Reliability and Validity of Hindi Version of the Confusion Assessment Method for Intensive Care Unit (CAM-ICU) for Diagnosis of Delirium: A Cohort Study

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ABSTRACT

Background: The confusion assessment method for the intensive care unit (CAM-ICU) is a bedside tool to diagnose delirium in critically ill patients. This study aims to determine the reliability and validity of the Hindi version of CAM-ICU against the Diagnostic and Statistical Manual (DSM), fourth edition text revision (DSM-IV-TR), and DSM, fifth edition (DSM-5) criteria for diagnosis of delirium.

Methods: Seventy-five Hindi-speaking consenting patients ≥18-year-old with Richmond Agitation Sedation Scale ≥−3 and an anticipated ICU stay > 48 hours were included. Patients with known severe mental illnesses, visual/hearing loss, neurological injury, burns, drug overdose, and Glasgow Coma Scale <9 at the time of screening were excluded. After 48 hours of ICU stay and ensuring at least 2 hours of sedative interruption, within a 4-hour period, two examiners independently assessed delirium using the Hindi version of the scale and an experienced psychiatrist assessed the patients independently and applied the DSM-IV-TR and DSM-5 criteria for diagnosing delirium. Time taken for CAM-ICU assessment, inter-observer reliability, sensitivity, specificity, and positive and negative predictive values were calculated.

Results: The Cohen's κ value was 0.944 ($p < 0.001$). The Cronbach's α for observer 1 and observer 2 was 0.961 and 0.968, respectively. The sensitivity and negative predictive value of the tool was 100% with both DSM-IV-TR and DSM-5. The specificity was 90.2% and 92% and the positive predictive value was 82.8 and 86.2% with DSM-IV-TR and DSM-5, respectively.

Conclusions: The Hindi version of CAM-ICU is a reliable and valid tool for the diagnosis of delirium in an ICU setting.

Trial registration: The study was registered with the Clinical Trials Registry, India (CTRI) as per the research guidelines laid down by the Indian Council of Medical Research before enrolling the participants. (CTRI number- CTRI/2021/01/030471). The registration date was 14th January 2021. URL of registry is http://ctri.nic.in.

Highlights: Delirium in the ICU is often undiagnosed due to unfamiliarity, lack of understanding of symptoms, non-availability of psychiatric consultation, and validated diagnostic tools in the native language of the patient. This study aims to find the reliability and validity of the Hindi version of CAM-ICU.

Keywords: Critical care, Diagnosis, Diagnostic and Statistical manual of mental disorders, translation, Delirium.

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HIGHLIGHTS

The Hindi version of CAM-ICU has near-perfect inter-observer reliability and good internal consistency. It is a reliable and valid tool for screening patients with delirium in the ICU in the Hindi-speaking parts of India.

INTRODUCTION

Delirium is a neurocognitive disorder, characterized by a disturbance in attention, awareness, and cognition developing within a short period (ranging from a few hours to days).[1]

The diagnosis of delirium is established based on diagnostic and statistical manual IV text revision (DSM-IV-TR) criteria as laid down by the American Psychiatric Association. These include disturbance of consciousness, and altered cognition usually over hours to days, and tend to fluctuate during the course of the day. The DSM-5 criteria for diagnosing delirium include disturbance in attention and cognition, with a tendency to fluctuate in severity during the course of a day not explained by a pre-existing, established, or evolving neurocognitive disorder and do not occur in the context of a severely reduced level of arousal such as coma but due to another medical condition or due to multiple etiologies.[1]

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It is more common in mechanically ventilated patients (50–80%) than non-mechanically ventilated ones. Incidence varies as per the critical care settings and can range from 26% in cardiac care unit (CCU) to as high as 88% in terminally ill cancer patients.[2] Development of delirium is associated with a longer

hospital stay, increased costs of treatment, and increased chances of re-hospitalization.[3] Delirium often goes undiagnosed due to unfamiliarity, lack of understanding of symptoms, non-availability of psychiatric consultation, and validated diagnostic tools in the native language of the patient.

Several risk factors of delirium in the ICU have been identified like the use of steroids and sedation, presence of chronic obstructive pulmonary disease (COPD), age, and hypertension. Patients with delirium had longer ICU stays.[4] Patients who were not exposed to natural light, patients who had physical restraints, were on mechanical ventilation, with higher Acute Physiology, and Chronic Health Evaluation (APACHE-II) score, and deranged blood investigations like hypoalbuminemia, hyperbilirubinemia, hyperuricemia, and raised creatinine were found to be risk factors of delirium in Indian studies that used Confusion Assessment Method for intensive care unit (CAM-ICU) to diagnose delirium.[5,6]

CAM-ICU is a simple tool for diagnosing delirium and can be applied quickly.[7] This tool has been translated into various languages.[8] The CAM-ICU has four features. Feature 1 assesses a change in the patient's baseline mental status, Feature 2 checks for attention, Feature 3 checks for an altered level of consciousness, and Feature 4 checks for organization of thinking. Both Features 1 and 2 and either of Features 3 and 4 should be positive for the diagnosis of delirium.[3] It is convenient and easy to apply and takes a very short time to complete the test. A pictorial representation of the CAM-ICU is also available for testing "attention" (Feature 2). However, in our study, we excluded the patients with visual or hearing loss, as we did not aim to test the pictorial version of Feature 2. For effective use of CAM-ICU during assessment, patient should be able to understand the questions asked to them. So, it has been translated and validated in various languages for its global application.[9–12] Hindi is the mother tongue of 43.63% of India's total population.[13] The Hindi version of the tool should be used in the northern part of India where Hindi is the commonly spoken language. As per the Census of 2011, the Government of India defines literacy as a person's ability to read and write with understanding in any language and the minimum age of such a person should be above 7 years.

Our hospital is a 1,502-bed, tertiary care teaching hospital with approximately 200 admissions every day. Clinical departments include Anaesthesiology and Critical Care, Burns and Plastic Surgery, ENT, General Surgery, Medicine, Neurosurgery, Obstetrics and Gynaecology, Ophthalmology, Orthopaedics, and Paediatrics. Our ICU is an 8-bed general ICU with a variety of patients from all the above disciplines.

To the best of our knowledge and extensive database search, the reliability and validity of the Hindi version of CAM-ICU have not been assessed in the Hindi-speaking population. The current study aims to determine the reliability and validity of the Hindi version of the CAM-ICU against the DSM-IV TR and DSM-5 criteria for bedside recognition of delirium in critically ill patients.

Methods

This cross-sectional study was conducted in a government medical college in Delhi between January 2021 and July 2022. Institutional Ethics Committee-Human Research approval was obtained. The study was registered with the Clinical Trials Registry, India (CTRI).

Consent for participation in the study was obtained from the patients or their next of kin. Consecutive Hindi-speaking patients ≥18 years old with Richmond Agitation Sedation Scale (RASS) ≥ −3 and an anticipated ICU stay > 48 hours were included. In our study, 11 patients themselves consented and the rest by proxy. Patients who consented themselves had a RASS of 0, i.e., alert and calm. Only the index admission was considered. Patients with severe mental illnesses like schizophrenia and bipolar disorder, visual/hearing loss, traumatic brain injury, or spinal cord injury, burns, drug overdose, and Glasgow Coma Scale (GCS) < 9 at the time of screening were excluded.

A baseline RASS scoring was done. Two well-trained examiners independently assessed delirium using the Hindi version of CAM-ICU within a 4-hour period on day 3, after completion of at least 48 hours of ICU stay and 2 hours of sedative interruption. Time taken for administration of CAM-ICU by each examiner was noted.

One of the investigators obtained a detailed history with a focus on complete physical and mental health check-ups. This was followed by independent assessment of patient and reliable informant interviews by a psychiatrist with >20 years of experience within the same 4 hours window of CAM-ICU evaluation. The clinical assessments were conducted using both DSM-IV-TR as well as DSM-5 on all study subjects. Patients found to have delirium as per DSM-IV-TR and DSM-5 criteria were considered as delirious (true positive). All assessors carried out the ratings independent of each other, blinded to the findings of the others until all examinations were complete.

Demographic profile, underlying systemic abnormality for which patient required ICU admission, clinical course [Sequential Organ Failure Assessment (SOFA), RASS, and GCS were recorded on the day of admission and at the time of performance of CAM-ICU], outcome (mortality or discharge from ICU) and time taken for CAM-ICU assessment.

Sample Size and Statistical Analysis

Taking Cronbach's α as 0.88[11] and the kappa (κ) agreement as 0.84,[11] to estimate a relative difference of 10% at α = 5%, a sample size of 55 cases and 75 cases respectively is required to estimate the reliability of the CAM-ICU. Therefore, 75 cases were included in this study. Statistical analysis was done using SPSS version 20.0. Inter-observer reliability was expressed as Cohen's kappa coefficient. Kappa coefficient above 0.80, 0.60, and 0.40 was considered as measuring "near perfect," "substantial," and "moderate" levels of agreement,[14] respectively. Cronbach's α coefficient between each item of the CAM-ICU Score obtained by assessors 1 and 2 was calculated and used as a measure of internal consistency (reliability across items) of CAM-ICU. Validity was determined based on sensitivity, specificity, and positive and negative predictive values. A p-value < 0.05 was taken as significant.

Results

A total of 80 patients were assessed for eligibility, out of which 5 patients did not fulfill the inclusion criteria (two patients had RASS <−3 at the time of assessment while the other 3 patients were discharged before completing 48 hours of ICU stay). Therefore, 75 patients were enrolled in the study. Hindi version of CAM-ICU was administered to each of them. The patient enrolment and study flowchart is shown in Figure 1.

Most of the patients were admitted to the ICU with primary disease of the respiratory system (31%), followed closely by gastrointestinal diseases (25%) and disease of the central nervous system (CNS) (19%). Patients with CNS diseases mentioned in the exclusion criteria were not considered. However, Guillain–Barré syndrome,
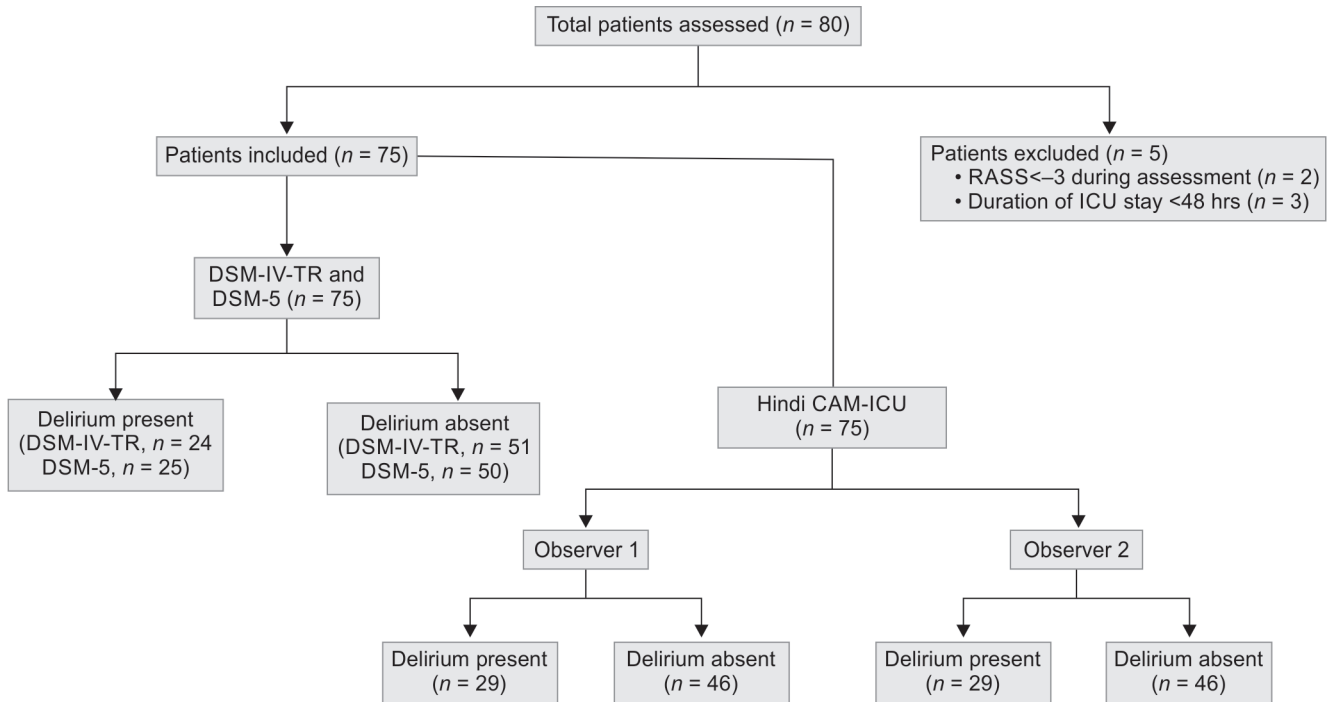
Fig. 1: Patient recruitment and study flowchart

Table 1: Demographic characteristics based on the diagnosis of delirium

Variable	Delirium present (n = 24)	Delirium absent (n = 51)	p-value
Age (Year)[a]	41 (22–59)	30 (25–45)	0.165
Sex[b]			
Male	9 (37.5%)	16 (31.37%)	0.600
Female	15 (62.5%)	35 (68.63%)	
Education status[b]			
Illiterate	18 (75%)	17 (33.33%)	0.001
Literate	6 (25%)	34 (66.67%)	
History of substance abuse[b]			
Present	10 (41.67%)	14 (27.45%)	0.218
Absent	14 (58.33%)	37 (72.56%)	

[a]Expressed as median [IQR]. [b]Expressed number (percentage). $p < 0.05$ is significant

a known seizure disorder without brain lesions, extradural compression of the spinal cord because of Pott's spine, neurotoxic snakebite, and eclampsia were included. The involvement of cardiovascular, renal system, and septicemia was seen in 11, 6, and 8% of patients, respectively. The demographic and ventilator assistance details, length of ICU stay, and patient outcome (mortality) are shown in Table 1. Table 1 also shows that significantly more illiterate people had delirium compared to literate people ($p < 0.05$).

Table 2 shows the comparison of GCS, SOFA score, and RASS on the day of admission and assessment, clinical course, and outcome of patients based on the diagnosis of delirium. Patients with delirium had significantly higher mortality ($p < 0.001$) and a longer ICU ($p = 0.001$) and hospital stay ($p = 0.021$). Delirium is common in ICU with an incidence of 32%. The patients who develop delirium

are those who have a poor GCS and SOFA score on admission. The patients have a higher chance of ICU morbidity including longer duration of ICU stay and days of mechanical ventilation. The mortality rate in these patients is also high (50%).

The median time taken for administering the CAM-ICU by observers I and II was 51.00 (31–130) seconds and 46.00 (34.00–135.00) seconds, respectively ($p = 0.087$). Both observers I and II found delirium in 29/75 (38.7%) patients as per CAM-ICU. Upon psychiatric evaluation with DSM-IV-TR and DSM-5 criteria, 24/75 (32%) and 25/75 (33.3%) patients were diagnosed to be delirious, respectively. All patients diagnosed with delirium on psychiatric evaluation (DSM-IV-TR or DSM-5) were among those who were screened to have delirium as per CAM-ICU.

The inter-observer reliability (Cohen's κ) for all four features of CAM-ICU is shown in Table 3. The κ value for the overall diagnosis of delirium by both observers using CAM-ICU was 0.944 ($p < 0.001$), which is "near perfect." The study found an excellent internal consistency for observers 1 and 2 with a Cronbach's α of 0.961 and 0.968, respectively (Table 4). The sensitivity, specificity, and positive and negative predictive values of CAM-ICU with reference to DSM-IV-TR and DSM-5 are given in Table 5.

Discussion

Traditionally, the diagnosis of delirium is established per the Diagnostic and Statistical Manual of Mental Disorders criteria. The application of this method requires an expert psychiatric evaluation. Most of the ICUs in India do not have a psychiatric liaison. The CAM-ICU is a very simple bedside tool to diagnose delirium which can be performed by the ICU staff and does not rely upon a trained psychiatrist.

In an extensive search of the database, we did not find any study to validate the Hindi version of CAM-ICU, though it is available freely for use on the internet. A major portion of the Indian population

Table 2: Clinical characteristics, clinical course, and outcome of patients, categorized based on the diagnosis of delirium as per DSM-IV-text revision

Variable	Delirium present (n = 24)	Delirium absent (n = 51)	p-value
GCS on admission[a]	14.5 (9.5–15.0)	15 (15–15)	0.009
GCS at assessment[a]	11 (8.3–13.8)	15 (14–15)	<0.001
SOFA admission[a]	4 (2.3–7.0)	3 (1–5)	0.026
SOFA assessment[a]	5 (4–8)	2 (1–4)	<0.001
RASS admission[a]	−1 (−1.0 to 0.0)	0 (−1.0 to 0.0)	0.051
RASS assessment[a] (observer 1)	−1 (−2.0 to −1.0)	0 (−1.0 to 0.0)	<0.001
RASS assessment[a] (observer 2)	−1 (−2.0 to −1.0)	0 (0.0–0.0)	<0.001
Duration of ICU stay[a] (days)	9.00 (7–11.8)	4.00 (3–6)	0.001
Duration of hospital stay[a] (days)	19.50 (11.5–30.5)	12.00 (10–16)	0.021
Discharge from ICU[b]	12 (50%)	50 (98.0%)	<0.001
Death In ICU[b]	12 (50%)	1 (1.96%)	<0.001
Duration of mechanical ventilation[a] (days)	4 (3–7) (n = 15)	1 (0.8–2.5) (n = 13)	<0.001

[a]Values are expressed as median [IQR], [b]Values are expressed as number (percentage)

Table 3: Inter-observer reliability (agreement) for each feature of Hindi CAM-ICU

	Number of cases having delirium (n = 75)			
	Observer 1	Observer 2	Kappa	p-value
Feature 1	41	42	0.973	<0.001
Feature 2	34	33	0.973	<0.001
Feature 3	29	29	0.944	<0.001
Feature 4	26	29	0.857	<0.001
Overall	29	29	0.944	<0.001

Table 4: Internal consistency of the CAM-ICU questionnaire within each observer (n = 75)

Observer	Item	Mean ± SD	Cronbach's α
	Feature 1	0.56 ± 0.49	
	Feature 2	0.44 ± 0.49	
Observer 1	Feature 3	0.38 ± 0.49	0.961
	Feature 4	0.38 ± 0.49	
	Overall	0.38 ± 0.49	
	Feature 1	0.54 ± 0.5	
	Feature 2	0.45 ± 0.5	
Observer 2	Feature 3	0.38 ± 0.49	0.968
	Feature 4	0.34 ± 0.47	
	Overall	0.38 ± 0.49	

Table 5: Validity of Hindi CAM-ICU with DSM-IV-TR and DSM-5 criteria

	DSM-IV-TR	DSM-5
Sensitivity	100 (87.8–100.0)	100 (86.3–100)
Specificity	90.2 (78.6–96.7)	92.0 (80.8–97.8)
PPV	82.8 (67.6–91.7)	86.2 (70.9–94.1)
NPV	100	100

Values are expressed as percentage (95% confidence interval)

ventilator assistance and hospitalization for a longer period, and had higher mortality than those who did not. Such observations are in line with the findings reported by previous studies.[3,15,16]

The original version of CAM-ICU developed in English was validated by Ely et al. The sensitivities of the two observers and intensivists were reported as 95, 96, and 100%, respectively while their specificities were 93, 93, and 89%, respectively.[17] This tool was validated against DSM-IV criteria. Later, it was translated and validated into many other languages including Korean, Greek, Chinese, Japanese, Arabic, Dutch, etc. The sensitivity in the studies on translated versions ranged from 72.4% for the Korean CAM-ICU[18] to 100% for the Chinese version.[19] The specificities ranged from 75.8% for the Korean version[18] to 100% for the Dutch version.[20] In our study, the inter-observer reliability and validity were in accordance with the results of previous researchers.[10,12,18,21,22] The chance of missing a patient with delirium is negligible with Hindi CAM-ICU, making it a very good screening tool. The positive predictive value of CAM-ICU was >82% against the gold standard. It slightly over-diagnosed delirium in a few patients (four as per DSM-5 and five as per DSM-IV-TR).

The strengths of our study are as follows. First, since Hindi is among the top five most commonly spoken languages of the world, the validated tool will find a widespread applicability in more than 4.42% of the world population who communicates in Hindi. Secondly, in this study, CAM-ICU was applied in a mixed ICU where patients with multisystem involvements were admitted, unlike previous studies done in ICUs dedicated to a particular specialty like cardiac ICU, cancer ICU, and surgical ICU.[23–25] This strengthens its usability. Third, the tool was validated against DSM-IV-TR and the latest DSM-5 criteria for delirium diagnosis, which was applied by a senior psychiatrist. Fourth, all assessments were done within a 4-hour window thereby reducing the effect of fluctuating mental

speaks and understands Hindi. So, there is a necessity to validate the tool in the Hindi language to maximize its utility in the Indian scenario.

The median time taken by each observer was <1 minute. This is because the absence of one of the two Features 1 and 2 excludes delirium and the test is terminated without having to check for Features 3 or 4. In the present study, the point prevalence of delirium was 38.67% (29/75) as per the Hindi version of CAM-ICU. It was similar to previous studies where incidence ranged from 26% in CCU to 89% in survivors of stupor or coma.[2] Patients who developed delirium were sicker on admission, at assessment, required

status of the patient with time. Fifth, a careful history elicitation from a reliable informant and the patient, wherever feasible, along with a detailed clinical examination gave us important clues and helped in instituting timely clinical intervention and counseling. Sixth, all assessors were blinded to the findings of the others until all three examinations were complete. Therefore, the chances of observer bias were reduced.

Conclusions

From the above results, we conclude that the Hindi version of CAM-ICU has a near-perfect inter-observer reliability. It has a good internal consistency. It is a valid tool with a sensitivity and negative predictive value of 100% with both, DSM-IV-TR, and DSM-5 criteria. The specificity is 90.2 and 92% and the positive predictive value is 82.8 and 86.2% with DSM-IV-TR and DSM-5, respectively. It is therefore a good screening tool for delirium in patients admitted to ICU and might help to reduce the work burden on psychiatry departments.

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