

# Additional Examination of a Cross-Sectional Research on Elements Linked to Patients' Quality of Life with Dementia and Lewy Bodies.

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## ABSTRACT

**Background :** While creating treatment plans, it's crucial to take the patients' and their caregivers' quality of life (QOL) and treatment requirements into account.

**Objective :** To look into aspects related to activities of daily living (ADL) if ADL was linked to QOL, and to look into factors related to QOL in patients with DLB.

**Methods :** In order to learn more about the therapeutic requirements of patients with DLB and their caregivers, we previously carried out a questionnaire survey study. The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II total score was used to assess ADL, and the Physical Component Score (PCS) and Mental Component Score (MCS) of the Short Form-8 were used to assess QOL in this pre-specified supplementary analysis.

**Results :** There were 38 doctors and 231 patient-caregiver pairs in all. The MDS-UPDRS Part II total score (standard regression coefficient  $\beta$ , -0.432) was linked to the PCS, while the presence of depression ( $\beta$ , -0.330) was linked to the MCS, according to multivariable analysis of QOL. Worsened ADL was linked to the degree of rigidity and postural instability/gait disorder (PIGD) ( $\beta$ , 0.337, 0.266), the presence of hallucinations ( $\beta$ , 0.165), male sex ( $\beta$ , 0.157), and the use of "short stay" or "small-scale, multifunctional home care" ( $\beta$ , 0.156).

**Conclusion :** ADL was significantly impacted by rigidity, hallucinations, male sex, and the use of "short stay" or "small-scale, multifunctional home care," while QOL was negatively impacted by the severity of ADL disability and depression in patients with DLB.

**Keywords :** Activities of daily living, Alzheimer's disease, cross-sectional studies, dementia, depression, hallucinations, Lewy body, parkinsonism, quality of life.

## INTRODUCTION

Lewy body dementia, which includes Parkinson's disease dementia and dementia with Lewy bodies (DLB), is the second most prevalent kind of primary neurodegenerative dementia after Alzheimer's disease (AD) [1-3]. Cognitive impairment precedes DLB, a neurodegenerative form of dementia. Its core features include cognitive fluctuations, parkinsonism, rapid eye movement sleep behavior disorder, specific and reproducible visual hallucinations, and occasionally delusions, autonomic dysfunction, sleep disturbances, and depression.

Quality of life (QOL) is generally understood to be the standard of living for an individual and encompasses a wide range of factors, such as emotional, social, and physical components [5]. One important result of health and social interventions is quality of life (QOL), which is frequently measured by analyzing how a disease, disability, or disorder affects a patient over time. Quality of life (QOL) is a crucial result in DLB patients. There is currently no clinical information about the quality of life (QOL) of DLB patients [6, 7], and no officially validated index exists to measure QOL in DLB patients. Prior research has indicated that patients with DLB have reduced QOL compared to AD patients, as measured by the EQ-5D and QOLAD [8, 9]. Depression, anxiety, dementia-specific disability assessment, and Geriatric Depression Scale scores were linked to quality of life in a mixed group of patients with DLB and AD [10]. The Neuropsychiatric Inventory (NPI) scores, independence of instrumental activities of daily living (ADL), caregiver living with the patient, apathy, delusion, depression, constipation, lower instrumental ADL, age, parkinsonism, hallucinations, cognitive fluctuations, and daytime sleepiness are reportedly associated with QOL, despite the fact that there are few pertinent published studies in patients with DLB alone.

ADL was found to be a critical component associated with QOL in patients with dementia other than DLB [13], meaning that enhancing ADL is required to raise QOL in this patient group. Two categories of ADL exist: instrumental ADL, which are required to live independently in the community and include

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tasks like housework, transportation, money management, and hobbies, and basic ADL, which are required to manage basic physical needs like eating, dressing, and bathing [14]. Compared to individuals with AD, patients with DLB exhibit the same level of cognitive decline and worse impairment in both basic and instrumental ADL functions [15, 16]. Furthermore, compared to patients with AD, patients with Lewy body dementia exhibited a larger behavioral burden and were less independent with regard to basic and instrumental ADLs, according to a prior South American study [17]. Similar to QOL, not many research have looked at ADL-related aspects in individuals with DLB alone. Prior research has demonstrated a correlation between instrumental ADL and depression symptoms, parkinsonism, hallucinations, cognitive fluctuations, and scores on the Mini-Mental State Examination (MMSE) in individuals with DLB [9, 18].

Prior research has assessed the quality of life and activities of daily living (ADL) of patients with DLB; however, it has not taken into account factors like the patients' utilization of social resources or the attending physicians' communication styles. In patients with DLB, these variables might also have an impact on ADL and QOL. Positive patient-physician relationships may enhance patients' QOL and ADL because patients depend on and see their doctors to improve their QOL and ADL [19]. Additionally, good communication between patients and doctors is crucial for a dementia diagnosis. In light of this, it is still necessary to identify the variables influencing QOL and ADL in patients with DLB alone.

The treatment requirements of DLB patients, their caretakers, and the understanding of those needs by their doctors have all been previously examined and reported on [20]. The attending physicians must develop treatment plans that take into account the quality of life (QOL) of each patient as well as the specific needs of each patient and caregiver, including those pertaining to parkinsonism, cognitive impairment, and mental disorders. Using information gathered from the primary trial, we looked into a total of 28 factors that might have an effect on patients with DLB's quality of life in our follow-up analysis. Based on earlier reports of DLB and other dementias [8-11], we identified potential QOL-related characteristics. Additionally, we included patient-physician communication and caregiver (nursing) services based on routine clinical practice. If ADL was found to be a factor linked to QOL, we also looked at aspects related to ADL.

## MATTERS AND METHODS

### Design

The primary study design's specifics have already been published [20]. The primary study comprised patients with DLB, their caretakers, and attending physicians. It

was a multicenter, cross-sectional, observational survey research. The pre-specified extra analysis was carried out in accordance with the research protocol, the Ethical Guidelines for Medical and Health Research Involving Human Subjects (partially revised in 2017), and the Declaration of Helsinki (revised in 2013), all of which serve as ethical guidelines. The Osaka University Hospital's Ethical Review Board for Observational Research first gave its approval to the project. Furthermore, each study site's corresponding Ethical Review Committee gave its approval before the study could begin. Prior to implementation, a summary of the primary study was published and registered in the UMIN Clinical Trials Registry (UMIN ID: UMIN000041844). Patients and their caretakers provided written informed consent. Physicians gave their online approval to take part in the trial.

### Participants

Patients with suspected DLB who were  $\geq 50$  years old and regularly attended an outpatient clinic met the inclusion criteria. The DLB Consortium's 2017 consensus report [4] served as the foundation for the probable DLB diagnosis. Patients whose attending physician had not seen them for more than three months prior to obtaining consent, patients with Parkinson's disease with dementia (if parkinsonism had been present for more than a year prior to the onset of dementia), and patients deemed by the physicians incapable of completing the questionnaire without the help of a caregiver were excluded. Furthermore, Some patients did not have their attending physicians check for cognitive impairment when filling out the cognitive impairment questionnaire, maybe for insignificant reasons like forgetting to check. Patients without cognitive impairment that were not evaluated for it by their attending physician were eliminated in order to guarantee that patients with DLB were included. For caregivers to be eligible, they had to be at least 20 years old and predominantly provide care for the patient with DLB. The attending physicians had to meet a specific need in order to be included: they had to be specialists in DLB therapy in Japan, as previously described [20].

### Assessments

The attending physician distributed questionnaires to patients and caregivers with DLB, and the patients/caregivers mailed back the completed forms [20]. Emails with the questionnaire were forwarded to the attending physicians, who responded online. Prior to responding to the questionnaires, the patients were assessed using the MDS-UPDRS Part II for activities of daily living (ADL), the MDS-UPDRS Part III for Parkinson's disease, and the Japanese version of the MMSE (MMSE-J) for cognitive function. The NPI-12 was used to ask caregivers about the behavioral and psychological symptoms of dementia (BPSD) and the Cognitive Fluctuation Inventory (CFI) was used to ask

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them about the cognitive fluctuations in their DLB patients [21–24]. The following 13 items were on the MDS-UPDRS Part II questionnaire, which was used to assess the motor experiences of daily living in patients with DLB: speech; drooling and salivation; chewing and swallowing; eating tasks; dressing; hygiene; handwriting; engaging in hobbies and other activities; turning in bed; tremor; getting out of bed, car, or deep chair; walking and balance; and freezing.

In order to assess their quality of life in relation to their health, patients were also asked to self-complete the Short Form-8 (SF-8) [25]. Since the EQ-5D is a “value-type scale” and the SF-8 is a “profile-type scale” that is easier to administer, we used the SF-8 to assess QOL instead of the DLB-specific QOL evaluation index. General health, physical function, role physical, body discomfort, vitality, social functioning, mental health, and role emotional are among the eight items covered by the SF-8. The Physical Component Score (PCS) and the Mental Component Score (MCS) were computed as measures of physical and mental QOL, respectively, in accordance with the guidelines of the SF-8’s original edition [26]. In cases when a patient’s parkinsonism or other conditions prevented them from completing the SF-8 on their own, their caregiver was permitted to interview the patient and complete the questionnaires. In these situations, the caregivers had to state that they had filled out the SF-8 and questionnaire on the patient’s behalf.

## Outcomes

The following were the pre-specified outcome measures used in this additional analytic study: 1) The PCS and MCS of the SF-8 for patient QOL, and 2) The MDS-UPDRS Part II total score for ADL. Higher scores on the MDS-UPDRS Part II total score suggest worse functioning in ADL, while lower PCS and MCS on the SF-8 imply worse QOL.

## Statistical analysis

The 28 elements listed below were utilized to influence the outcome measurements for QOL: 1) The age (under 80, beyond 80 years old), 2) The sex (male, female), 3) time following DLB diagnosis (<24, ≥24 months), 4) time spent in school (<12, ≥12 years),

5) The patient’s understanding of DLB (high knowledge, little knowledge, or neither yes nor no), 6) How frequently you attend the hospital or clinic (every two to three weeks, once a month, once every two months, once every three months, or once every four months or more), 7) The degree to which the doctor pays attention to the patient’s feedback (very well, well, normal, little, none at all, or don’t know), 8) In a hospital or clinic, patients can speak with anybody outside their doctor (yes, no, or don’t know); 9) The number of persons the patient lives with (alone, ≥2), 10) Utilizing “outpatient rehabilitation” or “long-term care” (yes, no), 11) Using “small-

scale, multifunctional home care” or “short stay” (yes, no), 12) Total score for MMSE-J (<22, ≥22), 13) Total score for MDS-UPDRS Part III (<18, ≥18), 14) Total score for NPI-10 (<11, ≥11), 15) No, no, yes, yes, yes, NPI-nighttime behavior score; 16) No, appetite; yes, NPI-appetite score; yes, yes; NPI-appetite score ≥ 1); 17) No, no, yes, CFI score = 0, yes; CFI score ≥ 1); 18) Autonomic dysfunction; yes, yes; 19) Sensory disorder; yes, yes, yes; (20) Age of the caregiver (<65, ≥65 years), 21) The gender of the caregiver, 22) the level of information the caregiver has about DLB (high, low, neither yes nor no), 23) Does the caregiver live with the patient (yes, no); 24) How much time does the caregiver spend with the patient (less than 16 hours per day, more than 16 hours); 25) Does the caregiver work concurrently (yes, no); 26) How does the caregiver relate to the patient (spouse, non-spouse); 27) Who filled out the SF-8 (patient, caregiver); and 28) MDSUPDRS Part II total score (less than 9 or more). Patient ADL was evaluated using factors 1 through 26 out of the 28 mentioned above.

The NPI-12’s “nighttime behavior” and “appetite” subitems were removed in order to use the NPI-10.

All continuous variables were binarized by the median value, with the exception of NPI-night behavior and appetite score.

We looked at the factors that affected the outcome measures (patient QOL and ADL) using linear regression analysis. To investigate the reasons causing the decline in QOL, the PCS and MCS from the SF-8 were used as dependent variables; to investigate the factors causing the decline in ADL, the MDS-UPDRS Part II total score was utilized as the dependent variable.

The stepwise selection strategy was employed by the multivariable model. Specifically, after univariable analysis to identify relevant components, variable selection was carried out using the stepwise method. Additionally, we developed a new model that included items other than the MDS-UPDRS Part III total score or the NPI-10 that were significant in the univariable analysis, as well as four parkinsonian symptoms (tremor [sum of MDS-UPDRS items 3.15–3.18], rigidity [sum of item 3.3], bradykinesia [sum of items 3.4–3.8 and 3.14], and postural instability/gait disorder [PIGD, sum of items 3.9–3.13]) [27] or the NPI-10 subitems that were significant in the univariable analysis. Inflexibility, worsened QOL in terms of the body and mind. Tremor was binarized by 0 and ≥ 1 since the median severity of tremor was 0, and bradykinesia, PIGD, and other conditions were binarized by median score of severity. Every NPI subsubplate was binaryized between 0 and ≥ 1. Because this was an exploratory analysis, the number of candidate factors was high compared to the sample size, and collinearity could be statistically avoided, these stepwise multivariable models were chosen. In multivariable analyses for PCS and MCS, factors with statistically significant negative coefficient values were considered as factors related.

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Missing information was not included in the study on an item basis that is missing. If a variable in the multivariable analyses contained missing data, analytical model, it was disregarded on an individual basis. Unless otherwise specified, the study's threshold for statistical significance was set at 0.05 (two-sided). The significance threshold was multiplicity-adjusted when multiple multivariable analyses were conducted by dividing 0.05 by the total number of multivariable analyses. SAS ver. 9.4 (SAS Institute Inc., Cary, NC, USA) was used for all analyses.

## RESULTS

From September 2020 to July 2021, 35 facilities in Japan with DLB-trained physicians participated in this trial. Fig. 1 depicts the study participants' disposition. The whole analysis set in the primary investigation comprised 263 pairs of patients with DLB and their caregivers with 38 attending physicians [20]. Out of the entire analysis set, 231 pairs with 38 attending physicians made up the analysis set for this study. Six patients did not respond to any of the SF-8's eight questions, and 26 patients had their attending physician neglect to check for cognitive impairment on the questionnaire.

Displays the background information about the 231 patients and caregivers, while Supplementary Table 1 displays the information about the 38 attending physicians. The patients' age (mean  $\pm$  standard deviation [SD]) was  $79.8 \pm 6.4$  years, and  $30.5 \pm 31.1$  months passed following the DLB diagnosis. Fifty-nine percent of the patients were male. The mean clinical score (MCS) for the SF-8 measured mental QOL at  $48.8 \pm 6.9$ , while the PCS measured physical and 47 (20.3%) made use of medical services that required overnight stays (either brief visits or minimal, multipurpose home care). The total scores for the MMSE-J, NPI-12, and MDS-UPDRS Part III were  $20.5 \pm 5.9$ ,  $17.0 \pm 17.1$ , and  $22.2 \pm 19.8$ , respectively, suggesting that patients QOL at  $45.9 \pm 8.2$ . The ADL indicator obtained from the MDS-UPDRS Part II total score was  $10.1 \pm 10.0$ . 110(47.6%) of the 214(92.6%) patients who were living in their own homes utilized day care or day services (outpatient rehabilitation or long-term care).

Supplementary Table 2 and Table 2 display the univariable and multivariable assessments of the factors connected to the PCS of the SF-8. With a standard regression coefficient of  $-0.432$  ( $p < 0.001$ ), the MDS-UPDRS Part II total score was the only extracted factor that was significantly associated with physical-related QOL, according to a multivariable analysis that used the stepwise method with the six factors extracted in the univariable analysis.

## DISCUSSION

We carried out an extra analysis of a multicenter, cross-sectional survey study to look into factors like communication patterns between attending physicians and patients or factors related to patients' use of social resources that are connected to physical and mental health-related QOL and ADL in patients with DLB. Fig. 2 shows a diagram that summarizes the study's main findings. In summary, we discovered that the presence of depression was linked to the mental QOL of patients with DLB, while the degree of ADL disability was linked to the physical QOL of these patients. Additionally, we discovered that the severity of parkinsonism, including PIGD and stiffness, the presence of hallucinations, male sex, and the use of "short stay" and/or "small-scale, multifunctional home care" were significantly linked to ADL in patients with DLB.

The physical component of QOL was directly correlated with the degree of ADL handicap in the current study, and the presence of depression showed connected to the psychological aspect of QOL. Although different indices were employed in the present and previous research to measure quality of life and activities of daily living (AQL and ADL), our results are largely in line with previous studies of individuals with DLB and other kinds of dementia [8, 10–13]. According to Boström et al., in patients with DLB, the NPI score, instrumental ADL, delusions, and apathy were related to QOL.

ADL has also been found to be a critical component for QOL in people with dementia [13]. Another study found that sadness, constipation, and lower instrumental ADL were linked to reduced QOL in individuals with DLB [11]. In terms of depression, DLB patients have a higher risk of suicide than those with other varieties of dementia [29], and the condition is linked to a comparatively high rate of depression as a consequence [28]. Additionally, a prior study found that older adults with depression had lower living and walking functioning [30], which may lower the activity level of DLB patients and worsen their prognosis. Although depression was evaluated as having minimal treatment needs in the primary study [20], an active therapy intervention for depression may also improve quality of life.

The element most closely linked to ADL was stiffness, which is the degree of PIGD; other parkinsonian symptoms, like tremor and bradykinesia, were not shown to be as significant factors in the multivariable analysis following adjustment. Lack of defensive movement (abduction or extension of the upper extremity) is frequently observed during lateral falls and falls with the upper extremity in adduction or flexion in Parkinson's disease, which is on the same neuropathologic spectrum as DLB and can cause fractures [31]. With time, these severe traumatic injuries cause patients to become less active [32] and worsen cardiopulmonary function, which increases the



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risk of aspiration pneumonia and restricted breathing, both of which are factors in the patients' poor prognoses. Therapy for parkinsonism, particularly for stiffness and PIGD, can falls and prevent patients' ADLs from getting worse. Consequently, it is believed that parkinsonian treatment is crucial to take into account while evaluating the quality of life of DLB sufferers. In individuals with DLB, bradykinesia is more common than tremor at rest [33], and tremor is less common in DLB patients than in Parkinson's disease patients [34]. Parkinson's disease patients' ADL and QOL have been linked to motor symptoms including bradykinesia [35, 36], but no such relationship has been observed in DLB patients. Tremor, rigidity, bradykinesia, and postural stability/gait dysfunction are the four parkinsonian symptoms. More research is required to determine the severity cut-off scores of these symptoms and investigate the association between tremor or bradykinesia and ADL.

This study also showed a correlation between poor ADL and the presence of hallucinations.

Prior research shown that DLB patients experienced more frequent hallucinations and decreased ADL compared to AD patients [37], and that hallucinations made caring for DLB patients more difficult [15]. Hallucinations have been linked to decreased ADL in patients with DLB [9], Parkinson's disease, and AD [38], despite the lack of data to conclusively assess whether they are an independent factor related with impaired ADL in patients with DLB. One would infer that engaging in hobbies and amusement is restricted when visual hallucinations are present.

It's interesting to note that male sex was linked to worse ADL performance in the current research. According to Utsumi et al., among DLB patients, women experienced hallucinations more frequently than men did, and men had a higher frequency of parkinsonism at the time of diagnosis [39]. Furthermore, among DLB patients, the intensity of hallucinations remained constant over time, although the severity of Parkinsonism increased over time, according to a study by Matar et al. [40]. Nonetheless, no appreciable variations were seen in the frequency or intensity of parkinsonism or hallucinations between male and female patients in the current study (data not shown). Notably, sex variations in ADL have been observed in a number of general population investigations [41, 42]. Though the reason behind these results is uncertain, it's probable that the relationship between male sex and decreased ADL is not unique to DLB patients. Alternatively, it's probable that a confounding factor related to sex that existed in the patients' background characteristics and was not evaluated in this study affected the patients' ADL.

According to the current study, using "short stay" and/or "small-scale, multifunctional home care" was linked to worsening ADL. Since we did not look at ADL changes before

and after service use, our findings may not always suggest that receiving "short stay" or "small-scale, multifunctional home care" made ADL worse. According to our understanding, patients who have worsened their ADLs may have a propensity to employ "small-scale, multifunctional home care" or "short-stay" services. To ascertain whether using these services enhances ADL or QOL in people with DLB, longitudinal studies are required.

The current study's findings supported a prior study's conclusion that there was no correlation between cognitive impairment as measured by an MMSE score and quality of life [9]. Furthermore, we discovered no connections between delusions and QOL. The fact that this study excluded patients with severe delusions could be one explanation for this discrepancy. Another explanation could be that even when objective QOL evaluation instruments are employed, the patient's subjective symptoms could still influence QOL. Delusions are probably the outcome of a patient's ignorance of their condition, which leads to an underestimation of the correlation with quality of life.

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