Reliability and Validity of the Thai Version of the PAINAD Scale: An Extended Application of Pain Assessment in the Moderately Severe Stage of Dementia

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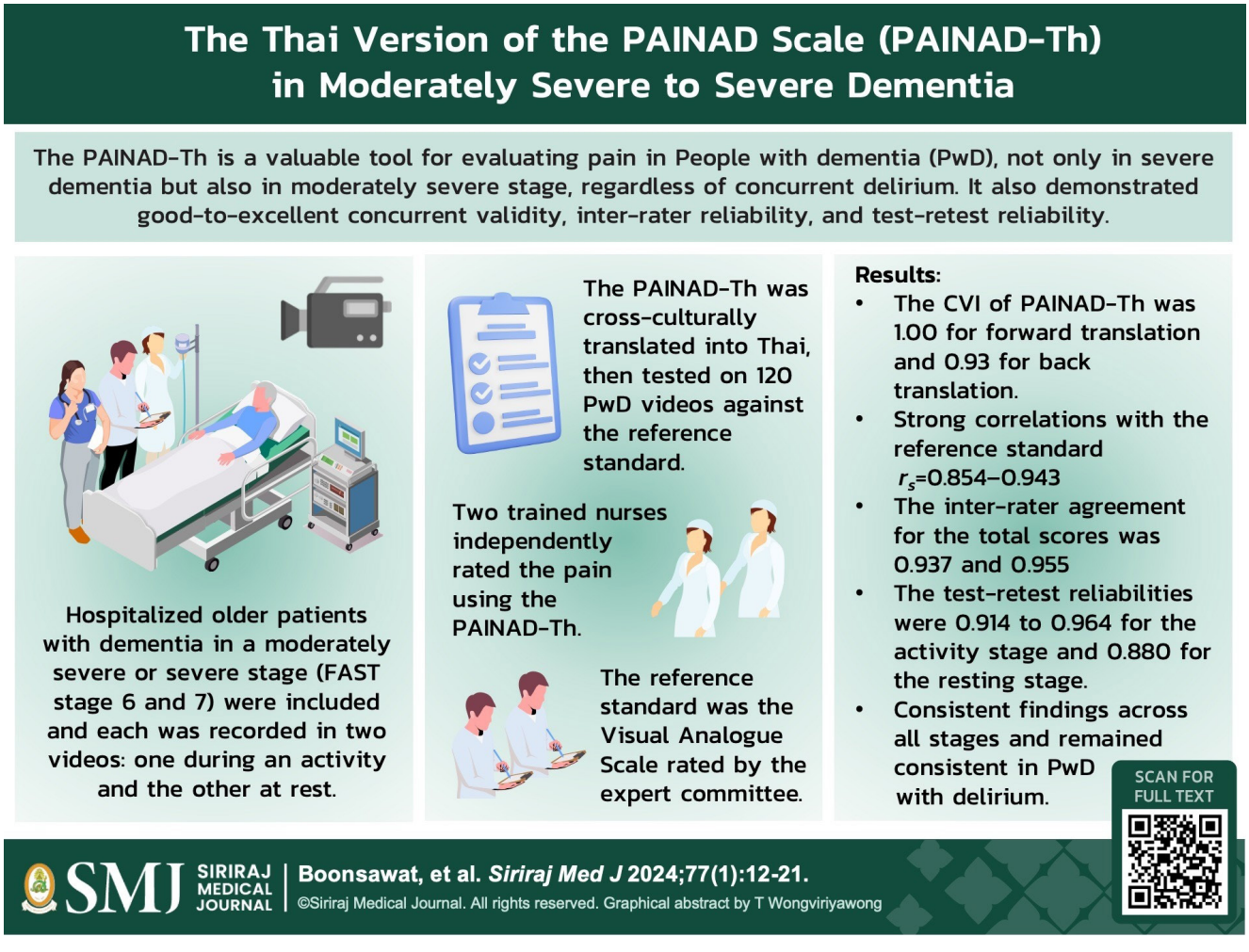

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ABSTRACT

Objective: To evaluate the reliability and validity of the Thai version of the PAINAD (PAINAD-Th) scale for assessing pain in people with dementia (PwD).

Materials and methods: A cross-cultural translation of the PAINAD scale involving forward and back-translation to and from Thai was conducted, and then the content validity index (CVI) of semantic equivalence was evaluated. The PAINAD-Th was tested on 120 videos of PwD. Each participant was recorded in two videos: one during an activity and the other at rest. Subsequently, two trained nurses independently observed the videos and rated the PAINAD-Th to assess inter-rater reliability. The rating process was repeated in one week to investigate the test-retest reliability. The concurrent validity was assessed against the Visual Analogue Scale rated by the expert committee.

Results: The CVI of PAINAD-Th was 1.00 for forward translation and 0.93 for back translation. The PAINAD-Th showed strong correlations with the reference standard (r_s=0.854–0.943, p-value <0.001). The inter-rater agreement for the total scores was 0.937 and 0.955, and the test-retest reliabilities were 0.914 to 0.964 for the activity stage and 0.880 for the resting stage, respectively. The concurrent validity index did not vary significantly across different stages of dementia; the findings remained consistent in the delirium subgroup analysis.

Conclusions: The PAINAD-Th is a valuable tool for evaluating pain in PwD, not only in severe dementia but also in moderately severe stage, regardless of concurrent delirium. It also demonstrated good-to-excellent concurrent validity, inter-rater reliability, and test-retest reliability.

Keywords: Pain; dementia; reproducibility of results (Siriraj Med J 2025; 77: 12-21)

INTRODUCTION

Dementia is a complex syndrome characterised by impairment across multiple cognitive domains, resulting in a progressive decline in daily functioning.[1] In addition to cognitive decline, dementia affects behaviour, mood, mental state, and interpersonal relationships.[2] In the early stage, people with dementia (PwD) may not need assistance in basic daily activities and can communicate their needs well, but as the disease advances to the severe stage, they usually have limited expression of their needs and are unable to perform daily activities without assistance.[3]

Pain detection is one of the challenging problems in PwD. Despite the high prevalence of pain up to 50% of people with dementia in hospital settings,[4] it is often inadequately identified and managed due to the difficulties in expressing pain,[5] resulting in depression, further cognitive and physical decline, increased risk of falls, poor sleep quality, and a reduction in the quality of life of affected individuals.[6,7]

Pain self-reporting is considered the gold standard for evaluating pain in patients who can express the characteristics and severity of their pain. In people with mild to moderate cognitive impairment, it is suggested that pain can be evaluated by querying their pain using the Numerical Rating Scale or verbal expression.[8,9] However, pain assessment in people with severe cognitive impairment using self-report is challenging because of their decreased communication ability. Notwithstanding the difficulty in verbally expressing pain, PwD possibly manifest their pain in non-specific manifestations such as confusion, agitation, restlessness, irritability, or changes in appetite.[10-12]

This adversity has led to the development of various pain assessment tools in PwD, based on behavioural observation, including the "Discomfort Scale-Dementia of the Alzheimer's Type" (DS-DAT), "Checklist of Nonverbal Pain Indicators" (CNPI), "the ABBEY Pain Scale", "Mobilization-Observation-Behavior-Intensity-Dementia Pain Scale" (MOBID), "Pain Assessment Checklist for Seniors with Limited Ability to Communicate" (PACSLAC), "Pain Assessment in Advanced Dementia" (PAINAD) scale, and Doloplus-2 scale. Among the tools mentioned, the UK National guidelines recommend using the PAINAD and Doloplus-2 scales to assess pain in PwD.[9]

The PAINAD scale was developed by Warden, et al. to assess pain in PwD. It includes observing individuals in five features: breathing, negative vocalisation, facial expression, body language, and consolability. Each feature is scored on a scale ranging from 0 to 2 based on specifically described characteristics. The scale exhibited good construct validity, strong interrater reliability, and a good correlation with the DS-DAT scale and the Visual Analogue Scale (VAS).[13] The PAINAD has shown strong concurrent validity in clinical research, regardless of cognitive status in older adults undergoing hip fracture surgery.[14] Additionally, it has demonstrated a high sensitivity of 92% in identifying and detecting pain in older people with severe dementia.[15]

The PAINAD scale has been translated into multiple languages, including Italian, German, Portuguese, Dutch, Chinese, and Korean.[16-22] However, it has not been translated into Thai. Given the absence of an optimal pain assessment tool for individuals with moderate to severe dementia in Thailand, despite the increasing prevalence of dementia among older adults as a result of a rapid transition of the Thai population into a super-aged society within a decade,[23] this study aims to assess the reliability and validity of a Thai version of PAINAD (PAINAD-Th) for measuring pain in PwD. Moreover, this study aimed to explore the validity of the PAINAD-Th in delirium superimposed on dementia patients, given the high prevalence of delirium varying between 38–72% in a tertiary hospital setting.[24-26]

MATERIALS AND METHODS

This study comprised three phases of validity processes carried out at Siriraj Hospital, a large university hospital in Bangkok, Thailand. The study protocol was approved by the Siriraj Institutional Review Board before commencing (Si 560/2019). The process of cross-cultural translation and the evaluation of the validity and reliability of PAINAD-Th involved three distinct phases, as outlined below.[27,28] Video recordings were used for training and interrater reliability processes to minimise the disturbance of vulnerable subjects and ascertain that the assessments were based on the exact circumstances.

Phase 1: Translation of PAINAD to a Thai version

In the initial forward-translation step, the original English version of the PAINAD scale was translated into Thai after receiving permission from one of the PAINAD developers, Prof. Ladislav Volicer, by two bilingual geriatricians with Thai mother tongues. Subsequently, a complete translated version was created through consensus between the two translators. A back-translation was then independently undertaken by another translator, who is bilingual in traditional Thai and English and has a master's degree in linguistics. Subsequently, a team of three subject-matter experts (two geriatricians and one anesthesiologist) reviewed the back-translation and rated each feature from 1–4. Higher scores (3 or 4) indicated closer equivalence to the original version. The content validity index for semantic equivalence to the original version of the PAINAD was then assessed.[29] Any uncertainties about the translation were discussed with the back-translator. All features underwent a thorough review to ensure accuracy and grammatical correctness. Subsequently, the final version of the PAINAD-Th scale was attained.

Phase 2: Training process

The two nurses underwent a two-step training process facilitated by a geriatric fellow. Initially, they participated in a one-hour instructional session where they received detailed explanations of each component of the PAINAD-Th scale and were assessed to confirm their comprehension of the tool. Subsequently, each nurse independently practised using the scale while observing the same set of 10 videos. The objective was to sufficiently acquaint the nurses with the patient-observation procedures, enabling them to independently and consistently utilise the PAINAD-Th scale in the later evaluation.

Phase 3: The test of reliability and validity of PAINAD-Th

The reliability and validity of the PAINAD-Th scale were assessed through inter-rater reliability, test-retest reliability, and concurrent validity analyses.

Study design

From September 2019–March 2020, patients aged over 60 who had been admitted to Siriraj Hospital were enrolled in the study if any one of the following conditions were met:

1) they had a prior diagnosis of dementia in their medical records;

2) they had been diagnosed with dementia by a geriatrician on admission or

3) they had an abnormal cognitive assessment[30] (namely, a modified Informant Questionnaire on Cognitive Decline in the Elderly score (modified IQCODE)[31] ≥ 3.42, a Thai Mental State Examination score (TMSE)[32] < 24, or a Montreal Cognitive Assessment score(MoCA)[33] < 25).

After the dementia patients were identified, the geriatric fellow assessed the severity of dementia using the Functional Assessment Staging Test (FAST)[34] in order to enrol patients with a moderately severe or severe stage of dementia (FAST stage 6 and 7). The family members or guardians of patients were informed about the research aims and procedures, including video recordings, and then informed consent was obtained. Patients were excluded if they were comatose or quadriplegic, had severe sepsis or septic shock,[35] or had been admitted to an intensive care unit.

On the initial assessment, baseline characteristics were collected and assessed by the geriatric fellow. These included age, sex, comorbidities, the Barthel Index,[36] for assessing basic activities of daily living, FAST stage for dementia, and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) classification for

delirium.[1] The delirium diagnosis made by the geriatric fellow had previously demonstrated a substantial agreement with an experienced geriatrician with Cohen's kappa coefficient of 0.783.

Pain diagnosis reference standard

A researcher recorded videos of each participant for two episodes, each for a 5-minute duration. The first record, labelled as "activity", was captured during an activity that could provoke pain, such as wound dressing, bed-bathing, or physical therapy session, while the second one, labelled as "rest", was recorded while the patient was at rest. Two geriatricians who were unaware of the scoring of the PAINAD-Th established a comprehensive pain assessment as a reference standard by reviewing the participants' medical histories from electronic medical records and inpatient documents, including potential sources of pain, and then used a Visual Analogue Scale (VAS)[37] to assess the participants' pain levels based on their behaviour in the activity and rest videos, given the participants were unable to communicate their pain accurately.

Determination of PAINAD-Th reliability

The primary outcomes included assessing the reliability and validity of PAINAD-Th for measuring pain in PwD in moderately severe to severe stages. To test inter-rater reliability, two trained nurses independently evaluated the participants' pain using PAINAD-Th by observing the same sets of video records. One week later, the rating process was reproduced to investigate the test-retest reliability of PAINAD-Th. Concurrent validity was investigated by evaluating it against the VAS assessment by the geriatricians.

Statistical analysis

The sample size calculation for exploring the concurrent validity of PAINAD-Th was based on the previous study reporting a moderate correlation (correlation coefficient; r=0.65) of translated PAINAD (Italian version) with the Visual Rating scale.[16] Our study expected the lowest value that still represents a moderate correlation (r=0.4–0.69),[38] thus, the correlation coefficient of 0.4 was used to estimate the sample size, given an acceptable significant level of 5% (p=0.05) with a power of 80% and a 20% dropout rate; the calculated sample size was 57.

Demographic data for categorical variables were reported as percentages. For continuous variables, data were presented as means with standard deviations for parametric data, and medians with interquartile ranges for non-parametric data. The content validity index was used to determine the semantic equivalence to the original PAINAD scale by summing the percentages of agreement of all items given a rating of 3 or 4 by the expert committee. Intraclass correlation coefficients (ICCs) were analyzed for inter-rater reliability using a two-way mixed-effects model with absolute agreement type and for test-retest reliability using a two-way mixed-effects model with consistency type.[39,40] The concurrent validity of PAINAD-Th compared to the reference standard was analyzed using Spearman's rank correlation coefficient, due to the non-parametric nature of the data. Analyses were conducted using PASW Statistics for Windows (version 18.0; SPSS Inc., Chicago, Ill., USA).

RESULTS

Baseline characteristics

A total of 60 participants were enrolled in the study, with a mean age of 84.7 ± 7.1 years. In total, 120 video recordings were obtained. Women comprised 66.7% of the sample, with the majority (60%) diagnosed with Alzheimer's disease. Approximately two-thirds of the participants were in the moderately severe stage of dementia. The most common diagnosis associated with painful conditions was fractures, accounting for 38.3% of cases. Delirium was present in 23.3% of participants, with hypoactive delirium being the most prevalent subtype. Characteristics of the included participants are outlined in Table 1.

Content validity index

The content validity indices for the semantic equivalence were 1.00 for the forward translation and 0.93 for the back translations.

Concurrent validity

The concurrent validity of the PAINAD-Th at rest demonstrated strong correlation coefficients (r_s), ranging from 0.854 to 0.943, with a p-value <0.001. During activity, the correlation coefficients (r_s) ranged from 0.897 to 0.904, also with a p-value <0.001 (Table 2). Subgroup analyses were conducted to assess concurrent validity across different dementia stages and based on the presence of delirium. The results indicated a slightly stronger correlation with the reference standard in the severe stage compared to the moderately severe stage. In participants without delirium, the PAINAD-Th exhibited a very strong correlation with the reference standard (Table 2).

Inter-rater reliability and test-retest reliability

Concerning inter-rater reliability, the ICCs for the

TABLE 1. Baseline characteristics.

Characteristics	Results (N=60)
Age, mean ± SD	84.7 ± 7.1
Male, n (%)	20 (33.3)
Education, median (P25, P75)	4.0 (4.0, 12.0)
Charlson comorbidity index[a], n (%)	
0	–
1–2	32 (53.3)
3–4	18 (30.0)
≥ 5	10 (16.7)
Admission ward, n (%)	
Medical	17 (28.3)
Surgical	17 (28.3)
Orthopedic	26 (43.3)
Diagnoses related to painful conditions, n (%)	
Fracture	23 (38.3)
Surgical procedure	16 (26.7)
Joint contracture/ arthritis	4 (6.7)
Limb ischemia	3 (5.0)
Headache	3 (5.0)
Abdominal pain	1 (1.7)
None	10 (16.7)
Diagnoses related to dementia, n (%)	
Alzheimer's disease	36 (60.0)
Vascular dementia	12 (20.0)
Other dementia types	9 (15.0)
Mixed-type dementia	3 (5.0)
Cognitive test, median (P25, P75)	
Thai Mental State Examination (TMSE)	14.5 (10.3, 17.5)
Caregiver, n (%)	
Spouse	9 (15.0)
Child	31 (51.7)
Relative	8 (13.3)
Formal caregiver	12 (12)
FAST stage, n (%)	
Stage 6, moderately severe	
6A	5 (8.4)
6B	7 (11.6)
6C	11 (18.3)
6D	4 (6.7)
6E	17 (28.3)
Stage 7, severe	
7A	7 (11.7)
7B	1 (1.7)
7C	1 (1.7)
7D	3 (5.0)
7E	3 (5.0)
7F	1 (1.7)

TABLE 1. Baseline characteristics. (continue)

Characteristics	Results (N=60)
Delirium, n (%)	
Total	14 (23.3)
Hypoactive	8 (13.3)
Hyperactive	4 (6.7)
Mixed	2 (3.3)
Barthel Index, n (%)	
Very severely disabled	19 (31.7)
Severely disabled	14 (23.3)
Moderately disabled	20 (33.3)
Mildly disabled	7 (11.7)

Note: [a] Age-unadjusted Charlson comorbidity index

TABLE 2. Concurrent validity: the correlation between the VAS (reference standard) and the PAINAD-Th.

	Spearman's Rank Correlation Coefficient (rs; 95% CI)			
	Rater 1		Rater 2	
	Activity	Rest	Activity	Rest
All cases	0.904	0.854	0.897	0.943
(N=60)	(0.807–0.960)	(0.756–0.940)	(0.801–0.951)	(0.879–0.990)
Stages of Dementia				
Moderately severe stage	0.883	0.878	0.884	0.949
(N=44)	(0.765–0.955)	(0.748–0.964)	(0.775–0.954)	(0.891–1.000)
Severe stage	0.995	0.834	0.965	0.964
(N=16)	(0.973–1.000)	(0.472–0.966)	(0.865–0.997)	(0.842–1.000)
Delirium Diagnosis				
Delirium	0.843	0.827	0.861	0.883
(N=14)	(0.530–0.976)	(0.560–1.000)	(0.495–0.993)	(0.667–1.000)
No delirium	0.952	0.878	0.922	0.966
(N=46)	(0.898–0.977)	(0.750–0.960)	(0.833–0.965)	(0.906–1.000)

Abbreviation: VAS, Visual Analogue Scale
Note: all p-value <0.001

total PAINAD-Th scores were 0.937 (activity stage) and 0.955 (rest stage). At rest, each item showed a moderate-to-good ICC, ranging between 0.691 and 0.818. The ICCs for the activity stage also showed moderate-to-good ICCs of 0.671 to 0.861 (Table 3). The test-retest reliabilities for the total scores were good to excellent (ICCs of 0.880 to 0.964). When examining each feature, the ICCs generally showed good reliabilities, except for a few features that displayed moderate reliabilities. These include the breathing feature assessed during the activity stage, and the body language feature assessed both in the rest stage and during the activity stage (Table 4).

TABLE 3. Inter-rater reliability for each feature and total score.

PAINAD-Th feature	Intraclass correlation coefficient (ICC; 95% CI)	
	Activity	Rest
Breathing	0.671 (0.566–0.789)	0.735 (0.594–0.833)
Negative vocalisation	0.861 (0.778–0.914)	0.818 (0.713–0.887)
Facial expression	0.701 (0.470–0.829)	0.773 (0.647–0.858)
Body language	0.780 (0.658–0.862)	0.766 (0.631–0.855)
Consolability	0.827 (0.726–0.893)	0.691 (0.531–0.803)
Total score	**0.937 (0.880–0.965)**	**0.955 (0.926–0.973)**

TABLE 4. Test-retest reliability for each feature and total score.

PAINAD-Th feature	Intraclass correlation coefficient (ICC; 95% CI)	
	Rater 1	Rater 2
Activity		
Breathing	0.676 (0.511–0.793)	0.606 (0.417–0.744)
Negative vocalisation	0.746 (0.609–0.840)	0.792 (0.674–0.870)
Facial expression	0.828 (0.727–0.893)	0.771 (0.643–0.856)
Body language	0.695 (0.538–0.806)	0.680 (0.517–0.796)
Consolability	0.767 (0.638–0.854)	0.861 (0.778–0.915)
Total score	**0.964 (0.941–0.978)**	**0.914 (0.861–0.948)**
Rest		
Breathing	0.764 (0.633–0.852)	0.857 (0.772–0.912)
Negative vocalisation	0.789 (0.670–0.868)	0.635 (0.455–0.764)
Facial expression	0.731 (0.586–0.830)	0.741 (0.601–0.837)
Body language	0.720 (0.572–0.823)	0.622 (0.439–0.756)
Consolability	0.884 (0.813–0.929)	0.846 (0.754–0.905)
Total score	**0.880 (0.807–0.926)**	**0.880 (0.807–0.927)**

DISCUSSION

This study demonstrated good validity and reliability of the PAINAD-Th scale for pain assessments among patients with moderately severe or severe dementia. The result was consistent with previous studies.[13,16-21] The content validity indices of the PAINAD-Th, as evaluated by experts, demonstrated high scores, signifying semantic equivalence to the original version and suitability for implementation in a Thai context. The concurrent validity of the PAINAD-Th, evaluated by comparing the results against the VAS determined by the two geriatricians, showed an excellent correlation. This result was similar to a study by Warden, *et al.*,[13] which was tested against the VAS and was slightly higher than that of D. Costardi, *et al.*[16] The strong correlation may be influenced by the comprehensive pain assessments by an expert committee across multiple domains. This includes observing the participant's body language, facial expressions, and pain-indicating vocalizations, all of which may partly resemble those of the PAINAD-Th features. Regarding pain-indicating vocalizations assessed by the expert committee, some of the PwD may be able to accurately report their pain verbally, even in moderate to severe stages,[41,42] which could correspond to an observational comprehensive assessment of pain recommended for individuals with severe dementia.[43]

In this study, the use of PAINAD-Th also effectively measured pain in patients with dementia in their moderately severe and severe stages, addressing the gap left by previous studies that focused only on patients in the severe stage.[13,16-21] Additionally, the PAINAD-Th scale accurately identified pain in both resting and active stages.

We also observed that the assessment of the breathing feature during activity demonstrated lower inter-rater reliability and test-retest reliability compared to other features, which is consistent with the previous study.[13] The findings may be attributed to the difficulty of accurately assessing breathing patterns through video recordings when PwD could have altered respiratory pathology, leading to apnea or breathing dysrhythmias.[44,45] Besides, Cheyne-Stokes respiration may not be a specific indicator of pain, as this pattern is commonly seen in patients with unstable central respiratory control, such as those with stroke and heart failure.[46] As a result, the variation of breathing patterns in PwD could perplex the rating of the breathing feature.

Despite the discrepancy in each feature score between the two raters, the decision to proceed with further management was based on the total score rather than each feature. It is important to note that the lower agreement on each feature may not diminish the overall rating result.

Our study demonstrated that the PAINAD-Th effectively evaluated pain in PwD who also experienced delirium. The data revealed a strong correlation between the PAINAD-Th scores and the established reference standards, suggesting that this tool is reliable in complex clinical situations, such as acute care settings where delirium is frequently encountered.[24,25] Although the correlation was slightly reduced in PwD with delirium compared to those without, this discrepancy likely stems from the inherent challenges of assessing pain in delirious patients. Delirium often manifests with various symptoms, such as disorganized thinking, perceptual disturbances, and inattention, that can obscure the accurate interpretation of pain-related behaviours. For example, negative vocalizations may not necessarily indicate pain but could reflect other unmet needs, making it difficult to differentiate. However, considering that pain is a well-documented precipitating factor for delirium[47], the availability of a tool like the PAINAD-Th, which can capture pain signals even in these complex cases, is crucial for ensuring timely and effective clinical interventions. The test's ability to operate reliably in such challenging contexts underscores its value in managing pain in PwD, particularly in settings where delirium is a common complicating factor.

This study presents both strengths and limitations that should be recognized. A key strength was the methodology employed to assess test-retest reliability, inter-rater reliability, and concurrent validity. Geriatricians and nurses observed the same set of video recordings, enabling direct comparison of the pain ratings provided by nurses against the reference standard values determined by geriatricians, without any interval between assessments. This approach ensured consistency and robustness in evaluating the tool's validity. Additionally, the study demonstrated that pain assessment using the PAINAD-Th could be effectively conducted after a one-hour training session. It is plausible that further competency could be achieved through more extensive training or supplementary self-learning resources, which may enhance understanding of the tool. This could serve as a framework for the tool's integration into daily clinical practice and support its feasibility for use by non-specialist personnel.

However, several limitations must be acknowledged. A primary limitation is that patient assessments were conducted via video recordings, while in clinical settings, pain assessments are typically performed in person, allowing for a more comprehensive and time-sensitive evaluation. Furthermore, the validity of the reference

standard could be strengthened by confirming the resolution of symptoms following pain relief, thereby providing additional verification of the tool's accuracy in identifying pain.

Another limitation is that we did not account for behavioural and psychological symptoms of dementia (BPSD) diagnoses prior to the reference-standard pain assessment. BPSD is highly prevalent, affecting up to 90% of PwD,[48,49] and includes a variety of manifestations, such as agitation, anxiety, irritability, and abnormal vocalization. These symptoms may contribute to the overdiagnosis of pain by the reference standard, as certain behavioural cues assessed by the PAINAD-Th scale can overlap with features of BPSD. This overlap could lead to a high correlation between the reference standard and the PAINAD-Th scale.

However, it is important to note that BPSD is often triggered by unmet needs such as pain, hunger, toileting, or communication difficulties. Thus, diagnosing and addressing potential pain may be more beneficial than overlooking it, given the significant impact untreated pain can have on the quality of life in PwD.

CONCLUSION

The PAINAD-Th is an effective tool for assessing pain in people with dementia, regardless of the presence of delirium. Compared to the standard reference, it has demonstrated good-to-excellent content validity, concurrent validity, inter-rater reliability, and test-retest reliability. Furthermore, its utility extends not only to severe dementia cases but also to moderately severe stages.

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DECLARATION

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Conceptualisation and methodology, T.W., N.B., P.S., and V.S.; Investigation, N.B., S.P., N.P., S.M., P.S., T.W.; Formal analysis, N.B., T.W.; Visualization and writing – original draft, N.B.; Writing – review and editing, T.W., V.S.; Funding acquisition, N.B., T.W.; Supervision, T.W. All authors have read and agreed to the final version of the manuscript.

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