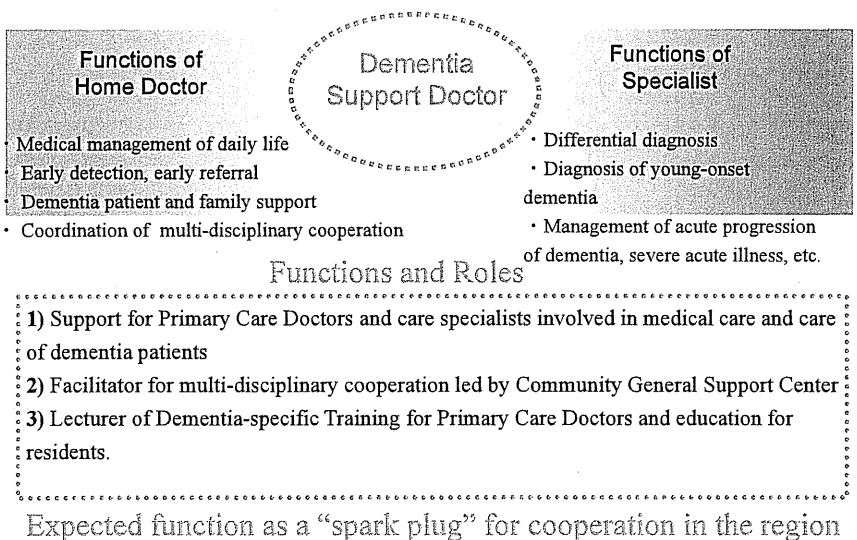


Figure 1 Functions and roles of Dementia Support Doctor.

Dementia Support Doctors in Japan

[n=957] Questionnaire to 1,974 Dementia Support Doctors undergoing training between 2005-2011

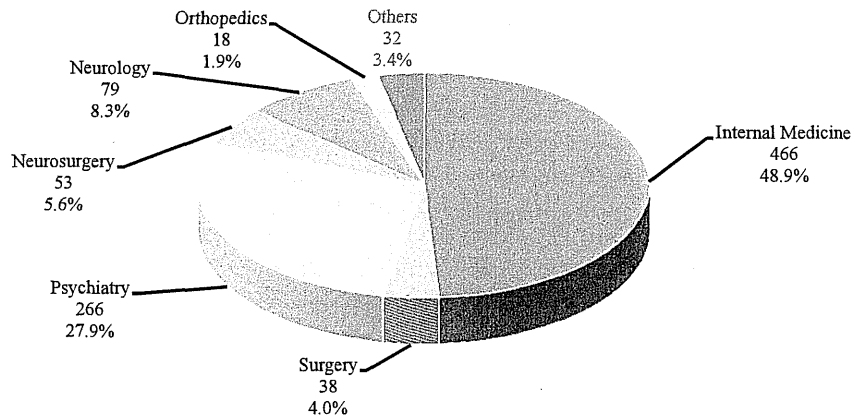


Figure 2 Breakdown of clinical departments of Dementia Support Doctors.

other fields of internal medicine, orthopedics, and urology account for 58%. Although DSD of the former group are frequently required for specialized medical services, such as the differential diagnosis of dementia, diagnosis of early-onset dementia, and treatment of advanced symptoms and severe somatic complications, those of the latter group are frequently required for primary care doctor functions, such as daily medical management, early identification and treatment of diseases, patient and family support, and multiprofessional cooperation. Considering that the necessary DSD functions also vary among different areas, it has been pointed out that the roles of DSD are unclear. According to a survey carried out from January to February 2011 involving DSD-related departments of a total of 66 municipalities, including 47 prefectures and ordinance-designated cities, those with 10–19 DSD accounted for the majority (24), followed by those with 30 or more (13) and those with fewer than 10 (16).⁴ The number of DSD was highest in Tokyo (284), followed by Chiba (88) and Hiroshima (72). Support for The Skill-up Program of Dementia Medicine for Primary Care Doctors was available in 95.5%, and education for residents was provided in 48.5%, whereas community liaison systems were not established, or their establishment was uncertain in 60%. As a reason for the latter, a large number of municipalities answered that community liaison was regarded as part of community-based activities, and they were not actively engaged in them; this shows that administrative bodies might not have been involved in the establishment of community liaison systems. Furthermore, information regarding accessibility to DSD in each area is important; however, DSD lists were available to the Community General Support Center in 70%, to residents in 50% and not available in 30% of all areas. Regarding networks among DSD, broad area networks

(the metropolitan area and districts) had been established in 14 (21.5%), and local networks (local demographic division of medical services where the DSD gives medical care) had been established in 12 (18.5%) areas. In 2012, a direct questionnaire survey was carried out to clarify the status of DSD,⁵ involving 1974 doctors who had completed the training program within the period between 2005 and 2011. The questionnaire sheet was distributed by mail, and 957 responded (response rate: 48.5%). Respondents were specialized in: internal medicine (48.9%), psychiatry (27.2%) and neurology (8.3%). Specialists certified by dementia-related academic associations accounted for 41.4% (Fig. 2). Their daily DSD activities included: (i) medical care for dementia patients (904: 94.5%); (ii) medical and multiprofessional liaison activities (804: 84.0%); and (iii) training and education (614: 64.2%; Fig. 3). The contents of (i) included treatment (96.9%), early identification (88.9%) and diagnosis (87.3%), nearly 90% of all DSD were carrying out these activities daily. A liaison system had been established with residents in 87.4%, long-term care support specialists in 78.0%, and the Community General Support Center in 73.9%; nearly 80% answered that a liaison system had been established. In contrast, a liaison system with primary care doctors had been established at a relatively low rate of 65.9%. The respondents participated in the planning and development of training and educational programs, such as dementia-specific training for primary care doctors (83.1%), multiprofessional training (79.3%) and educational seminars for residents (83.4%). These activities were carried out daily by approximately 80% of all DSD. These results suggest that individual DSD might be carrying out activities, such as medical services, liaison activities and education, daily in general; however, a liaison system with primary care doctors,

[n=957] Responses from 1,974 who completed DSD training program between 2005 and 2011

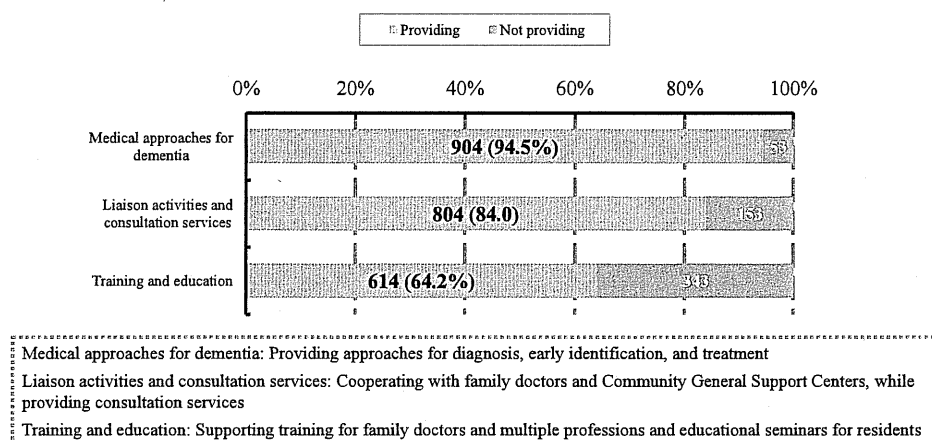


Figure 3 Activities of Dementia Support Doctors.

compared with residents and the Community General Support Center, had been established less frequently, showing the necessity of promoting and improving approaches in this respect. Regarding the large number of DSD (and medical institutions) as available resources, it might be necessary to sufficiently utilize them as a medical base supporting residents, care providers and primary care doctors engaged in dementia care. It might also be necessary to discuss and determine their roles, functions, and directionality in consideration of the statuses of related medical fields and association-certified specialists. In order to appropriately utilize DSD in the community, the municipalities' and Community General Support Centers' understanding is indispensable; in line with this, it might be desirable to develop community systems, while discussing appropriate methods to promote DSD activities, including grants for comprehensive dementia support plans among municipalities, Community General Support Centers and medical associations.

Awata carried out a study using the Medical Service Questionnaire Sheet for Dementia to evaluate the ability of general clinics located in the Tokyo metropolitan area to deal with dementia, and reported that medical institutions with doctors who had completed The Skill-up Program of Dementia Medicine for Primary Care Doctors showed a significantly greater ability than those without this training in the following respects: primary care doctor functions; differential diagnosis; outpatient services to deal with behavioral and psychological symptoms of dementia; community liaison; and home care.⁶ He also pointed out that medical institutions with DSD showed even higher levels of these functions (Fig. 4).

To promote liaison among DSD, and provide a basis for their information exchange, a portal site named the DSD Network (<http://www.dsd-network.jp>) was launched in May 2011, with a Grant for Geriatric Medicine Research and Development. The contents shown in Table 1 are viewable on this site, with a view to facilitating DSD activities. As another approach to support DSD, follow-up training programs have been used in some areas since 2009 to provide the DSD with opportunities to acquire new knowledge and learn other areas' approaches. In addition, as described in the following section, multiprofessional simulation conferences are being planned to enhance the knowledge of long-term care and liaison systems.

Long-term care training programs for doctors

In dementia care, it is essential to have a viewpoint based on a daily living activity model, in addition to a medical model. In other words, dementia care aims to improve patients' quality of life, rather than providing treatment and life-saving approaches, and focuses on disabilities (maintenance of activities of daily living), rather than diseases (maintenance of a normal physiological state). In line with this, it might be necessary to establish appropriate systems to provide team-based approaches with cooperation from multiple professions, as well as medical professionals. Honma pointed out that it is not reasonable to draw a line between medical and long-term care services when supporting dementia patients, and it is necessary to share knowledge and ideas among all those involved in dementia care, based

Dementia Support Doctors in Japan

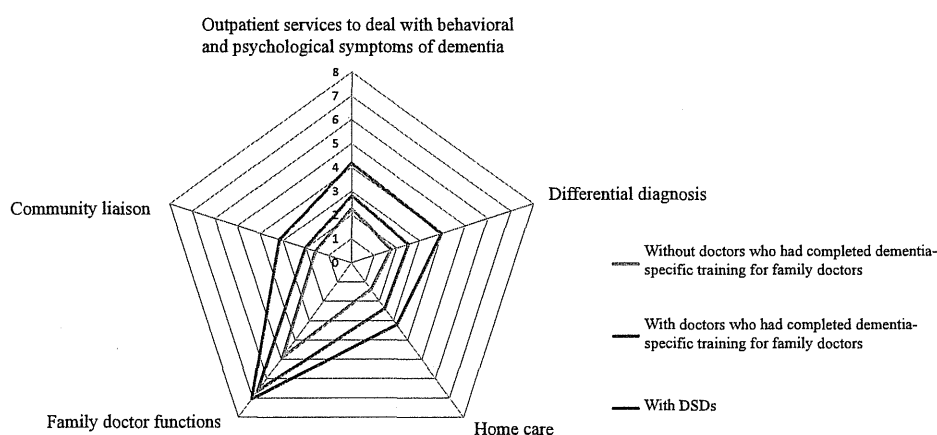


Figure 4 Outcomes of Dementia Support Doctors (DSD) and dementia-specific training programs for primary family doctors.

Table 1 Contents of the Dementia Support Doctors portal site

Category 1	Examples of community-based activities
Contents	
	Nagata-ku, Kobe City, Tokyo Metropolitan Area, Nagoya City, Shiga Prefecture, Nagano Prefecture
Category 2	Dementia-related issues
Contents	
	Roles of DSD: Development of new dementia guidelines, vascular dementia, development of neuroimaging for diagnosis of dementia, dysphagia due to dementia, non-pharmacological therapies, treatment of delirium, early-onset dementia (presenile dementia)
	Status of long-term care insurance systems (under commission), status of medical centers specialized in dementia care
Category 3	Materials, texts and DVDs previously used for DSD training
Category 4	List of DSD (by prefecture)
Category 5	Case studies
Category 6	Activities of academic study groups

DSD, Dementia Support Doctors.

on common training programs; however, such programs have not yet been developed.⁷ Furthermore, although study visits to long-term care facilities and nursing training programs have already been adopted in some medical schools as part of education regarding long-term care, these approaches are completely insufficient. Considering that Japan is becoming a super-aged society, this might be a serious problem, requiring prompt solutions.

Conclusion

Increasing the numbers of medical and care professionals specializing in dementia, and establishing systems to provide them with necessary education is urgently required.

Acknowledgement

This work was supported in part by a Grant-in-Aid from the Intramural Research Program of the National Center for Geriatrics and Gerontology (24-24 2012).

Disclosure statement

The authors declare no conflict of interest.

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Original Investigation

Preventive Effects of Ramelteon on Delirium A Randomized Placebo-Controlled Trial

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IMPORTANCE No highly effective interventions to prevent delirium have been identified.

OBJECTIVE To examine whether ramelteon, a melatonin agonist, is effective for the prevention of delirium.

DESIGN, SETTING, AND PARTICIPANTS A multicenter, rater-blinded, randomized placebo-controlled trial was performed in intensive care units and regular acute wards of 4 university hospitals and 1 general hospital. Eligible patients were 65 to 89 years old, newly admitted due to serious medical problems, and able to take medicine orally. Patients were excluded from the study if they had an expected stay or life expectancy of less than 48 hours.

INTERVENTIONS Sixty-seven patients were randomly assigned using the sealed envelope method to receive ramelteon (8 mg/d; 33 patients) or placebo (34 patients) every night for 7 days.

MAIN OUTCOMES AND MEASURES Incidence of delirium, as defined by the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition).

RESULTS Ramelteon was associated with a lower risk of delirium (3% vs 32%; $P = .003$), with a relative risk of 0.09 (95% CI, 0.01-0.69). Even after risk factors were controlled for, ramelteon was still associated with a lower incidence of delirium ($P = .01$; odds ratio, 0.07 [95% CI, 0.008-0.54]). The Kaplan-Meier estimates of time to development of delirium were 6.94 (95% CI, 6.82-7.06) days for ramelteon and 5.74 (5.05-6.42) days for placebo. Comparison by log-rank test showed that the frequency of delirium was significantly lower in patients taking ramelteon than in those taking placebo ($\chi^2 = 9.83$; $P = .002$).

CONCLUSIONS AND RELEVANCE Ramelteon administered nightly to elderly patients admitted for acute care may provide protection against delirium. This finding supports a possible pathogenic role of melatonin neurotransmission in delirium.

TRIAL REGISTRATION University Hospital Medical Information Network Clinical Trials Registry Identifier: UMIN000005591

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JAMA Psychiatry. 2014;71(4):397-403. doi:10.1001/jamapsychiatry.2013.3320
Published online February 19, 2014.

Delirium represents an acute change in cognition with altered consciousness and impaired attention that fluctuates over time.¹ The prevalence of delirium is 11% to 33% on admission, and the incidence during hospitalization is 3% to 56% among elderly patients presenting to emergency departments or medical and surgical wards in general hospitals.²⁻⁵ With the increase in the aged population, further increases in delirium seem likely. However, no medications against delirium have yet been approved. Delirium prevention has been investigated in several randomized clinical trials (RCTs). Based on a single RCT, programs for proactive geriatric consultation may reduce the incidence and severity of delirium in patients undergoing surgery for hip fracture.^{6,7} In contrast to the lack of efficacy of cholinergic enhancement in preventing delirium,⁸⁻¹⁰ some benefits of antipsychotics have been shown.¹¹⁻¹³ However, physicians may hesitate to use antipsychotics for delirium prevention given the risk of adverse effects.

Melatonin, a pineal gland hormone that regulates the sleep-wake rhythm, is reportedly associated in an RCT with a lower risk of delirium.¹⁴ Ramelteon, an agonist of melatonin that has been approved by the US Food and Drug Administration for the treatment of insomnia characterized by difficulty at sleep onset, has been suggested as an option for preventing delirium in case series.¹⁵⁻¹⁷ We examined whether ramelteon has effects in preventing delirium in elderly patients.

Methods

Setting and Participants

This randomized placebo-controlled trial was conducted from September 1, 2011, through October 31, 2012, in 4 university hospitals and 1 general hospital. All study protocols were approved by the institutional review board at each site, and written informed consent was obtained from patients or their proxy decision makers. This activity was conducted by the DELIRIA-J (Delirium Intervention Research for Improving Acute phase outcomes in Japan) study group.

Eligible patients were 65 to 89 years old, newly admitted due to serious medical problems, and able to take medicine orally. Patients were admitted via emergency departments to intensive care units or regular acute wards. Patients were excluded from the study if they had an expected stay or life expectancy of less than 48 hours.

The observation period was 1 week, and we considered that it would be difficult during such a short time to discriminate between delirium and cognitive fluctuation in certain diseases, such as severe liver dysfunction or Lewy body disease. Patients with such diseases were therefore excluded in advance.

Fluvoxamine is known to interact with ramelteon as a major interaction. Withdrawal syndromes associated with alcohol dependency and drug abuse can include delirium, obviously differing etiologically from delirium caused by systemic diseases. Patients with psychotic or bipolar disorders are usually receiving treatment with antipsychotics, which may prevent the development of delirium. Patients with other mood

disorders are also often treated with antipsychotics, so they were also excluded. Patients were approached before the first night after admission; those who were already delirious at admission were excluded.

Randomization and Intervention

We intended to perform this RCT in emergency situations. Although double blinding is ideal, we supposed that the participation rate of patients with such a design would have been much lower than with single blinding. The lower the participation rate, the less representative the results would be for real-world practice. We therefore chose to use only rater blinding. Patients were randomized using the sealed envelope method in a rater-blind manner to receive either ramelteon or placebo. For randomization, we referred to a random number table, with sequentially numbered, opaque, sealed envelopes used to conceal the allocation sequence. Study medication was managed by nurses and administered daily at 9 PM. This regimen was continued until the development of delirium or up to 7 days. The physician in charge kept the randomization code, and no rater became aware of treatment allocations until requesting unmasking on December 12, 2012.

Nurses were blinded except those who managed the study medication. Nurses provided all patients equally with preventive care, such as avoidance of immobilization, adequate lighting, noise reduction, on-time clocks and calendars, and regular verbal communication. Other staff, such as physiotherapists, were blinded. Family members were not allowed to stay in hospitals after 8 PM, and study medication was given at 9 PM. Therefore, there was low likelihood of bias due to interactions with family members. Thus, neither nursing care nor family interactions could have been different in the ramelteon group.

The dosage of ramelteon was 8 mg/d, given as a single tablet nightly, representing the standard dosage for the approved indication of sleep disturbance. The placebo comprised 330 mg of lactose powder. The placebo did not match the ramelteon active agent in appearance. This was a shortcoming of the study, but we considered that this drawback would have little effect on the development of delirium, which is characterized by impaired consciousness, including attention and awareness.

We had to select an as-needed drug for patients who would show insomnia and require a sleeping pill because we intended to perform the trial in real-world practice. We discussed which drug would be optimal for this purpose among trazodone, zolpidem, zopiclone, and hydroxyzine. Trazodone is often used to treat delirium in Japan because Japanese researchers have reported a case series showing the efficacy of trazodone against delirium.¹⁸ The effects of trazodone could thus have masked the preventive effects of ramelteon.

Although zolpidem and zopiclone are not listed in the Beers criteria,¹⁹ the Japanese package inserts for these drugs list adverse effects including delirium, confusion, hallucinations, excitement, disinhibition, aggression, abnormal behavior, and twilight state. In practice, we sometimes encounter elderly patients with delirium induced by these drugs. In contrast, we have seldom encountered elderly patients with delirium induced by hydroxyzine. We therefore suppose that zolpidem

and zopiclone could have exaggerated differences in outcome between the active and placebo arms more than hydroxyzine, and would be less ethical to prescribe than hydroxyzine owing to the higher risk of inducing delirium, based on our experience.

Because hydroxyzine is approved by the Ministry of Health, Labour and Welfare in Japan, all institutional review boards approved its use for such purposes. Hydroxyzine reportedly has low affinity for muscarinic receptors (mean [SD] inhibition constant [K_i], 3800 [100] nmol/L) in the bovine cerebral cortex.²⁰ The pharmaceutical company producing hydroxyzine (Atarax; Pfizer Japan Inc) informed us that they had no human data on the K_i values of hydroxyzine for the muscarinic receptor because it was an old drug. Data on inhibition constants of hydroxyzine for muscarinic acetylcholine receptors in humans thus seem to be lacking. Although the Beers criteria¹⁹ listed hydroxyzine as a strong anticholinergic drug, available data indicate that it has weak anticholinergic effects. We thus chose it as an as-needed drug for patients with insomnia who required a sleeping pill, with a nightly dose limit of 25 mg, as needed for insomnia.

Outcomes and Measurements

Before starting the trial, site coordinators were trained to assess outcomes as raters. All site coordinators were experienced psychiatrists. At the time of admission, baseline characteristics were collected. Acute Physiology and Chronic Health Evaluation II (APACHE II)²¹ scores and the Charlson Comorbidity Index²² were also assessed to evaluate physical condition. The Eastern Cooperative Oncology Group performance status²³ was assessed to evaluate how the disease affected activities of daily living in patients. The Clinical Dementia Rating was assessed to evaluate the existence and severity of dementia.²⁴ The Delirium Rating Scale-Revised-98 (DRS-R98) was assessed to measure delirium symptoms (Paula T. Trzepacz, MD, José R. Maldonado, MD, Jacob Kean, PhD, Malene Abell, BS, and David J. Meagher, MD, MRCPsych, unpublished data, 2010). The APACHE II scores, performance status, and DRS-R98 scores were determined daily up to 7 days. The DRS-R98 score was determined between 10 and 11 AM in all patients. Once delirium occurred, the cause was recorded according to the Delirium Etiology Rating Checklist.²⁵

The primary outcome measure was incidence of delirium, defined according to the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition).¹ Simultaneously, we censored patients in whom delirium developed, using the DRS-R98 total score, with a cutoff score of 14.5, established for the Japanese population by investigating the reliability and validity of the Japanese version of the DRS-R98.²⁶

Raters reviewed all nursing records before morning rounds and collected information about each patient directly from bedside nurses. Raters then assessed each patient to determine whether delirium had occurred. Raters also made their rounds every afternoon. Although delirium waxed and waned, there was little risk of missing its occurrence under such close observation. Adverse events, such as somnolence, dizziness, and fatigue, were observed. Sleep metrics, such as difficulty falling and staying asleep, waking too early, poor sleep quality,

number of awakenings per night, sleep duration, and disturbance of the natural sleep-wake rhythm during study drug administration were analyzed based on patient reports, nursing observations and records, and rater observations.²⁷

Statistical Analysis

Data were collected on standardized forms and statistical analyses were performed using SPSS, version 20-J, software (IBM Japan). Differences between categorical variables in patient demographics and clinical characteristics were calculated by using Fisher exact tests. Differences between sequential variables were calculated by using unpaired *t* tests (with Welch correction if applicable). If data were not sampled from gaussian distributions, a nonparametric test (Mann-Whitney test) was used. Kaplan-Meier curves were used to estimate the probability of delirium at 7 days. We constructed multivariate logistic regression models to control for risk factors in estimating independent associations between the effects of ramelteon and the outcome of delirium as an exploratory analysis. All statistical tests were 2 tailed. Differences were considered statistically significant at $P < .05$.

The incidence of delirium during hospital stays reportedly ranges between 3% and 56%.⁵ Although patients with risk factors for delirium (eg, old age and dementia) are increasingly encountered in general hospitals, we thought that 56% was too high an incidence of delirium during general hospital stays in Japan. We therefore assumed that the incidence of delirium in patients receiving placebo would be half the upper limit (ie, 28%) and the incidence in those receiving ramelteon would be the lower limit (3%). To enable detection of differences, we set the statistical power as $1 - \beta = 80\%$ and the sensitivity as $\alpha = 5\%$. Through power analysis, we consequently set the required number of patients at 32 patients per group.

Results

During the study period, 1126 patients were assessed for eligibility; 1059 were excluded. Of the 697 patients admitted to intensive care units, 658 were intubated or had a life expectancy of less than 48 hours, and 306 of the 429 patients admitted to regular acute wards had an expected stay of less than 48 hours. Diagnoses of severe liver dysfunction, Lewy body disease, alcohol dependency, psychotic disorder, or bipolar disorder accounted for exclusion of 61 patients. As a result, 1025 patients did not meet the inclusion criteria. In addition, 3 patients admitted to intensive care units and 31 admitted to regular acute wards refused to participate.

Thus, 67 patients (24 admitted to intensive care units and 43 admitted to regular acute wards) were included in the study. Figure 1 shows the trial profile. The 67 patients were randomly assigned to the 2 treatment groups (Figure 1). The rate of study participation among eligible patients was 66% (67 of 101). No patients withdrew consent, and all were therefore included in the final analysis. Baseline characteristics of randomized patients were much the same in both groups (Table 1).

Table 2 shows outcomes. Five patients in the placebo group and 8 in the ramelteon group were discharged before 7 days,