

Development and validation of a screening instrument for cognitive fluctuation in patients with neurocognitive disorder with Lewy bodies (NCDLB): the Mayo Fluctuations Scale-Thai version

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ABSTRACT

Background Prevalence of neurocognitive disorder with Lewy bodies (NCDLB) is low in Asian populations, which may partially reflect its diagnostic difficulty. The Mayo Fluctuations Scale, a short questionnaire that evaluates cognitive fluctuation, has been shown to significantly differentiate NCDLB from Alzheimer's disease.

Aim This study aimed to develop the Mayo Fluctuations Scale-Thai version and assess its validity to screen NCDLB in an elderly population.

Methods The Mayo Fluctuations Scale was translated into Thai. The process involved back-translation, cross-cultural adaptation, field testing of the prefinal version, as well as final adjustments. From all patients attending the Psychiatric and Memory Clinic at Ramathibodi Hospital, 135 patients accompanied by their primary caregivers were included. Caregivers were interviewed by research assistants using a four-item scale, and psychiatrists determined patients' diagnosis based on the diagnostic and statistical manual of mental disorders (DSM)-5 criteria. Evaluations performed by psychiatrists and research assistants were blinded.

Results Seventeen participants had been diagnosed with major NCDLB. At a cut-off score of 2 or over, the Mayo Fluctuations Scale exhibited excellent performance to differentiate major NCDLB from other major neurocognitive disorders (NCDs), with a sensitivity of 94.1% and a specificity of 71.4%, and acceptable performance to differentiate mild NCDLB from other mild NCDs, with a sensitivity of 60% and a specificity of 93.1%.

Conclusion The Mayo Fluctuations Scale-Thai version is an excellent screening tool for major NCDLB and an acceptable tool that may be used with other additional tests for mild NCDLB. The tool is practical for use in memory and psychiatric clinics. Further validation studies in participants with other specific clinical conditions are required.

INTRODUCTION

Neurocognitive disorder with Lewy bodies (NCDLB), or previously known as dementia with Lewy bodies (DLB), is the second

Strengths and limitations of this study

- This study was a first study that validated a short, easy to use, screening tool for screening major NCDLB in Thai.
- However, a limited number of mild and major NCDLB may have had negative impact on the level of sensitivity and specificity in this study.

most common cause of neurocognitive disorder (NCD) after Alzheimer's disease (AD) in the Western population.¹ The prevalence of NCDLB in the Asian population seems to be lower than vascular NCD.^{2,3} This may reflect real lower prevalence or difficulties in the diagnosis of NCDLB. Until recently, the consensus guidelines from the consortium on DLB international workshop⁴⁻⁶ had been the only tool for clinical and pathological diagnosis of NCDLB. In 2013, the DSM-5⁷ added major or mild NCDLB diagnosis, which may promote awareness of this disorder for psychiatrists worldwide.

The clinical features of NCDLB are spontaneous parkinsonism, recurrent visual hallucination, and fluctuating cognition along with progressive cognitive decline.⁵⁻⁷ The new consensus criteria moved rapid eye movement (REM) sleep behaviour disorder, which may precede cognitive decline, into core clinical features.⁶ While memory impairment often presents in the later stages of NCDLB, involvement of non-amnesic cognitive domains, for example, attention, executive function and visuospatial, can be found in the earlier stage of the disease.⁸ Other supportive features are severe neuroleptic

sensitivity, postural instability, repeated falls, syncope, or other transient episodes of unresponsiveness and severe autonomic dysfunction.⁹ Lower dopamine transporter uptake in the basal ganglia by single-photon emission CT or positron emission tomography suggests a diagnosis of NCDLB. However, this is not available worldwide. Basic history taking, physical exam and conventional brain imaging are still the mainstay of clinical diagnosis for most patients. Cognitive fluctuation is a core symptom that is relatively specific to this disease, since visual hallucination and parkinsonism can often be presenting symptoms of other conditions.

The Mayo Fluctuations Scale, originally developed with 19 items, is a four-item questionnaire assessing the common symptoms of cognitive fluctuation shown to significantly differentiate DLB from AD.¹⁰ These four items are daytime drowsiness, daytime sleepiness, disorganised thought and staring spell.¹⁰ Endorsement of three or four items resulted in a positive predictive value (PPV) of 83% for clinical diagnosis of NCDLB, while endorsement of fewer than three items yielded a negative predictive value of 70% for the absence of clinical diagnosis of NCDLB.¹⁰

The objective of this current study was to translate and validate the Mayo Fluctuations Scale-short version in Thai language as a potential screening tool for the diagnosis of NCDLB in an outpatient psychiatric clinic elderly population.

METHODS

Study design

The study was a cross-sectional study conducted at the outpatient Psychiatric and Memory Clinic, Ramathibodi Hospital. All participants who could give consent by themselves provided written informed consent prior to participation. If participants were unable to consent, spouses, next of kin or legal representatives were asked to provide consent.

Participants

Participants were elderly people, aged 60 years or older, who visited the outpatient Psychiatric and Memory Clinic. They had to be accompanied by primary caregivers who could provide information about their symptoms and illness. Recruitment took place from March 2014 to February 2016. Participants were excluded from the study if participants/caregivers had delirium, unstable psychiatric symptoms—for example, severe psychosis or suicide—severe visual or auditory impairment, were not able to communicate or follow commands in Thai, or were unwilling to participate.

Development of the Mayo Fluctuations Scale-Thai version

The Mayo Fluctuations Scale-Thai version was developed by the first author (PT) of this paper, following the 'Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes

Measures'.¹¹ First, PT translated the Mayo Fluctuations Scale-short version into Thai. Then a bilingual translator, who had never been exposed to the original Mayo Fluctuations Scale, did a backward translation. Then, all authors reviewed for consensus on forward and backward translation. Five elderly patients with their caregivers attending the outpatient department were invited to complete and to give comments on the prefinal version. Final modifications and adjustments were made accordingly.

The Mayo Fluctuations Scale-Thai version assesses four symptoms of cognitive fluctuation in the past 6 months: (1) drowsy and lethargic during the day, (2) over 2 hours of daytime sleep, (3) disorganised ideas/illogical thought and (4) period of staring into space.

Procedure

Participants were recruited on their scheduled clinic visit. Demographic data (eg, sex, date of birth, marital status, education, previous occupation and medical conditions) were recorded. The research assistants asked participants to perform the Mini-Mental Status Examination (MMSE-Thai 2002)¹² to briefly evaluate participants' cognitive status and the Geriatric Depression Scale-15 Thai version to evaluate current depression.¹³ The research assistants then interviewed the primary caregivers using the Thai Mayo Fluctuations Scale-short version. After that, a geriatric psychiatrist (PT), who had been trained in this field and has experience in geriatric research, met with the participants and caregivers to conduct an interview, review medical records, and perform a physical examination and make a clinical diagnosis based on the DSM-5.⁷ PT classified patients into five groups: (1) not meeting the criteria for NCD, (2) mild NCDLB, (3) major NCDLB, (4) other mild NCD and (5) other major NCD. Psychiatrist and research assistant evaluations were blinded to each other.

Statistical analysis

Demographic variables were presented as means (SD) for continuous data, and frequency and percentage for categorical data. Performance of the Mayo Fluctuations Scale-Thai version was presented by using sensitivity, specificity, PPV and negative predictive value. The area under the receiver operating characteristic (ROC) curve was reported. All statistics were analysed using SPSS V.18.0. P value less than 0.05 was considered statistically significant.

RESULTS

Descriptive statistics

During this 2-year period, 200 participants were invited to participate in the study. A total of 65 patients were excluded as 35 declined participation, 20 were not accompanied by primary caregivers and 10 patients had communication problems. One hundred and thirty-five participants were enrolled into the study as described

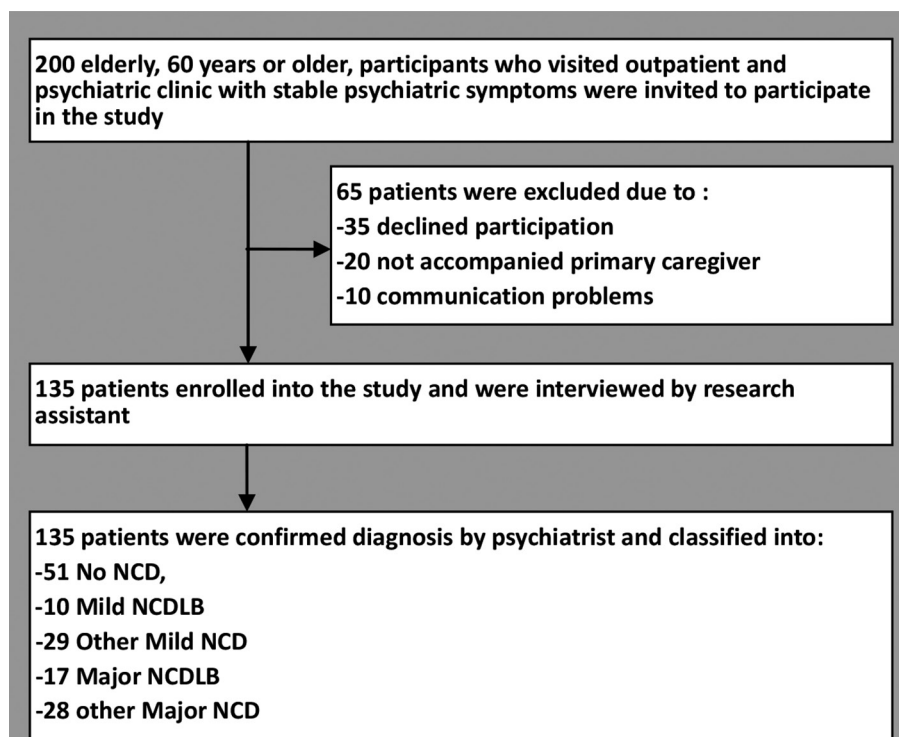


Figure 1 Flow chart of the study. NCD, neurocognitive disorder; NCDLB, neurocognitive disorder with Lewy bodies.

in figure 1. Participants' baseline characteristics are presented in table 1.

The average age of participants was 71 (7.3). Most of them were women, married, living with their spouse and/or children, had ≥ 12 years of education and had a professional career in the past. Based on DSM-5 diagnosis, 37.7% did not meet the criteria for NCD, 7.4% had mild NCDLB, 12.6% had major NCDLB, 21.5% had other mild NCDs and 20.7% had other major NCDs.

Clinical characteristics of participants classified by DSM-5 diagnosis

The clinical characteristics of each group of participants classified by DSM-5 diagnosis are presented in table 2.

The participants in each group had comparable mean age, but the participants in the other major NCD group were slightly older than other groups. Almost every group had more female participants than male; however, the numbers of male and female participants were roughly equal in the mild and major NCDLB groups.

Regarding psychiatric history, there were participants who had a history of depression in every group. The mild NCDLB group had the highest percentage of participants with a history of depression (40%). Participants with no NCD had 3.9% with a history of bipolar disorder, the other mild NCD group had 6.9% with a history of bipolar disorder and the other major NCD group had 3.6% with a history of bipolar disorder. One patient in the no NCD group (1.9%) and major NCDLB (5.9%) group had been diagnosed with schizophrenia. The other major NCD group had a greater number of participants with a

history of anxiety disorder (10.7%) compared with other groups.

The average MMSE scores were 25.4, 23.1, 25.1, 10.4 and 11.5 in the no NCD, mild NCDLB, other mild NCD, major NCDLB and other major NCD groups, respectively. For TGDS scores, all groups had less than 6 out of 15 scores, which reflected mild depression or less in their current status. The average Mayo Fluctuations Scale scores were higher in the major and mild NCDLB groups (3.1 and 1.9, respectively) compared with other groups.

Performance of Mayo Fluctuations Scale-Thai version

The performance of the Mayo Fluctuations Scale-Thai version in helping differentiate major NCDLB from other major NCDs and all others (including no NCD, mild NCD and other major NCDs) is presented in table 3.

Table 3 shows the numbers of participants in each group who had a positive score on the Mayo Fluctuations Scale. Sensitivity and specificity are also presented, using scores of 1–4 as a cut-off. There were 14 participants in the no NCD group who had a score of 1 on the Mayo Fluctuations Scale, while 1, 3, 7 and 6 participants in the major NCDLB group had scores of 1, 2, 3 and 4, respectively. Eight, five and three participants in the other major NCD group also had scores of 1, 2 and 3, respectively.

For screening of major NCDLB from other major NCDs, the score of 2 or over had a sensitivity of 94.1% and a specificity of 71.4%, a PPV of 66.7% and a negative predictive value of 95.2%. The result of ROC analysis showed the area under the curve was 0.72 (95% CI 0.55 to 0.89) (figure 2). For screening of major NCDLB

Table 1 Baseline characteristics of study participants

	Frequency (n=135)
Age (years), mean (SD)	71.0 (7.3)
Male, n (%)	48 (35.6)
Married, n (%)	89 (66)
Level of education	
Primary school	38 (28.1)
Secondary school	23 (17.0)
University and over	72 (53.4)
Unknown	2 (1.5)
Occupation	
Professional	60 (44.4)
Skill worker	22 (16.3)
Agricultural	1 (0.7)
Business	29 (21.5)
Others	23 (17.0)
Living status	
Alone	10 (7.4)
With spouse and/or children	110 (81.5)
Facilities	2 (1.5)
Others	13 (9.6)
Diagnosis, based on DSM-5	
Not meeting the criteria for NCD	51 (37.7)
Mild NCDLB	10 (7.4)
Major NCDLB	17 (12.6)
Other mild NCDs	29 (21.5)
Other major NCDs	28 (20.7)

NCD, neurocognitive disorder; NCDLB, neurocognitive disorder with Lewy bodies.

from all others, the score of 2 or over had a sensitivity of 94.1% and a specificity of 86.4%, a PPV of 50% and a negative predictive value of 99%. The result of ROC analysis showed the area under the curve was 0.95 (95% CI 0.90 to 0.98) (figure 3).

The performance of Mayo Fluctuations Scale in differentiating mild NCDLB from other mild NCDs was not as good as for major NCDLB. At a score of 2 or over, the sensitivity was 60%, specificity was 93.1%, PPV was 75% and negative predictive value was 87.1%.

Most of the participants in the major NCDLB group (94.1%), while only 28% of participants in the other major NCD group, had a score of at least 2 on the Mayo Fluctuations Scale. However, if participants in the other major NCD group reported any fluctuation of symptoms, it was mostly limited to one to two symptoms.

DISCUSSION

Main findings

This study's objective was to develop and validate a short, easy-to-use screening test for the diagnosis of NCDLB in elderly outpatients. The Mayo Fluctuations Scale

performed excellently in screening for major NCDLB with high sensitivity and specificity, while its performance was only acceptable for mild NCDLB. The Mayo Fluctuations Scale mainly evaluates cognitive fluctuation, which usually presents during the course of a major NCDLB.^{6 14} Expectedly, we found that the sensitivity of this test for mild NCDLB was less than for major NCDLB. Therefore, the test may not be sufficient to screen patients in the very mild stages of NCDLB. Recognising additional symptoms, such as REM sleep behaviour disorder, decrease in sense of smell, constipation and others,¹⁴ or using biomarkers/advanced imaging,^{9 14 15} may potentially increase sensitivity in the diagnosis of mild NCDLB.

Compared with the original study,¹⁰ this study reported similar ability to differentiate patients with NCDLB from other types of NCD. The score of 3 or over results in a PPV of 81.3% for identifying those with clinically diagnosed major NCDLB from those with other major NCDs, while the original study reported endorsement of three or four of these items yielded a PPV of 83% for the clinical diagnosis of NCDLB against an alternate diagnosis of AD, and a negative predictive value of 70% for not having clinical diagnosis of NCDLB compared with AD.¹⁰ The need of a higher score to differentiate major NCDLB from other major NCDs was congruent with a previous study, which demonstrated that more than 50% of patients with AD also reported one or two of the cognitive fluctuation features, while patients without NCD were unlikely to report any of these four features.⁸ It should be noted that PPV is affected by the prevalence of the disease, and we still have no data on the prevalence of NCDLB in our clinical population. However, it is likely to be lower than the prevalence in Western countries. The prevalence of NCD overall in our community is estimated to be around 2%–3%^{16 17}; AD would be the most common type at about 75% and vascular NCD the second most common at about 12.5%.¹⁷ It should also be noted that the majority of the other major NCD group in our study may have AD. This leads to another interesting question about what exact cognitive fluctuation features can distinguish major NCDLB from other major NCDs. As a result, they should be evaluated in future larger comprehensive research and populations.

Regarding cross-cultural differences between the Mayo Fluctuations Scale-Thai version and the Mayo Fluctuations Scale, we did not find any major differences. The scale was pretty easy to understand by both the interviewer and participants. The patterns that participants with major NCDLB were more likely to have at least two fluctuation composites or over, while participants with other major NCDs might have only one to two fluctuation composites and participants with no NCD usually had no more than one fluctuation composite, were consistent in both cultures.

Our study participants were patients in a memory and psychiatric clinic. Patients who did not meet the criteria for NCD could not be considered cognitively normal, since they may have had underlying diseases that could

Table 2 Baseline clinical characteristics of participants classified by DSM-5 diagnosis

Clinical characteristics	No NCD (n=51)	Mild NCDLB (n=10)	Other mild NCDs (n=29)	Major NCDLB (n=17)	Other major NCDs (n=28)
Age, mean (SD)	68.8 (5.9)	71.6 (6.0)	69.5 (7.1)	72.1 (8.4)	75.9 (7.8)
Male, n (%)	21 (41.2)	5 (50)	6 (20.7)	8 (47.1)	8 (28.6)
Psych Hx, n (%)					
Depression	11 (21.6)	4 (40)	7 (24.1)	2 (11.8)	6 (24.3)
Bipolar	2 (3.9)	0	2 (6.9)	0	1 (3.6)
Schizophrenia	1 (1.9)	0	0	1 (5.9)	0
Anxiety	1 (1.9)	0	0	0	3 (10.7)
MMSE, mean (SD)	25.4 (3.5)	23.1 (3.6)	25.1 (3.8)	10.4 (8.8)	11.5 (5.3)
TGDS, mean (SD)	4.0 (3.0)	5.2 (3.3)	3.9 (3.6)	5.8 (2.4)	5.5 (3.8)
Mayo Fluctuations Scale, mean (SD)	0.3 (0.5)	1.9 (1.4)	0.6 (0.8)	3.1 (0.9)	1.0 (1.0)

NCD, neurocognitive disorder; NCDLB, neurocognitive disorder with Lewy bodies; Psych Hx, psychiatric history; TGDS, Thai Geriatric Depression Scale.

interfere with their cognitive function, for example, depression. However, patients in this group still showed an average MMSE >23 and Thai Geriatric Depression Scale (TGDS) <5, which implied no active depression nor NCD. Almost every group had more female participants than male; however, the percentages of male participants were higher in the mild and major NCDLB groups compared with other groups. This is congruent with a previous study where NCDLB was more prevalent in men.¹⁸ Participants with no NCD, mild NCDLB and other mild NCDs had MMSE scores over 23, but major NCDLB and other major NCDs had scores of 10.4 and 11.5, respectively, which means that MMSE has the ability to differentiate patients with major NCD, but not mild NCD, from patients without NCD.

The Mayo Fluctuations Scale-Thai version is an excellent screening tool for major NCDLB. However, additional clinical findings and tests are needed to improve the sensitivity for mild NCDLB screening. For elderly outpatients in our memory and psychiatric clinic who had abnormal scores on the MMSE, positive of 2 out of 4 scores on the Mayo Fluctuations Scale would be sufficient to work up more on major NCDLB diagnosis. In addition, higher scores on this scale indicate higher likelihood of

NCDLB diagnosis over other types of NCD. Nevertheless, in patients with normal MMSE, this scale itself may not be sensitive enough to differentiate patients with mild NCDLB from those with other types of mild NCD. It should be noted that a high percentage of participants in the mild NCDLB group had a history of depression (40%), while a high percentage of participants in the other major NCD group had a history of anxiety disorder (10.7%) compared with other groups. These differences in the characteristics of psychiatric symptoms as prodromal state of NCD seem to be important in terms of early differentiation of NCD from late-onset psychiatric disorder, which is congruent with a previous study.⁹

Limitations

Our study had some noteworthy limitations. First, our study was done in a memory and psychiatric clinic. Patients with NCDLB who went to other clinics, for example, a neurology clinic, may have different initial clinical presentations since this disease involves multiple system manifestations. Second, a limited number of participants in mild and major NCDLB (total of 27) may have had negative impact on the level of sensitivity and specificity in this study. Since NCDLB is a

Table 3 Performance of the Mayo Fluctuations Scale-Thai version

Mayo score positive (total=4)	No NCD (n=51) (%)	Major NCDLB (n=17) (%)	Other major NCDs (n=28) (%)	Sensitivity (%)	Specificity related to other major NCDs (%)	Specificity related to all others* (%)
1	14 (27.4)	1 (5.9)	8 (28.6)	100	42.9	57.6
2	0	3 (17.6)	5 (17.9)	94.1	71.4	86.4
3	0	7 (41.2)	3 (10.7)	76.5	89.3	93.2
4	0	6 (35.3)	0	35.3	100	98.3

*Specificity related to all others (including no NCD, mild NCD and other major NCDs).
NCD, neurocognitive disorder; NCDLB, neurocognitive disorder with Lewy bodies.

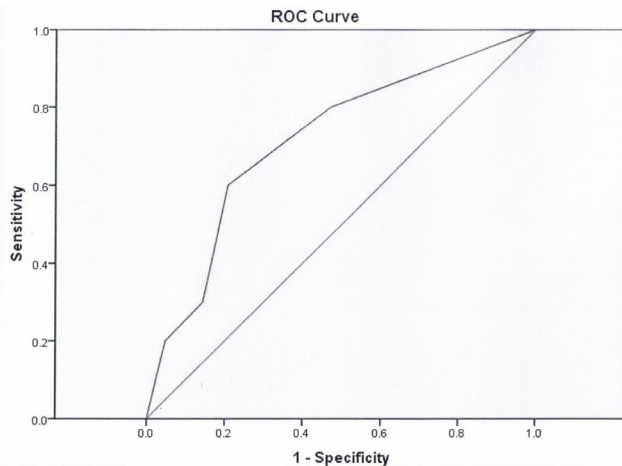


Figure 2 Area under the curve from plotting the receiver operating characteristics (ROC) curve of the Mayo Fluctuations Scale performance in detecting major neurocognitive disorder with Lewy bodies from other major neurocognitive disorder. Blue lines indicate plotting true positive rate (TPR) against false positive rate (FPR) at various cut-offs. Green line indicate chance levels.

low prevalence disease, especially in the Asian population, more validation studies in larger populations are required before the test can be applied to be used in different clinical situations. Finally, our gold standard for NCDLB diagnosis was based solely on the DSM-5 criteria, from which we performed history taking, physical exam and basic cognitive testing with participants and caregivers. A more comprehensive cognitive evaluation and objective investigations can be used to obtain a more definitive diagnosis. This should be done in the future with more comprehensive research.

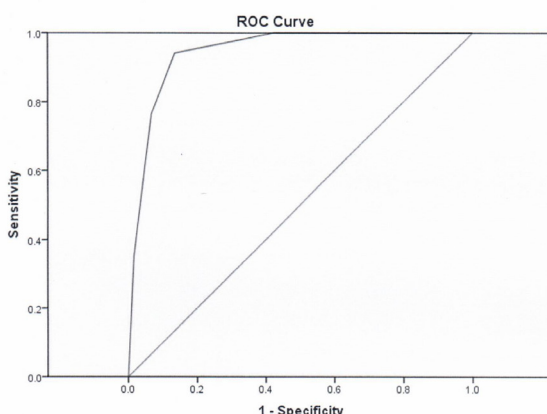


Figure 3 Area under curve from plotting the receiver operating characteristics (ROC) curve of the Mayo Fluctuations Scale performance in detecting major Neurocognitive disorder with Lewy bodies from all others (including no NCD, mild NCD and other major NCD). Blue lines indicate plotting true positive rate (TPR) against false positive rate (FPR) at various cut-offs. Green line indicate chance levels. NCD, neurocognitive disorder.

Implication

The Mayo Fluctuations Scale-Thai version is an excellent screening tool for major NCDLB and an acceptable tool that may be used with other additional tests to determine mild NCDLB. The tool is practical for use in a memory and psychiatric clinic. Further validation studies in participants with other specific clinical conditions are required.

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