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Vietnamese Version of Cornell Scale for Depression in Dementia at an Outpatient Memory Clinic: A Reliability and Validity Study

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Keywords
Depression · Dementia · Cornell scale · Vietnamese · Reliability · Validity

Abstract

Background: In Vietnam, there has been, currently, no standardized tool for depression assessment for people with dementia (PWD). Cornell Scale for Depression in Dementia (CSDD) is a widely studied and used scale for PWD worldwide. ***Objectives:*** The aim of this study was to standardize the Vietnamese version of the CSDD (V-CSDD) in depression assessment in PWD through reliability and validity examination. ***Methods:*** V-CSDD was rated in terms of reliability and validity with gold standard regarding "major depressive episode" and "major depressive-like episode" of DSM-5. Cronbach's α, ICC, exploratory factor analysis (EFA), and receiver operating characteristic analysis were performed. ***Results:*** V-CSDD was found to have a high internal consistency reliability (Cronbach's α = 0.80), inter-rater reliability at sound ranking (ICC = 0.89; 95% CI = 0.81–0.94), maximum cut-off mark of 13 (sensitivity = 70%, specificity = 92%), and EFA, which suggested that V-CSDD may comprise 5 factors. ***Conclusions:*** Results indicate the V-CSDD to be a reliable and valid assessment and to be beneficial in classifying and diagnosing depression in dementia outpatients in clinical contexts.

Introduction

Depression, one of the most common mental disorders, occurs in 7% of the general elderly population; especially, this number is up to more than 20% in people with Alzheimer's disease [1, 2]. Depression and dementia are closely related, adversely affecting patients' cognitive function and life quality, especially as a comorbidity. The rate of people with dementia (PWD) comorbidity with a major depressive disorder is about 25% [3–5]. However, the fact that depression and dementia symptoms share many similarities makes depression detection and diagnosis in this patient group difficult, leading to missed diagnosis, even with a psychiatrist. In Vietnam, no accurate tool or criteria have been identified in approaching depression diagnosis in this patient population other than (DSM-5) and ICD-10 – which have been developed in a healthy population.

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The Cornell Scale for Depression in Dementia (CSDD) was originally developed with the aim of depression screening in PWD receiving care and treatment in nursing homes [6]. The questionnaire consists of 19 items, divided into 5 parts, which are as follows: mood-related signs, behavioral disturbance, physical signs, cyclic functions, and ideational disturbance. The fact that CSDD is valid for different degrees of cognitive dysfunction from mild to severe is one advantage of this scale compared to a commonly used scale, the Hamilton Depression Rating Scale (HAM-D), which was only effective when used in subjects with no or only mild cognitive dysfunction [7]. This suggests that it is a useful tool to assess depression in PWD.

The primary objective of this study was to determine the Vietnamese version of the CSDD's (V-CSDD) reliability and validity in depression assessment in PWD in outpatient clinics. The secondary objective was to determine the number of factors of V-CSDD through exploratory factor analysis (EFA).

Materials and Methods

Design

We performed a cross-sectional study from January 2020 to June 2020 on PWD in an outpatient clinic at the Memory clinic of Memory and Dementia Unit, 30/4 Hospital, Ho Chi Minh City.

Subjects

Participants were recruited based on the patient list visiting or undergoing treatment at the clinic and meeting the sampling criteria ($n = 46$). Admission criteria were as follows: having been diagnosed with dementia by a neurologist; age at 40 or above; currently not being delirious; having no other acute medical problems, having a stable medical condition; having, at least, 01 regular and continuous caregiver within 06 months before participating in the study. Exclusion criteria were as follows: patients who are completely unable to express their basic needs, emotions, or engaging in verbal or behavioral behaviors to interact with caregivers and those around them; being treated with medications related to depression risk such as calcium channel blockers, corticosteroids, antiepileptic drugs; being diagnosed with either Parkinson's disease, cirrhosis, chronic kidney disease, or endocrine disorders (hyperthyroidism, hypothyroidism, hypopituitarism) excluding diabetes; and being treated with antidepressants.

Procedure

Demographic information was collected including age and gender. The participants were then randomly assigned to one of two groups ($n = 23$). Group 1 was assessed for "major depressive episode" or "major depressive-like episode" based on DSM-5 criteria by psychiatrists; Structured Clinical Interview for DSM-5 (SCID-5) was used to collect data. Then, each patient was evaluated by Mini-Mental State Examination (MMSE) and V-CSDD.

Conversely, group 2 was assessed by MMSE and V-CSDD first before being examined by psychiatrists. During the above process, two stages were performed completely independently, where the psychiatrist would not know the participant's MMSE and V-CSDD scores, while the observer would not know whether the participant was diagnosed with depression.

To determine inter-rater reliability, 32 of the 46 participants in the study were randomly selected. Caregivers and patients were interviewed using the V-CSDD scale by two independent data collectors. This process was carried out in the same data collection session with a 30-min interval between the two V-CSDD sessions.

Dementia Diagnosis

The neurologist took a thorough medical history, including information from the patient and those around them, related to the functional symptoms of the patient's cognitive domains. Next, the patient was examined clinically and laboratory tests were conducted to support the diagnosis, including brain MRI. The patient then underwent the following standard cognitive function tests: MMSE, word list recall, immediate recall, Trail Making Test A, Trail Making Test B), delayed recall, delayed recognition, digit span forward, digit span backward, animal fluency test, and clock drawing test. Dementia diagnosis was based on the neurocognitive disorder criteria in the DSM-5.

Depression Diagnosis

The psychiatrists used "major depressive episode" and "major depressive-like episode" criteria listed in the DSM-5 to identify depression for those patients participating in the study.

V-CSDD

V-CSDD was transcribed into Vietnamese following the official translation guide written by Sousa et al. [8] (2011). The observers, including four trained medical staff, had received training, where each would interview 5 dementia patient-caregiver pairs with V-CSDD. The approach and sample questions were discussed and agreed upon by all team members according to CSDD assessment guidelines from the author [9]. The PWD assessed in the training process were not included in the current study. The ability to use V-CSDD was ensured to be consistent among observers by peer evaluation.

Statistical Analysis

Data were analyzed using R language version 4.0.2. Descriptive analyses were performed. The significance threshold in our study was $p = 0.05$.

Internal Consistency Reliability

Cronbach's α was used to evaluate internal reliability of V-CSDD.

Inter-Rater Reliability

Intraclass correlation coefficient was applied to evaluate the inter-rater reliability of V-CSDD. Observers were randomly selected to evaluate participants, the results of which were analyzed based on a single assessment of each observer, the objective was to assess absolute agreement between observers. Two-way random effects, absolute agreement, and single measurement were used.

Criterion Validity

Criterion validity was determined through concurrent validity; thus, receiver operating characteristic (ROC) analysis was used.

Table 1. Characteristics of the memory clinic's outpatients in the V-CSDD reliability and validity study (*n* = 46)

Characteristic	Depression (*n* = 10)	No depression (*n* = 36)	*p* value
Median age (IQR), years	66.5 (62.8–69.8)	66.5 (62.0–74.0)	0 (–7 to 7)*
Gender, *n* (%)			
Male	2 (20.0)	10 (27.8)	1.000**
Female	8 (80.0)	26 (72.2)	
Dementia diagnosis, *n* (%)			
Alzheimer	7 (70.0)	25 (69.4)	0.858**
Vascular	0 (0.00)	3 (8.3)	
Other	3 (30.0)	8 (22.2)	
Mean MMSE score (SD), points	14.9 (10.7–19.1)	18.4 (16.2–20.7)	0.159
Mean V-CSDD score (IQR), points	13.5 (9.3–17.0)	4.0 (0.8–9.3)	9.5 (3–13.5)*

V-CSDD, Vietnamese version of Cornell Scale for Depression in Dementia; MMSE, Mini-Mental State Exam; IQR, interquartile range; SD, standard deviation. * Difference of median (95% CI for difference) by bootstrapping with 10.000 iterations. ** Fisher's exact test.

The criteria to evaluate the discriminant ability of the ROC curve were prevalence, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), AUC as well as precision, d distance, and Youden's Index for each cut-off point.

Construct Validity

EFA was used to probe the number of potential factors among 19 items of V-CSDD, principal component analysis (PCA) and scree plot were applied to consider the number of potential factors that should be extracted. The number of potential factors that fit was the number of factors that could explain about 60% of the variance (a minimum of 50% was required). Principal axis factoring (PAF) with oblimin rotation selected with a minimum loading score of 0.3 was considered significant. The packages used are as follows: compareGroups, gmodels, ggplot2, simpleboot, boot, psych, pROC, and caret.

Results

Among the 46 participants, 12 (26.1%) were males and 34 (73.9%) were females, with a median age of 66.5 (IQR = 62.0–73.8). The median age of male and female participants was 68.5 and 66.5, respectively. Thirty-two (69.6%) participants were diagnosed with dementia due to Alzheimer's disease, caused by vascular disease in 3 (6.5%) cases, the remaining participants (24%) were diagnosed with dementia due to other causes, 10 mixed dementia (Alzheimer's disease and vascular), and 1 frontotemporal dementia. The average MMSE score of the participants in this study was about 18 points (95% CI = 15.6–19.7). Ten (21.7%) present patients were with concomitant depressive episodes. Regarding the total V-CSDD score, the median of all patients participating in the study was 7 points (IQR = 2.0–11.0). No statistically significant differences in the characteristics were described between the male and female groups in the above diagnoses. The median V-CSDD score in the patient group diagnosed with depression was higher than that of the group without depression (13.5 vs. 4.0) (Table 1).

Reliability

Internal Consistency

Internal consistency of V-CSDD in dementia patients was good with Cronbach's α = 0.80. Besides, Cronbach's α did not change significantly when deleting items, ranging from 0.77 to 0.80.

Inter-Rater Reliability

V-CSDD had an absolute agreement between different observers, with an ICC coefficient of good (ICC = 0.89, 95% CI = 0.81–0.94).

Validity

Criterion Validity

The V-CSDD had an AUC = 0.86 (95% CI = 0.71–0.87; bootstrap 2,000 iterations). The results of prevalence, sensitivity, specificity, PPV, NPV, and precision calculated for each cut-off point are shown in Table 2. The highest accuracy was observed when choosing the cut-off point at the 13, 14, and 17 points (together of 87%). The results of distance d and Youden's index were also used to find the optimal cut-off point, Figure 1 depicts the ROC curve and provides a visual representation of these two indices. Corresponding to a cut-off point of 13 points, distance d had the lowest value of 0.31, and Youden's index had the highest value of 0.62 (Table 2).

Table 2. Results of ROC analysis of V-CSDD in predicting current depressive episode in outpatient dementia patients (n = 46)

Cut-off point	Prevalence, %	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Precision, %	d distance	Youden's index
8	43.5	90	69	45	96	74	0.32	0.59
12	23.9	70	89	64	91	85	0.32	0.59
13	**21.7**	**70**	**92**	**70**	**92**	**87**	**0.31**	**0.62**
14	13.0	50	97	83	88	87	0.50	0.47
17	8.7	40	100	100	86	87	0.60	0.40

Youden's Index, Sensitivity + Specificity − 1. Bold values represent the optimal cut-off point. ROC, receiver operating characteristic; V-CSDD, Vietnamese version of Cornell Scale for Depression in Dementia; PPV, positive predictive value; NPV, negative predictive value.

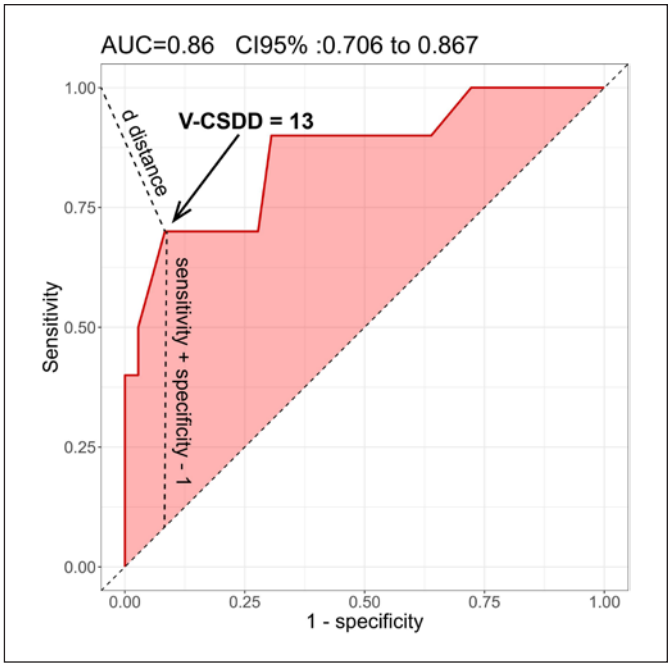

Fig. 1. ROC curve for the V-CSDD using "major depressive episode" and "major depressive-like episode" of the DSM-5 in dementia outpatients (n = 46).

Construct Validity

PCA results showed 7 components with eigenvalues >1, of which component number 1 had the highest eigenvalue of 4.34; component number 7 had an eigenvalue of 1.09 and the cumulative percentage variance started at >50% when the number of components was 4 or more. When the number of components started from 6 or more, the slope of the screen plot was not much (Fig. 2), suggesting that the maximum number of factors that could be extracted falls between 4 and 6 factors.

PAF results for the 4-factor case indicated that "diurnal variation of mood" was not loaded in any factor. In contrast, in the 6-factor case, up to 3 out of the 6 factors had only 2 questions, which would be difficult to interpret as well as apply in practice. The 5-factor model explained 54% of the variance (approximately 60% of the total variance), the extracted factors were easier to interpret than the clinical 4- or 6-factor case as well (Table 3).

Renamed extracted factors included (1) mood – affective (anxiety, sadness, lack of energy, diurnal variation of mood, suicide, pessimism); (2) irritability/delusion (irritability, agitation, difficulty falling sleep, multiple awakenings during sleep, mood-congruent delusions); (3) vegetative symptoms (appetite loss, weight loss, early morning awakening); (4) daily living functions (lack of reactivity to pleasant events, multiple physical complaints, loss of interest); and (5) psychomotor functions (retardation, poor self-esteem).

Discussion

Depression sometimes causes clinical signs of cognitive decline, also known as pseudodementia, even in patients who are previously perfectly normal in cognitive domains. Therefore, if a patient with dementia is depressed, cognitive decline may be more severe, which may simply be due to the depression rather than the impairment worsening. If it is possible to accurately diagnose whether a patient has depression, it will help to provide an appropriate treatment plan which will significantly improve the prognosis and quality of life of PWD as

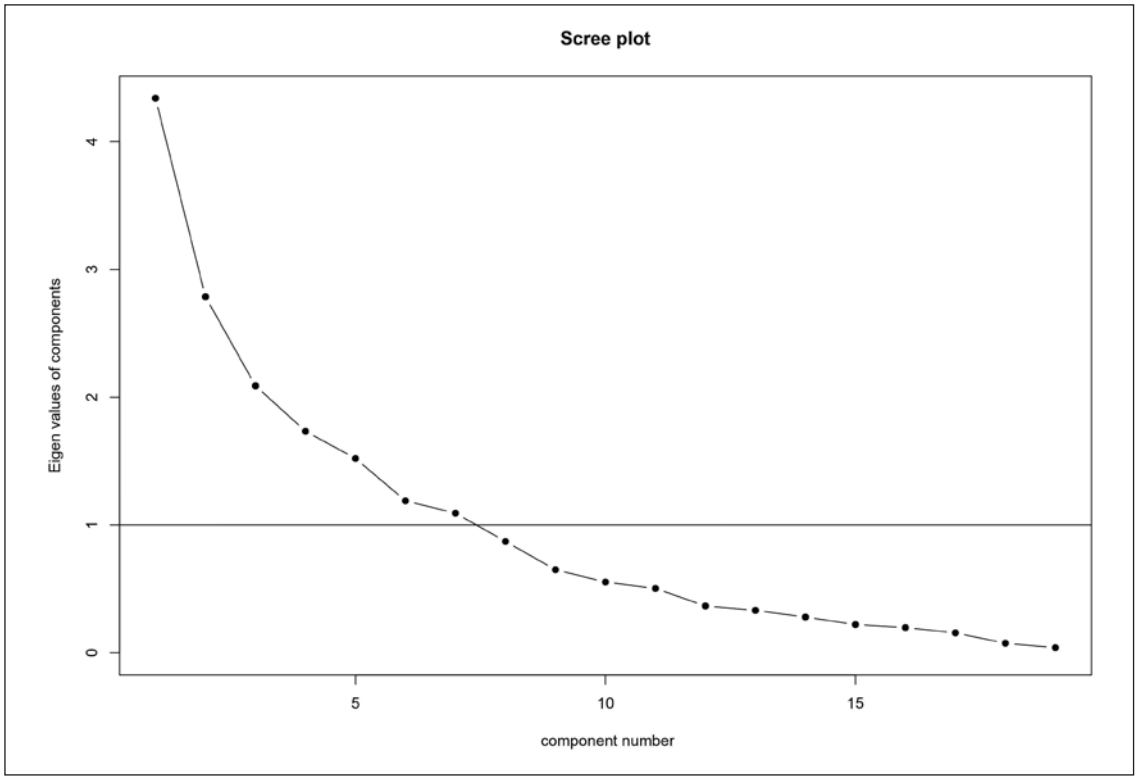

Fig. 2. Scree plot for the PCA in the V-CSDD study.

well as reduce unfortunate confusing situations for the treating doctors.

V-CSDD, when used on a sample of dementia patients in the outpatient clinic, was found to have a good internal consistency reliability (Cronbach's α = 0.80). This result indicated that the questions in the scale had a consistency and reflected the same underlying construct, which suggested that all questions of the scale should be kept. In the study of the original version of CSDD, Cronbach's α was reported as 0.84 on a sample of dementia patients in nursing homes or inpatients [6]. Similar results have been reported in studies using multiple versions of CSDD in different languages on patients with multiple dementia etiologies, as well as in both inpatient and outpatient settings, with Cronbach's α ranging from 0.84 to 0.92 [10–13]. These results may reflect the stability in the number of items of V-CSDD itself, after cultural and linguistic adaptation.

Inter-rater reliability of V-CSDD in this study was good (ICC = 0.89). In essence, V-CSDD is a semi-quantitative scale, the outcomes of which are determined based on the evaluator's observations rather than purely on content gathered from the patient or caregiver. Therefore, information about the reliability between different observers of V-CSDD was something to be considered. Although the result was found to be in contrast with the study on the original version of CSDD, the inter-rater reliability results used the Kappa coefficient for every single question [6]. The Kappa coefficient ranged from 0.60 to 0.97, showing the variation in the consensus level of each specific question; for example, the highest consensus on question 17 was poor self-esteem, and the lowest on question 4 was irritability. Another study also reported Kappa coefficient results for each question separately, ranging from 0.43 to 0.89 (mean 0.59) [11]. These results have shown differences in the assessment of individual items, each question being scored from 0 to 2 points (0 = absent, 1 = mild or intermittent, 2 = severe). The distinction between 0 and 1 (or 2 points) was probably easier when comparing 1 and 2 points, as both the patient and the caregiver would perceive better with the presence or absence of symptoms, rather than symptom severity. However, the practical application of V-CSDD was not based on the score of each item but was calculated as a total score, depending on whether the total score will be interpreted differently. Some reports based on absolute agree-

Table 3. Result of EFA by the PAF method with oblimin rotation of V-CSDD (n = 46)*

Item	Factor				
	1	2	3	4	5
Anxiety	**0.68**				
Sadness	**0.56**		0.31		
Lack of reactivity to pleasant events				**0.77**	
Irritability		**0.49**		0.46	
Agitation		**0.78**	−0.33		
Retardation					**0.53**
Multiple physical complaints				**0.50**	
Loss of interest				**0.73**	
Appetite loss			**0.73**		
Weight loss			**0.79**		
Lack of energy	**0.53**				
Diurnal variation of mood	**0.47**				−0.32
Difficulty falling asleep		**0.74**			
Multiple awakenings during sleep		**0.84**			
Early morning awakening		0.39	**0.56**		
Suicide	**0.66**				0.36
Poor self-esteem	0.39				**0.64**
Pessimism	**0.77**				
Mood – congruent delusions		**0.36**			
Eigenvalues	2.49	2.47	1.88	1.76	1.32
Explained variance, %	13	13	10	9	7
Cumulative explained variance, %	13	26	36	45	52
Cronbach's α	0.77	0.78	0.71	0.68	0.53

V-CSDD, Vietnamese version of Cornell Scale for Depression in Dementia. * Only factor loadings larger than or equivalent to absolute value of 0.30 are presented.

Table 4. Several studies standardized CSDD in dementia patients using DSM diagnostic criteria for depression

Author group	Language	Subjects	Gold-standard	Optimal cut-off point	Sensitivity, %	Specificity, %
Schreiner et al. [16]	Japanese	Inpatients and outpatients	Minor and major depression of DSM-IV	5	100	91.9
Knapskog et al. [18]	Norwegian	Outpatients from memory clinic	Major depression of DSM-IV	8	62	74
Portugal et al. [19]	Brazilian Portuguese	Brazilian elderly outpatients	Depression of DSM-IV-TR	13	83.3	53.9
Wongpakaran et al. [20]	Thai	Long-term care home residents	Major depression of DSM-IV	6	100	81.4
Jeon et al. [22]	English	Nursing home residents	Major depression of DSM-IV-TR	6	92.3	40

CSDD, Cornell Scale for Depression in Dementia; DSM, Diagnostic and Statistical Manual of Mental Disorders.

ment analysis had high inter-rater reliability, with ICCs ranging from 0.84 to 0.95 [14, 15]. These findings were supported by the current findings as there may be a difference in the evaluation of each question separately; however, V-CSDD, in general, was shown to have consistency when considering the total score. Thus, this has contributed to provide evidence of the scale's inter-rater reliability.

Criteria validity of V-CSDD when used in dementia patients was determined through the concurrent validity between the total score of V-CSDD and "major depressive episode" (or "major depressive-like episode") criteria of DSM-5. High cut-off accuracy (74–87%), when the total V-CSDD score was less than 8, may suggest that the patient did not have significant depressive symptoms at the time of assessment. Meanwhile, a total score greater

than or equal to 17 could identify depression, and a total score of 13 or more could lead to an assumption that the patient may be depressed at the time of assessment with a PPV of 70% and an NPV of 92%. In the original version of the CSDD assessment guide, the cut-off points selected and recommended by the authors included a total scale score over 10 indicators of probable major depression, over 18 indicators of definite major depression, and less than 6 indicators to rule out significant depressive symptoms [6]. These recommended cut-offs were based on diagnostic criteria for RDC that are used primarily for research purposes.

The optimal cut-off of CSDD in many previous studies have shown differences between different versions, ranging from 5 points to 17 points [7, 12, 13, 15–22]. This difference may be due to the fact that studies used different diagnostic criteria to serve as the gold standard for defining depression, along with depression severity, concurrently, feelings toward which the researcher is aiming (minor or major). The current study used DSM-5, the duration of depressive symptoms as well as the number of symptoms required to establish the diagnosis which was more than the criteria, such as RDC, PDC, PDCdA, ICD-10, applied by other studies. The characteristics of the other criteria were similar to the diagnosis of minor depression according to previous DSM versions. However, the current treatment regimens for depression pose a problem only for major depression – the aim of this study. All of the above problems may be the reason why the optimal cut-off point in our study was relatively high compared to many other studies (13 points). Among the studies that used DSM systematic criteria to define depression, there were also differences in the reported cut-off results (Table 4).

Potential reasons for the difference in cut-off scores could be due to the specific dataset of each study, the age and severity of dementia patients participating in the study as well as the regional cultural background. It is worth noting that in many other studies, caregivers are groups of medical staff, nurses, and professional caregivers who have received professional training in health problems. The difference may be due to the possibility that health care workers are more knowledgeable about symptoms of depression; therefore, they can report more symptoms than family members. Clinical users of V-CSDD should note whether the cut-off points are consistent with the diagnostic criteria to be compared (major depressive episode and major depressive-like episode according to DSM-5) so that major conclusions can be drawn.

Five factors can be extracted from the V-CSDD based on the number of similarities with the original version. However, the original author of CSDD did not publish the results of factor analysis, even though 19 questions in the scale were divided into 5 groups [6]. This classification was mainly based on similarities in the content of the questions on the scale, as well as the literature and expert opinion at the time when the authors' work was published. Currently, no consensus for the extracted factors of V-CSDD in versions across many different studies is identified; nevertheless, several groups of questions are often extracted into one factor. Specifically, the group of questions about anxiety, sadness, pessimism [11, 12, 23]; group with appetite loss and weight loss [11–14, 23, 24]; and difficulty-in-falling-asleep group, multiple awakenings during sleep, early morning awakening [10–12, 14, 23, 24]. The minimum loading score used in this study is 0.30, which is the minimum score used to assess whether a question is meaningfully loaded into a factor, as our research team wanted to limit it – the item removal mechanism when analyzing. However, in the studies that have been done before in the world, the minimum loading score used is 0.40. If the minimum loading score is applied to this study, item 19 (mood – congruent delusions) does not significantly load any of the 5 factors found. This may be due to the fact that the study population does not currently have many people with symptoms of delusions, as most outpatients are likely to have less severe thought disorders such as paranoia when compared with the inpatient group. Differences in the number of factors as well as the composition of the items loaded may be due to cultural differences in each country, which leave an impact on concepts belonging to the mental field. At the same time, differences in study subjects (inpatients, clinic patients, and different types of dementia) may contribute to the diversity of analysis results. The issue of extraction method selection also needs to be considered. The PCA method and varimax rotation ignore possible correlations between the factors while the PAF and oblimin rotation method assume that there is a correlation between the extracted factors – this can probably be more consistent with the analysis involving psychosocial aspects.

The use of DSM-5 depression diagnostic criteria as the gold standard for determining depression in study participants was one of the strengths of this study as the DSM-5 is the most recent and widely used in clinical practice. Result interpretation obtained from the study can be used in clinical as well as in future studies in a synchronized and easy way. The patients participating in the

study had a variety of disease levels (from mild, moderate, to severe) as well as the pathophysiological etiology of impairment, including common clinical etiologies. These make these findings-based interpretations more easily applicable in everyday clinical practice.

However, regarding the study participants, the inclusion criteria of our study did not include the group of patients with dementia caused by Parkinson's disease. In the case of patients with Parkinson's disease, motor and nonmotor symptoms of Parkinson's disease can present very similar to depression and would confuse the examiner, which can lead to erroneous data collection and difficulty in interpreting research results. Patients' median age in this study was also lower than many previous studies, the difference in age of each study was heavily influenced by the study design and the selection of subjects to participate in the study. Patients who are inpatients or begin to live in nursing homes at a time when they are relatively old. Simultaneously, although our study recruited patients with varying cognitive levels, from mild to severe based on the results of the MMSE scale, the obtained results can be applied to many patients. This was also a limitation in terms of specificity for each specific group because the V-CSDD cut-off point may be different in the group of patients having varying degrees of dementia. In summary, the results and interpretations drawn need to be carefully considered for each particular context. This study did not provide data on the correlation of results between V-CSDD and some other depression scores, most notably HAM-D. In Vietnam, at the time of this study, that HAM-D and depression rating scales specifically for the elderly had not been officially translated and standardized on the Vietnamese population themselves was an obstacle that our team had encountered in planning and designing the research process. Finally, EFA results drawn from this study were limited because the analysis was performed on a relatively small sample size and the resulting loading score was not high enough to ensure the stability of the structure of each sample.

In conclusion, the results of this study showed that V-CSDD was a reliable and valuable tool to assess depression in dementia patients in the outpatient clinic. The validated V-CSDD can begin to be used in clinical practice, contributing to the ability of clinicians to effectively detect dementia patients at risk of depression, enabling patients to receive early treatment for depression if necessary. In addition, V-CSDD could be used in future studies to aid in the identification of depression in people with dementia, as well as a resource for conducting more studies in different control groups, other subjects, or contribute to the development or standardization of other scales for the Vietnamese population.

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Statement of Ethics

This study has been submitted to the Protocol Approval Committee of Department of Psychiatry and the Ethics Committee for Biomedical Research of University of Medicine and Pharmacy at Ho Chi Minh City and approved on December 12, 2019. Consent was signed by the patient and/or caregiver prior to study participation.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

T.T.H. contributed to translating the CSDD, designing the research, reviewing patients, analyzing data, and writing the paper. N.T.T.N. contributed to designing the research and revising the paper. T.D.P.N. contributed to translating the CSDD and writing the paper. T.C.T. is a dementia specialist and contributed to reviewing patients, revising the paper, and giving final approval of the version to be published.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author, Dr. Tan Thanh Huynh. The data are not publicly available due to confidentiality as the containing information could compromise the privacy of research participants.

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