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Delirium assessment using Confusion Assessment Method for the Intensive Care Unit in Chinese critically ill patients☆,☆☆,☆☆☆,★,★★

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Abstract

Purpose: The aim of this study was to provide a method for delirium evaluation in simplified Chinese for patients speaking this language via validation of a translation of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU).

Materials and Methods: Two phases were conducted including initial reliability testing (phase I) of the Attention Screening Exam (ASE) followed by reliability and validity testing of the CAM-ICU (phase II). To analyze the reliability of the ASE, each patient was assessed sequentially by ASE Visual and ASE Auditory. The patients were assessed by 2 nurse investigators using CAM-ICU and 1 neurologist using *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* separately within 2 hours in the second phase.

Results: We found that the agreement between ASE Visual and ASE Auditory was high ($\kappa = 0.83$, $P < .01$, respectively). The educational level of the patients influenced the results of the inattention assessment, with the lower educational level of the patient yielding lower agreement on ASE. Even still, the κ consistencies were all above 0.61. The sensitivities of CAM-ICU were 91.8% and 93.4%, and the specificities were 90.8% and 87.7%, respectively. The interrater reliability of 2 nurse investigators was very high, with κ coefficient of 0.92 ($P < .001$).

Conclusions: This study affirmed the validity and reliability against reference raters using the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* of a brief nursing-conducted method of diagnosing delirium in ICU patients who speak simplified Chinese using the CAM-ICU.

1. Introduction

Delirium is a neurobehavioral syndrome characterized by acute confusion, inattention, disorganized thinking, and a fluctuating course of mental status changes [1]. It is a common complication among patients in intensive care unit (ICU) [2,3]. The incidence ranging from 16% to 87% depends on different population studied and different assessment instruments used [4-8]. It is associated with higher mortality and morbidity, prolonged length of ICU and total hospital stay, greater health care costs, and increased risk of nursing home placement after discharge [8-11].

Clinical practice guidelines recommend routine delirium screening, and the CAM-ICU has been translated into traditional Chinese and tested for psychometric qualities among ICU patients in Taiwan (training manual available at www.icudelirium.org). However, there are many differences between simplified Chinese and traditional Chinese not only in patterns of the characters but also in semantics and syntax. The Taiwanese traditional Chinese version of CAM-ICU may not be appropriate for mainland patients who speak simplified Chinese, for whom there is no available delirium tool (CAM-ICU [7], Intensive Care Delirium Screening Checklist [12], or otherwise) of any kind translated for use in the ICU. Thus, monitoring for delirium cannot become routine practice in mainland China, where it is estimated that 900 million people live and speak simplified Chinese.

Thus, working together as an international team, we translated CAM-ICU into simplified Chinese according to the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures [13]. We then conducted a 2-phase prospective cohort study to test the validity and reliability of the CAM-ICU in a Chinese ICU population.

2. Methods

The study population included adult patients admitted to coronary care unit (CCU), trauma ICU (TICU), surgical ICU (SICU), and respiratory ICU (RICU) in Xuan Wu Hospital, a 1000-bed university-affiliated teaching hospital in Beijing, with 42 adult ICU beds in the previously mentioned 4 ICUs. Xuan Wu Hospital institutional review board approved this study. Informed consent was obtained in all participants either from the patient or family surrogate decision makers if the patient was unable to consent for himself/herself. The research was conducted in 2 phases: the first phase was to test the reliability of the ASE in Chinese ICU patients; the second phase was to test the validity and reliability of the simplified Chinese version of CAM-ICU.

2.1. Patient recruitment

During the first phase of the study, adult patients admitted to CCU, TICU, SICU, and RICU were consecutively recruited to the study if they met the inclusion criteria such as being 18 years or older and could understand simplified Chinese and none of the following exclusion criteria: (*a*) preexisting severe dementia, encephalopathy, psychosis, or other neurologic disease (as defined in the chart or by family history); (*b*) history of vision or hearing impairment; (*c*) comatose at the time of screening (thus not testable for delirium), or (*d*) refusal of consent.

The inclusion criteria in phase II were modified to include those 50 years or older and only those admitted to the unit for more than 24 hours. The exclusion criteria were modified to include admission to the ICU after the predefined cap of 10 study patients per day had been reached because of research staffing limitations, but otherwise, the inclusion and exclusion criteria were the same as in phase I.

2.2. Sample size

Before the first phase (reliability testing), we conducted a 1-month pilot during which the study nurses became proficient in performing the CAM-ICU and, especially, the Feature 2 Attention Screening Exam (ASE) method of testing for inattention, the cardinal feature of delirium according to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (*DSM-IV*). To estimate the sample size for phase I of the investigation, we used the pilot comparisons of the ASE Visual (pictures) as the reference standard because it is believed to be a slightly more rigorous test of attention,

coupled with ASE Auditory (letters or numbers), and found that the sensitivity and specificity of ASE Auditory were 91.7% and 90.3%. Using an $\alpha = .05$ and $\beta = .2$, we determined that the sample size for this reliability testing would require 28 inattentive patients and 32 attentive patients.

In the second phase, we took the previously published 90% sensitivity and specificity of traditional Chinese version of CAM-ICU as an expected sensitivity and specificity of our simplified Chinese version of CAM-ICU. Again using an $\alpha = .05$ and $\beta = .2$, we determined that the sample size estimation for validating and determining the reliability of the diagnostic test would require 61 delirious patients and 61 nondelirious patients.

2.3. Phase I

2.3.1. Study design

Descriptive research design was used as the study design.

2.3.2. Research procedures

One study nurse screened patients daily according to the enrollment and exclusion criteria at 10:00 AM and 8:00 PM on weekdays. After informed consent was obtained, baseline data were collected, including the following: (1) demographic information (name, sex, age, ethnicity, culture, marital status) and (2) clinical data (main disease diagnosis, mechanical ventilation, visual or hearing impairment). Finally, only Feature 2 (ASE) of the CAM-ICU was assessed because this phase was geared toward advancing the methodology of this cardinal feature of delirium to build toward phase II. To analyze the reliability of the ASE, each patient was assessed sequentially with ASE Visual A, ASE Visual B, and ASE Auditory by the study nurse.

2.4. Phase II

2.4.1. Study design

This is a prospective cohort study.

2.4.2. The simplified Chinese version of CAM-ICU

In keeping with the recent action of the ICU delirium and cognitive impairment study group, we have switched the original numbering of features 3 and 4 for simplicity (see the current CAM-ICU flow sheet at www.icudelirium.org).

2.4.3. Training of interviewers

Before the study, 2 nurses in the study received formal training for 120 min/d in 1 week, which included instructions given by the researcher, during which definition and examples of delirium features were explained and discussed, a review of appropriate literature on delirium was provided, and practice sessions were conducted.

2.4.4. Structure of validity and reliability testing

2.4.4.1. Reference standard evaluations. Independently and without any knowledge of the nurses evaluations and within 2 hours of their evaluations, 1 of 3 neurologists (all with >10 years of experience) served as the reference standard for diagnosing each patient using their complete clinical examination of each patient and the *DSM-IV* criteria for delirium, as well as data from individual interviews with family members and the patient's nurse and chart review for laboratory data and nursing notes. To determine validity and reliability, we used the first alert or lethargic evaluation of each patient for the comparison evaluation. For these evaluations, the patient was tested as to whether or not he/she was arousable with verbal stimulation, demonstrated eye contact, and followed commands.

2.4.4.2. CAM-ICU evaluations. Two study nurses enrolled patients and performed daily, independent of CAM-ICU evaluation without any knowledge of the other nurse's evaluation or ratings and within 2 hours of each other. Assessment of the patient in ICU until he/she was discharged or nondelirious was conducted. At the time of enrollment, the following data were collected: demographics, severity of illness data by using the Acute Physiology and Chronic Health Evaluation II (APACHE II) score, activities of daily living (ADL), and Mini-Mental State Examination. Baseline visual or auditory deficits were recorded if patients reported that they had any impairment in vision or hearing.

2.5. Statistical analysis

Continuous variables were analyzed by using descriptive statistics (median, interquartile range, or mean [SD]) and compared by using a t test.; categorical data were analyzed as proportions (number, percentage) and compared by using χ^2 tests or the Fisher exact test. The agreement of ASE was assessed by κ consistency. Pairing McNemar χ^2 test was used to test the differences between the results of the expert and those of the nurses. Criterion validity was determined by comparing the 2 nurses in terms of the delirium expert rating of cognitive status by using the *DSM-IV* criterion as the reference standard. The performance test characteristics for the CAM-ICU were calculated using standard definitions: sensitivity, specificity, positive predictive value, negative predictive value, and Youden index. Interrater reliability was determined by comparing the CAM-ICU ratings of nurse 1 vs. nurse 2 using the κ coefficient. All statistical analyses were performed using SPSS 13.0 (SPSS, Chicago, Ill). A *P* value of less than .05 was considered statistically significant.

3. Results

The studies were conducted at 2 distinct periods sequentially called phase I and phase II. Results of ASE

Table 1 Baseline demographics for phase I and phase II cohort patients

Characteristic	Frequency	
	Phase I (n = 135)	Phase II (n = 126)
Age (y), median (IQR)	75 (65-79)	74 (63-78)
Male, n (%)	74 (54.5)	67 (53.2)
Han people, n (%)	109 (80.8)	121 (96)
APACHE II [a], median (IQR)	–	8 (6-12)
ADL [b], median (IQR)	–	20 (20-23)
Mechanical ventilation, n (%)	13 (9.0)	22 (17.5)
Visual or hearing deficit, n (%)	–	27 (21.4)
Division, n (%)		
CCU	41 (30.37)	27 (21.4)
TICU	23 (17.03)	41 (32.5)
SICU	49 (36.30)	35 (27.8)
RICU	22 (16.30)	23 (18.3)
ICU admission diagnosis, n (%)		
Cancer	22 (16.3)	23 (18.3)
COPD or pneumonia	18 (13.3)	13 (10.3)
Pancreatitis or cholecystitis	17 (12.6)	9 (7.1)
Coronary heart disease	24 (17.8)	25 (19.8)
Abdominal aneurysm	2 (1.5)	4 (3.2)
Intestinal obstruction	9 (6.7)	5 (4.0)
Low limb art sclerosis	14 (10.4)	13 (10.1)
Other	29 (21.4)	34 (27.0)

COPD indicates chronic obstructive pulmonary diseases.
   [a] For the APACHE II score, an assessment of severity of illness.
   [b] For the ADL score, an assessment of ADL.

reliability are presented first, followed by the results of validity and reliability data for the simplified Chinese version of the CAM-ICU.

3.1. Enrollment into phase I

This portion of the study was carried out between November 2008 and April 2009. During the study period, a total of 135 unique patient evaluations were conducted. General information and baseline characteristics are shown in Table 1.

3.2. Enrollment into phase II

The phase II of the study was carried out between March 2009 and May 2010. During the study period, 609 consecutive patients were admitted to these ICUs, and the patient enrollment and flow details are presented in Fig. 1. Four hundred eighty-three patients were excluded from the study according to the previously stated exclusion criteria. The remaining 126 patients were enrolled and subsequently evaluated by the *DSM-IV* reference standard expert and 2 study nurses to comprise the phase II study population (Table 1).

3.2. Phase I: reliability data

3.2.1. Reliability of ASE

The agreement of the ASE Visual was very high, with κ = 0.90 (95% confidence interval [CI], 0.76-1.00; P < .01). In addition, the agreement of ASE Visual and ASE Auditory was also very high, with κ = 0.83 (95% CI, 0.73-0.93) and κ = 0.85 (95% CI, 0.75-0.94; P < .01), respectively.

To explore the potential for variations in reliability according to educational level, we studied the agreement of ASE Visual and ASE Auditory for patients with 3 different educational levels (illiterate, primary/grade school, and
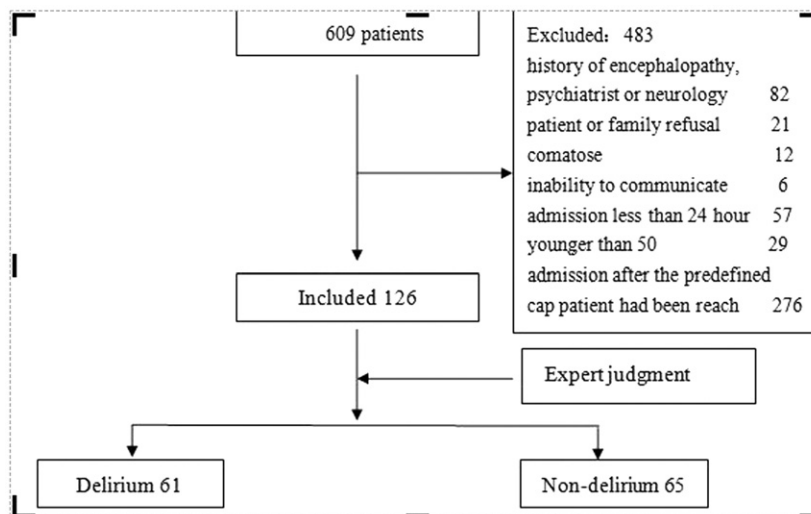

Fig. 1 Combined validation and reliability phase II patient enrollment and flow. Phase II Patient Enrollment and Flow during which 609 consecutive patients were admitted. Two hundred and seven patients were excluded from because a history of encephalopathy, psychiatrist or neurologic disease (n = 82); patient or family refusal (n = 21); comatose or stuporous (n = 12); inability to communicate with study nurse (n = 6); less than 24 hours admission in ICU (n = 57); younger than 50 (n = 29); admission after the predefined cap patient had been reach (276). One hundred and twenty-six patients who are evaluated by reference standard expert and two study nurses comprised the final study population.
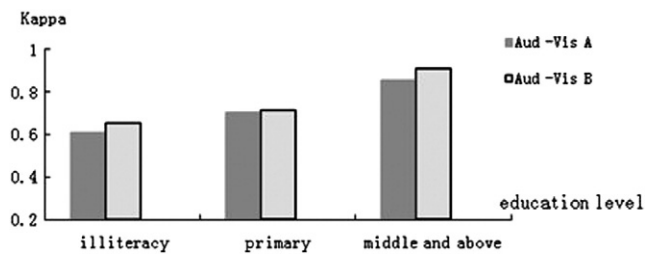
Fig. 2 Interrater reliability for inattention (cardinal feature of delirium) varies by educational level. Bar graphs showing Interrater Reliability Data using Phase I data showing 3 different educational levels within the cohort. Illiterate patients showed the lowest kappa, $\kappa = 0.61$ and 0.65, respectively. The kappas of patients with primary (e.g., grade school) educational level were $\kappa = 0.70$ and 0.71. Middle and above educational level showed statistically higher kappas in comparison to the other two groups, $\kappa = 0.85$ and 0.90, $p < 0.01$.

middle or higher educational levels) using κ statistics, and these data are presented in Fig. 2.

3.3. Phase II

3.3.1. Criterion-related validity of the CAM-ICU

The neurology experts and 2 study nurses completed 386 paired evaluations in 126 patients. Using the first alert or lethargic paired evaluation of each patient, the test performance of the CAM-ICU was determined. According to the *DSM-IV* reference raters, 61 patients were found to be delirious and 65 patients were nondelirious (Fig. 1). Nurse 1 found that 62 patients had delirium, whereas nurse 2 found that 65 patients had delirium (Table 2). Compared with the reference raters, the sensitivities of 2 study nurses were 91.8% and 93.4%, respectively, and their specificities were 90.8% and 87.7%, respectively (Table 3).

The study included 22 mechanically ventilated patients. Among the ventilated patients, the neurology experts found that 14 patients were delirious and 8 patients were not delirious. The 2 nurses found that 16 patients were delirious and 6 patients were not delirious. In these ventilated patients,

Table 2 Comparison of delirium assessment between nurse and the neurology expert (n = 126)[a]

Expert *DSM-IV* delirium rating	Study nurse 1			Study nurse 2		
	Yes	No	Total	Yes	No	Total
Yes	56	5	61	57	4	61
No	6	59	65	8	57	65
Total	62	64	126	65′	61	126

P > .05.

[a] Validation data from phase II, with calculated sensitivities and specificities shown in Table 3. The neurology experts and 2 study nurses completed the evaluation in 126 patients. The neurology expert found that 61 patients were delirious and 65 patients were not delirious. Nurse 1 found that 62 patients had delirium, whereas nurse 2 found that 65 patients had delirium.

the sensitivity of 2 study nurses was 100%, whereas their specificity was 75% (Table 3).

According to the expert diagnosis, every delirious patient was classified as hyperactive, hypoactive, or mixed type. The sensitivity and specificity of the subtype delirium are shown in Table 4.

3.3.2. Interrater reliability

Interrater reliability was defined as the agreement of CAM-ICU results between the 2 study nurses. There were a total of 292 paired assessments in the 126 patients. The CAM-ICU was completed with excellent interrater reliability between nurses 1 and 2 ($\kappa = 0.92$; 95% CI, 0.88-0.97; $P < .001$).

3.3.3. Ease of use

The mean (SD) time of CAM-ICU assessment was completed in 1.5 (1.2) minutes in our study.

4. Discussion

In this 2 phase investigation, we have shown the simplified Chinese version of CAM-ICU to have excellent validity and reliability in a varied population of ICU patients both on and off mechanical ventilation. Importantly, we spent extra efforts around the assessment of inattention because it is such a core component of the diagnosis of delirium according to the *DSM-IV* reference standard and data by Meagher et al [14]. In the first phases, we have shown that the ASE had good agreement even using letters, in which one might have worried that some Chinese people may be unfamiliar with the English alphabet. In ASE Auditory, the patient is asked to squeeze the tester's hand when the letter A is stated in a series of 10 letters. In this case, we tested for attention even among *non*-English speakers by telling the patients to squeeze on the sound of "A" and not when another sound was heard. Although others in non-Romanic languages have used numbers for Feature 2 rather than letters, we thought that it would be helpful to test this, and it worked very nicely as a test of inattention against the neurologist raters doing *DSM-IV* ratings in Chinese and was also very reliable between nurses administering the test. This study has shown that the lower the education level of the patient, the lower the agreement of ASE. This meant that the educational level of the patients influenced the results of the inattention assessment. The agreement of the illiterate was lower than that of the literate patients, but the κ value was above 0.61 and thus still demonstrating moderate consistency. This confirms again that the ASE Auditory can be used in Chinese ICU patients. However, the results also remind us that we should explain well the methods to the illiterate patients before using ASE Auditory. Meanwhile, the CAM-ICU raters preferred ASE Visual for illiterate patients to improve diagnostic accuracy.

In the second phases of the study, we showed that the CAM-ICU had high sensitivity and specificity against the

Table 3   Validity of the simplified Chinese version of CAM-ICU (phase II, 2 × 2 data shown in Table 2)

Rater	Total no. of patients (n = 126)		Ventilated patients (n = 22)	Nonventilated patient (n = 104)	
	Study nurse1	Study nurse2	Study nurse	Study nurse1	Study nurse2
Sensitivity (95% CI)	91.8 (84.8-99.2)	93.4 (85.4-100)	100.0 (78.5-100)	89.4 (81.3-97.5)	87.8 (78.6-97.0)
Specificity (95% CI)	90.8 (84.2-97.4)	87.7 (81.5-93.9)	75.0 (34.7-86.6)	89.8 (82.6-97.0)	92.7 (85.8-99.6)
Positive predictive value (95% CI)	90.3 (89.4-97.2)	87.7 (81.5-93.9)	87.5 (62.0-96.7)	87.5 (78.7-96.3)	91.5 (83.5-99.5)
Negative predictive value (95% CI)	92.2 (85.2-99.2)	93.4 (85.4-100)	100 (70.0-100)	91.4 (84.8-98.0)	89.5 (81.5-97.5)
Youden index a (95% CI)	82.6 (72.7-92.5)	81.1 (71.0-91.2)	75.0 (58.8-91.2)	79.2 (68.3-90.1)	80.5 (69.0-92.0)

$P < .01.$

   [a] Youden index is a single statistic that captures the performance of a diagnostic test. This index can be defined as $Y =$ sensitivity + specificity − 1 and ranges between 0 and 1.

DSM-IV reference raters. This was consistent with more than a dozen other original investigations [7,15-25]. It is important to consider reasons for discrepancies between the CAM-ICU and the *DSM-IV* ratings. In reviewing the 13 misclassified CAM-ICU ratings by the study nurses (of which there were 8 false positives and 5 false negatives), there were 3 likely explanations for these discordant ratings: (*a*) the fluctuating nature of delirium, (*b*) a dose of sedative or analgesic drug often given between the study nurses and the *DSM-IV* rating, and (*c*) variability of nurses' methodology of administration of the instrument. We studied both intubated (nonverbal) and nonintubated (verbal) ICU patients, which is in keeping with 6 other studies that reported good validity after inclusion of ventilated and nonventilated patients. The spectrum of psychomotor behavior seen in delirium can be classified as hyperactive, hypoactive, or mixed type. Hyperactive delirium is readily recognized. Hypoactive delirium, also referred to as "quiet delirium," is often unrecognized or misdiagnosed as sedation or depression. In our study, hypoactive delirium occurred in 44.3% (n = 27), and hyperactive delirium and mixed type occurred in 19.7% (n = 12) and 36% (n = 22), respectively. The sensitivity and specificity of the subtypes of delirium were high, which supports that the CAM-ICU is helpful in clarifying the presence and absence of delirium.

The CAM-ICU proved practical in that it was completed in a mean of 1.5 minutes, which was even shorter than reported by Brenda and Ely [26] (mean, 2 minutes). This could be explained by the fact that we admitted more nondelirium patients (65) than delirium patients (61). More time is required for assessing a patient with delirium than for nondelirious patients because they are often thinking more slowly and because the CAM-ICU flow sheet allows for the practical stance of stopping the evaluation without completing every feature if it becomes apparent that the patients are at their baseline mental status and are not inattentive.

Several limitations in this investigation deserve comment. First, the nurses who conducted this investigation were not bedside nurses but, rather, were working in the context of a study. Therefore, as previously published by Van Eijk et al [27,28] and Vasilevskis et al [27,28], implementation science and "quality improvement" efforts must be conducted in the context of routine use of this instrument, with the bedside nurses using the CAM-ICU to determine compliance pitfalls and any other issues needed in translating our findings into practice. Another limitation that we touched on before but requires more explanation was that we used the Vigilance A form of the ASE Auditory examination of the CAM-ICU (repeating letters and asking the patient to squeeze on every "A"). However, Latin alphabet is not known in some countries (like India). Many other regions of Asia (eg, Japan and Hong Kong to mention 2 locations) have adapted this attention test using numbers instead. With this adaption, the communication is as follows: "I am going to say some numbers. Every time you hear me say the number '3,'

Table 4   Validity of the simplified Chinese version of CAM-ICU assessment subtype delirium

Rater	Hyperactive (n = 12)		Hypoactive (n = 27)		Mixed type (n = 22)
	Study nurse1	Study nurse2	Study nurse1	Study nurse2	Study nurse
Sensitivity (95% CI)	83.3 (62.2-100)	91.7 (76.1-100)	92.6 (82.7-100)	92.6 (82.7-100)	95.5 (86.2-100)
Specificity (95% CI)	100 (84.2-100)	98.3 (94.9-100)	92.2 (85.6-98.8)	89.1 (81.5-96.7)	100 (67.9-100)
Positive predictive value (95% CI)	100 (89.4-100)	91.7 (76.1-100)	83.3 (70.0-96.6)	78.1 (63.4-92.4)	100 (78.2-100)
Negative predictive value (95% CI)	96.7 (92.2-100)	98.3 (94.9-100)	96.7 (92.2-100)	96.6 (92.0-100)	98.3 (94.9-100)
Youden index [a] (95% CI)	83.3 (62.2-100)	80.0 (64.0-96.0)	84.8 (73.0-96.6)	81.7 (69.3-94.1)	95.5 (86.8-100)

   [a] Youden index is a single statistic that captures the performance of a diagnostic test. This index can be defined as $Y =$ sensitivity + specificity − 1 and ranges between 0 and 1.

squeeze my hand. If I say another number other than '3,' you should NOT squeeze. OK let's practice." And then the person says, "THREE" in whatever language the patient understands. Once they have squeezed on that "3," then a string of 10 numbers is said with 5 of them "threes" and 5 of them are non-3's. As with any of the attention testing approach, the patient is said to be inattentive if he/she gets anything less than 8 correct squeezes or nonsqueezes. Although the Vigilance A form of the ASE Auditory had high agreement in our study, using the numbers to test inattention may be even easier and can be tested in future studies. The single site design is also a limitation, and further research is needed in a variety of ICU types.

5. Conclusions

In conclusion, this study has shown that the simplified Chinese version of CAM-ICU monitoring is valid, reliable, and feasible in Chinese ICU patients, including patients both on and off mechanical ventilation. Integration of the delirium monitoring into routine practice and quality improvement studies is recommended by the Society of Critical Care Medicine (SCCM) guidelines, and this may now be done in mainland China.

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