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学位論文

Diagnostic Reliability of Headset-Type Continuous Video EEG Monitoring for Detection of ICU Patterns and NCSE in Patients with Altered Mental Status with Unknown Etiology

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ORIGINAL WORK

Diagnostic Reliability of Headset-Type Continuous Video EEG Monitoring for Detection of ICU Patterns and NCSE in Patients with Altered Mental Status with Unknown Etiology

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Abstract

Background/Objective: Simplified continuous electroencephalogram (cEEG) monitoring has shown improvement in detecting seizures; however, it is insufficient in detecting abnormal EEG patterns, such as periodic discharges (PDs), rhythmic delta activity (RDA), spikes and waves (SW), and continuous slow wave (CS), as well as nonconvulsive status epilepticus (NCSE). Headset-type continuous video EEG monitoring (HS-cv EEG monitoring; AE-120A EEG Headset™, Nihon Kohden, Tokyo, Japan) is a recently developed easy-to-use technology with eight channels. However, its ability to detect abnormal EEG patterns with raw EEG data has not been comprehensively evaluated. We aimed to examine the diagnostic accuracy of HS-cv EEG monitoring in detecting abnormal EEG patterns and NCSE in patients with altered mental status (AMS) with unknown etiology. We also evaluated the time required to initiate HS-cv EEG monitoring in these patients.

Methods: We prospectively observed and retrospectively examined patients who were admitted with AMS between January and December 2017 at the neurointensive care unit at Asakadai Central General Hospital, Saitama, Japan. We excluded patients whose data were missing for various reasons, such as difficulties in recording, and those whose consciousness had recovered between HS-cv EEG and conventional cEEG (C-cEEG) monitoring. For the included patients, we performed HS-cv EEG monitoring followed by C-cEEG monitoring. Definitive diagnosis was confirmed by C-cEEG monitoring with the international 10–20 system. As the primary outcome, we verified the sensitivity and specificity of HS-cv EEG monitoring in detecting abnormal EEG patterns including PDs, RDA, SW, and CS, in detecting the presence of PDs, and in detecting NCSE. As the secondary outcome, we calculated the time to initiate HS-cv EEG monitoring after making the decision.

Results: Fifty patients (76.9%) were included in the final analyses. The median age was 72 years, and 66% of the patients were male. The sensitivity and specificity of HS-cv EEG monitoring for detecting abnormal EEG patterns were 0.974 (0.865–0.999) and 0.909 (0.587–0.998), respectively, and for detecting PDs were 0.824 (0.566–0.926) and 0.970 (0.842–0.999), respectively. We diagnosed 13 (26%) patients with NCSE using HS-cv EEG monitoring and could detect

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NCSE with a sensitivity and specificity of 0.706 (0.440–0.897) and 0.970 (0.842–0.999), respectively. The median time needed to initiate HS-cv EEG was 57 min (5–142).

Conclusions: HS-cv EEG monitoring is highly reliable in detecting abnormal EEG patterns, with moderate reliability for PDs and NCSE, and rapidly initiates cEEG monitoring in patients with AMS with unknown etiology.

Keywords: Electroencephalography, Continuous electroencephalogram, Headset-type continuous video electroencephalography, Periodic discharges, Nonconvulsive status epilepticus

Introduction

Continuous electroencephalogram (cEEG) monitoring with the international 10–20 system (conventional cEEG: C-cEEG) is the gold standard for detecting nonconvulsive status epilepticus (NCSE). Within the first 24 h of cEEG monitoring, seizures become detectable in approximately 90% of patients eventually diagnosed with seizures [1]. NCSE is a relatively common condition among critically ill patients and those in intensive care units (ICUs), with a prevalence of 8–20% of all patients in the ICU [2–6]; however, long-term cEEG monitoring is unavailable in many hospitals or is often delayed in its application [7], considering that it requires technicians and equipment that are often not immediately available [8–10]. Thus, most hospitals face challenges in adopting current guidelines, which state that EEG should be initiated within 15–60 min in urgent situations [11].

Recently, simplified cEEG monitoring has shown improvement in detecting seizures [12–14]; however, it cannot clearly detect abnormal EEG patterns, such as periodic discharges (PDs), rhythmic delta activity (RDA), spikes and waves (SW), continuous slow wave (CS), and NCSE. Moreover, considering that ICUs have increased chances of having artifacts, using a cEEG monitoring device with a video camera is suggested to improve the rates of detecting NCSE [15].

Headset-type continuous video EEG monitoring (HS-cv EEG monitoring; AE-120A EEG Headset™, Nihon Kohden, Tokyo, Japan) is a newly developed easy-to-use technology for such purposes (Fig. 1). It features eight electrodes: left frontal, left central, left temporal, O1, right frontal, right central, right temporal, and O2. Furthermore, it can simultaneously transmit EEG data via Bluetooth to a conventional computer, i.e., Neurofax EEG 1200 (Nihon Kohden, Tokyo, Japan), and is equipped with a video camera. After setting up the conventional computer, the headset part is assembled by applying gel-type electrodes. Finally, the headset is placed on the patient's head. As a result, EEG recording can be immediately initiated after the decision to use it.

Regarding the eight-channel EEG, the sensitivity and specificity of seizure identification with color density spectral array (CDSA) and amplitude-integrated EEG (aEEG) have already been reported as 83.3% and 81.5%,

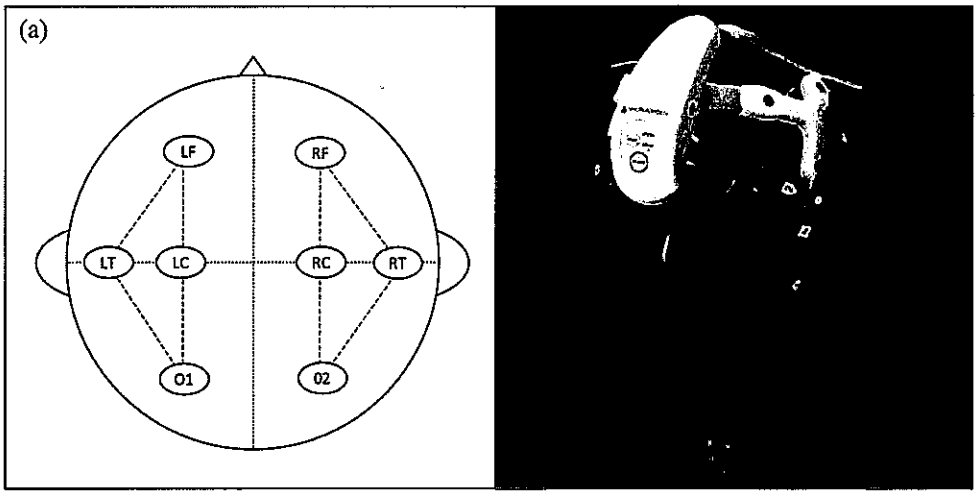

Fig. 1 **a** Electrodes used in this study: six electrodes (LF, LC, LT, RF, RC, and RT) were gel type, and two were plate type (O1, O2). **b** The headset-type EEG used in this study. *LF* left frontal, *LC* left central, *LT* left temporal, *RF* right frontal, *RC* right central, *RT* right temporal

respectively [16]. However, its ability to detect abnormal EEG patterns including PDs, RDA [17], SW, CS, and NCSE using raw EEG data (i.e., analysis of the EEG pattern itself) has not been fully evaluated.

Thus, this study aimed to examine the diagnostic accuracy of HS-cv EEG monitoring in detecting abnormal EEG patterns and NCSE in patients with altered mental status (AMS) with unknown etiology. We also evaluated the time required to initiate HS-cv EEG monitoring in these patients.

Methods

Study Design

This study prospectively observed and retrospectively examined consecutive patients who were admitted due to AMS with unknown etiology with or without subtle motor movement between January and December 2017 at Neuro-ICU in Asakadai Central General Hospital (Saitama, Japan), whose name was changed to TMG Asaka Medical Center in January 2018. This study utilized HS-cv EEG monitoring to examine the cause of AMS, which was defined as any alteration in the level of responsiveness, alertness, or arousability and could manifest lethargy, delirium, confusion, agitation, coma, disinhibition, labile/blunted affects, or unexpected psychosis [18]. The study protocol was reviewed and approved by the ethics committee of Asakadai Central General Hospital (approval number: 17-03).

Inclusion Criteria

We selected patients who met the inclusion criteria, i.e., AMS with unknown etiology.

Patients were excluded if their consciousness recovered completely between HS-cv EEG and C-cEEG monitoring, if C-cEEG monitoring was not performed due to unavailability, or if the HS-cv EEG data were not clear enough due to artifact interruption. Those with do not attempt resuscitation (DNAR) declarations were also excluded, considering that earlier initiation of HS-cv EEG was not performed.

Study Protocol

We performed HS-cv EEG monitoring for all included patients according to the following protocol, immediately followed by C-cEEG monitoring. The duration of HS-cv EEG monitoring depended on the time of the initiation of HS-cv EEG.

All EEG data were interpreted by one neurointensivist and one board-certified neurophysiologist, who classified the EEG data into four patterns, i.e., PDs, RDA, SW, and CS, and detected NCSE. Finally, we analyzed these data to distinguish normal or abnormal patterns (PDs, RDA, SW, and CS) and the presence or absence of PDs, RDA, SW, and NCSE. We attempted to detect EEG patterns in HS-cv EEG and C-cEEG merely using the EEG data. However, these data were not completely double-blind because the assessors were our team members.

We performed definitive diagnosis of abnormal EEG patterns and NCSE by employing C-cEEG monitoring (Neurofax EEG 1200; Nihon Kohden, Tokyo, Japan) with 21 collodion-type electrodes from the international 10–20 with video camera monitoring. All cEEG records were reviewed by at least two trained neurophysiologists or epileptologists.

If any of the EEG findings were equivocal, we discussed the findings and reached an agreement in the conclusions.

Definitions and Diagnosis of NCSE

The definitions of abnormal EEG patterns were based on the American Clinical Neurophysiology Society's (ACNS) Standardized Critical Care EEG Terminology: 2012 version [17, 19].

NCSE was defined as PDs or RDA with an evolution or >2.5/s of PDs or repeated SW that continued for >10 s [20, 21]. On the basis of the ACNS criteria, we defined "evolving" as having a minimum of two unequivocal, sequential changes in frequency, morphology, or location [17]. Evolution in frequency was defined as having a minimum of two consecutive changes in the same direction in at least 0.5/s. Evolution in morphology was defined as having a minimum of two consecutive changes in a novel morphology. Evolution in location was defined as spreading into or out of sequentially more than two different electrodes. Clinical diagnosis of NCSE was established based on the clinical symptoms and findings of EEG. If the EEG findings of some patients fluctuated, we carefully assessed the patients' clinical symptoms and response to antiepileptic drugs to decide whether these findings should be diagnosed as NCSE. To identify fluctuation, more than three changes in frequency (by at least 0.5/s and not more than 1 min apart), more than three changes in morphology, or more than three changes in location (by at least one standard interelectrode distance) are required, but this may not qualify as evolving [17].

Data Sampling

The following data were collected: age, gender, medical history, sequential organ failure assessment (SOFA) score at examination, acute physiology and chronic health evaluation (APACHE) II score at admission, admission diagnosis, Glasgow coma scale (GCS) score at examination, full outline of unresponsiveness (FOUR) score at examination [22], the protocol starting day, inspection time of HS-cv EEG, and clinical symptoms that are associated with NCSE.

Outcome Measures

As the primary outcome, we compared the diagnostic accuracy to detect abnormal EEG patterns (PDs, RDA, SW, or CS), (Fig. 2, Analysis 1), the presence or absence of PDs (Fig. 2, Analysis 2), and NCSE (Fig. 2, Analysis 3). As the secondary outcome, we calculated the time to initiate HS-cv EEG monitoring after making the decision.

The time to initiate HS-cv EEG monitoring was defined as the following two patterns. First, if applicable, we performed HS-cv EEG as soon as possible after making the decision. In such cases, the time to initiate HS-cv EEG monitoring after making the decision is only a few minutes because the HS-cv EEG monitoring equipment is stored in the ICU. Second, if adaptation was judged during the morning ICU rounds for cases under close observation without immediate application of HS-cv EEG, the decision time for performing HS-cv EEG monitoring was defined as 9:30 AM. For example, if HS-cv EEG monitoring was performed at 10:00 AM, the time to initiate HS-cv EEG monitoring after making the decision was calculated to be 30 min.

Statistical Analysis

Demographic factors and baseline characteristics of the patients were summarized using descriptive statistics. Sensitivity, specificity, positive likelihood ratios, and negative likelihood ratios with 95% confidence intervals (CIs) were calculated. The ability of HS-cv EEG was evaluated by receiver operating characteristic (ROC) analysis, with the areas under the curves showing the highest sensitivity. Statistical analysis was performed using the EZR software package (Saitama Medical Center, Jichi Medical University) [23]. A P value of <0.05 was considered to be statistically significant.

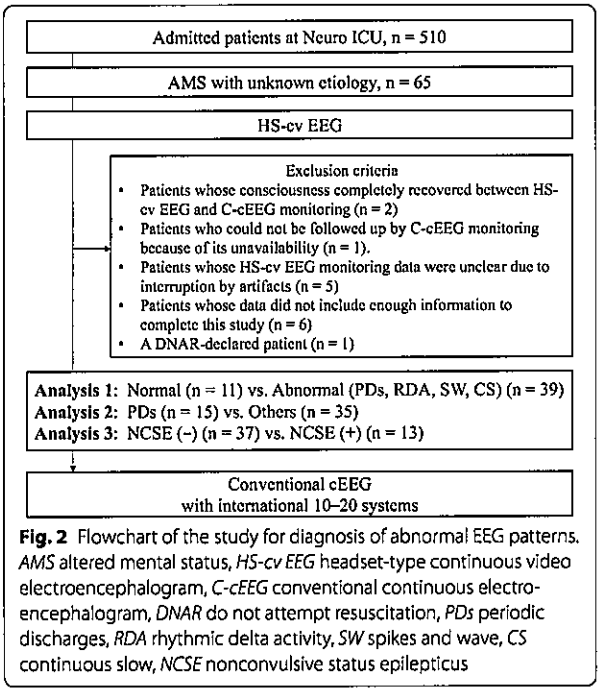

Fig. 2 Flowchart of the study for diagnosis of abnormal EEG patterns. *AMS* altered mental status, *HS-cv EEG* headset-type continuous video electroencephalogram, *C-cEEG* conventional continuous electroencephalogram, *DNAR* do not attempt resuscitation, *PDs* periodic discharges, *RDA* rhythmic delta activity, *SW* spikes and wave, *CS* continuous slow, *NCSE* nonconvulsive status epilepticus

Results

Baseline Characteristics

A total of 510 patients were hospitalized in the Neuro-ICU between January 1, 2017 and December 31, 2017 (Fig. 2). HS-cv EEG was used for 65 patients with AMS with unknown etiology. However, 15 patients (23.1%) were excluded owing to the following reasons: complete recovery from unconsciousness between the HS-cv EEG and C-cEEG monitoring ($n=2$), inability of the patients to be followed up by C-cEEG monitoring because of its unavailability ($n=1$), patients whose HS-cv EEG monitoring data were inadequate due to interruption by artifacts ($n=5$), patients whose data provided insufficient information to complete this study ($n=6$), and patients who provided a DNAR declaration ($n=1$).

Ultimately, 50 patients (76.9%) were analyzed. The median age of the patients was 72 years, 66% were male, median SOFA score at examination was 4, median APACHE II score at admission was 16, median GCS score was 6, and the median FOUR score was 10 (Table 1). The median examination day for performing HS-cv EEG monitoring was the second day after admission, and the recording duration of HS-cv EEG was 134.5 min. Diagnoses were as follows: subarachnoid hemorrhage, cerebral hemorrhage, cerebral infarction, cerebellar hemorrhage, cerebellar infarction, traumatic brain injury, post-cardiac arrest syndrome, and status epilepticus (Table 1). We did not observe any adverse events between HS-cv EEG and C-cEEG monitoring.

Details of Symptoms Associated with NCSE

We encountered 58 symptoms that were associated with NCSE in the patients, including AMS with unknown etiology only, fluctuation of consciousness, autism, subtle eye movement, nystagmus, conjugate deviation, disturbance of consciousness after generalized convulsive states epilepticus (GCSE), aphasia, delirium, facial myoclonus, and limb myoclonus (Table 2).

Accuracy of HS-cv EEG Monitoring

As shown in Fig. 2 and Table 3, in the 50 patients, HS-cv EEG monitoring detected 39 abnormal EEG patterns, including PDs ($n=15$), RDA ($n=1$), SW ($n=0$), and CS ($n=23$). The sensitivity and specificity of HS-cv EEG monitoring in detecting abnormal EEG patterns as the primary outcome were 0.974 (95% CI, 0.865–0.999)

Table 1 Baseline characteristics

	Total ($n = 50$)
Age	72 (52.5–80.0)
Male (gender)	33 (66)
Past medical history	
Subarachnoid hemorrhage	3 (6)
Cerebral hemorrhage	6 (12)
Cerebral infarction	7 (14)
Brain tumor	3 (6)
Traumatic brain injury	1 (2)
Epilepsy	6 (12)
Hydrocephalus	1 (2)
Arteriovenous malformation	1 (2)
Seizure	1 (2)
Diabetes mellitus	15 (30)
Hypertension	29 (58)
Hyperlipidemia	7 (14)
Cardiovascular disease	5 (10)
Arterial fibrillation	3 (6)
Chronic renal failure	1 (2)
Mental disorder	1 (2)
SOFA score	4 (3–6)
APACHE II	16 (12–19)
GCS score	6 (3–10)
FOUR score	10 (7–14)
Timing of the examination day	2 (1–3)
examination period, min	134.5 (70.8–237.8)
Diagnosis	
Subarachnoid hemorrhage	10 (20)
Cerebral hemorrhage	12 (24)
Cerebral infarction	4 (8)
Cerebellar hemorrhage	1 (2)
Cerebellar infarction	1 (2)
Traumatic brain injury	3 (6)
Post-cardiac arrest syndrome	1 (2)
Status epilepticus	18 (36)

Data are presented as median (interquartile range) for continuous variables and n (%) for categorical variables

APACHE acute physiology and chronic health evaluation, *FOUR* full outline of unresponsiveness, *GCS* Glasgow coma scale, *SOFA* sequential organ failure assessment

and 0.909 (95% CI, 0.587–0.998), respectively. In particular, for detecting PDs (Fig. 2 and Table 3), the sensitivity and specificity were 0.824 (0.566–0.926) and 0.970 (0.842–0.999), respectively. We diagnosed 13 (26%) patients with NCSE using HS-cv EEG monitoring (Fig. 2). HS-cv EEG monitoring could detect NCSE, with a sensitivity and specificity of 0.706 (0.440–0.897) and 0.970 (0.842–0.999), respectively.

Table 2 Symptoms associated with NCSE during HS-cv EEG initiation (58 symptoms)

NCSE associated symptoms	*N* (%)
AMS with unknown etiology only	15 (30)
Fluctuation of consciousness	4 (8)
Automatism	4 (8)
Subtle eye movement	6 (12)
Nystagmus	1 (2)
Conjugate deviation	2 (4)
Disturbance of consciousness after GCSE	15 (30)
Aphasia	1 (2)
Delirium	6 (12)
Facial myoclonus	2 (4)
Limb myoclonus	2 (4)

AMS altered mental status, *GCSE* generalizes convulsive status epilepticus, *HS-cv EEG* headset-type continuous video electroencephalogram, *NCSE* nonconvulsive status epilepticus,

Speed of HS-cv EEG

Following retrospective analysis, the median time required to initiate HS-cv EEG monitoring was 57 (5–142) min.

Cases

We have provided two cases to exemplify the findings of the present study.

Case 1: An 84-year-old man was admitted to our hospital with right acute subdural hematoma, which was surgically evacuated. His GCS score was E1VtM4. He was not awake after termination of sedation. We initiated HS-cv EEG monitoring on day 3 after ICU admission. The EEG pattern was CS (Fig. 3 - a), and the C-cEEG finding at initiation was also CS (Fig. 3b) also. As shown in Fig. 3c, d, after continuing C-cEEG monitoring, he developed NCSE along with evolution of PDs.

Case 2: A 24-year-old women was admitted to our hospital with GCSE caused by cerebral arteriovenous malformation. Consciousness disturbance was continued (GCS score was E4V2M5) with subtle eye movement. We immediately initiated HS-cv EEG monitoring followed by C-cEEG monitoring. The EEG patterns were PDs (Fig. 4a, b).

Discussion

In the present study, HS-cv EEG monitoring demonstrated high sensitivity and specificity for detecting abnormal EEG patterns (0.974 and 0.909, respectively) with moderate accuracy for PDs (0.824 and 0.970, respectively) and NCSE (0.706 and 0.970, respectively). It also

Table 3 Diagnostic accuracy for detection of abnormal EEG wave (the ictal–interictal continuum, SW, and CS) and NCSE

	No. of patients	Sensitivity, % (95% CI)	Specificity, % (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)	AUC (95% CI)
PDs, RDA, SW, and CS	39	0.974 (0.865–0.999)	0.909 (0.587–0.998)	10.718 (3.130–39.459)	0.028 (0.007–0.117)	0.942 (0.849–1.000)
PDs	15	0.824 (0.566–0.962)	0.970 (0.842–0.999)	27.176 (6.212–152.019)	0.182 (0.130–0.368)	0.897 (0.799–0.995)
RDA	1	0.500 (0.013–0.987)	1.000 (0.926–1.000)	Inf (9.879–Inf)	0.500 (0.500–0.903)	0.750 (0.260–1.000)
SW	0					
CS	23	0.900 (0.683–0.988)	0.833 (0.653–0.944)	5.400 (2.836–8.049)	0.120 (0.035–0.337)	0.867 (0.771–0.962)
NCSE	13	0.706 (0.440–0.897)	0.970 (0.842–0.999)	23.294 (4.965–134.985)	0.303 (0.248–0.506)	0.838 (0.722–0.953)

AUC area under the curve, *CI* confidence interval, *CS* continuous slow wave, *EEG* electroencephalogram, *LR* likelihood ratio, *NCSE* nonconvulsive status epilepticus, *PDs* periodic discharges, *RDA* rhythmic delta activity, *SW* spikes and waves

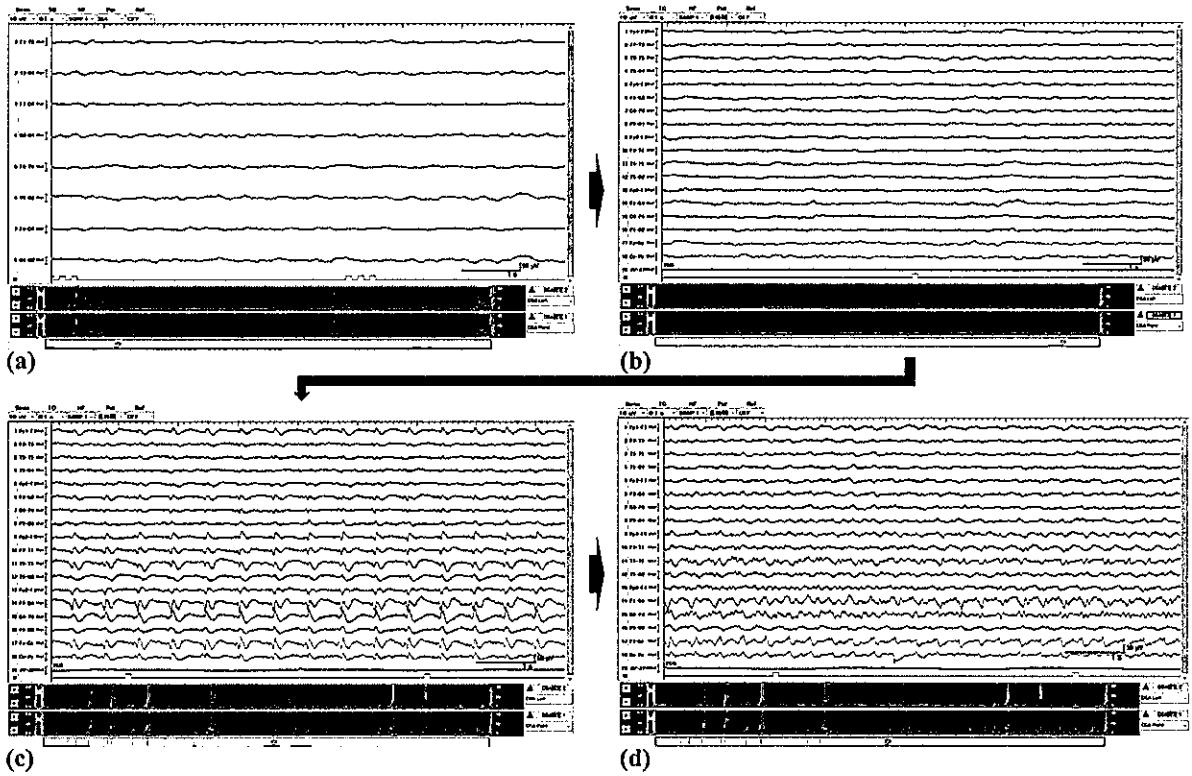

Fig. 3 An 84-year-old man admitted to our hospital had right acute subdural hematoma that was surgically evacuated. His GCS score was E1VtM4. He was not awake after termination of sedation. We initiated HS-cv EEG monitoring on day 3 after ICU admission. The EEG pattern was CS (Fig. 3a), and the C-cEEG finding at initiation was CS (Fig. 3b). As shown in Fig. 3c and d, after continuing C-cEEG monitoring, he developed NCSE pattern along with evolution of PDs. *GCS* Glasgow coma scale, *EEG* electroencephalogram, *HS-cv EEG* headset-type continuous video EEG monitoring, *CS* continuous slow, continuous video electroencephalogram, *C-cEEG* conventional continuous electroencephalogram, *NCSE* nonconvulsive status epilepticus, *PDs* periodic discharges

demonstrated rapid initiation of cEEG monitoring. (The median time needed to initiate HS-cv EEG was 57 min.)

Compared with the sensitivity of standard EEG, such as the international 10–20 system, the sensitivity of simplified EEG for seizure detection was 93% in one study using seven electrodes [24], 68% in another study using four electrodes [13], and 40% with single-channel EEG [12]. Moreover, the sensitivity of seizure identification

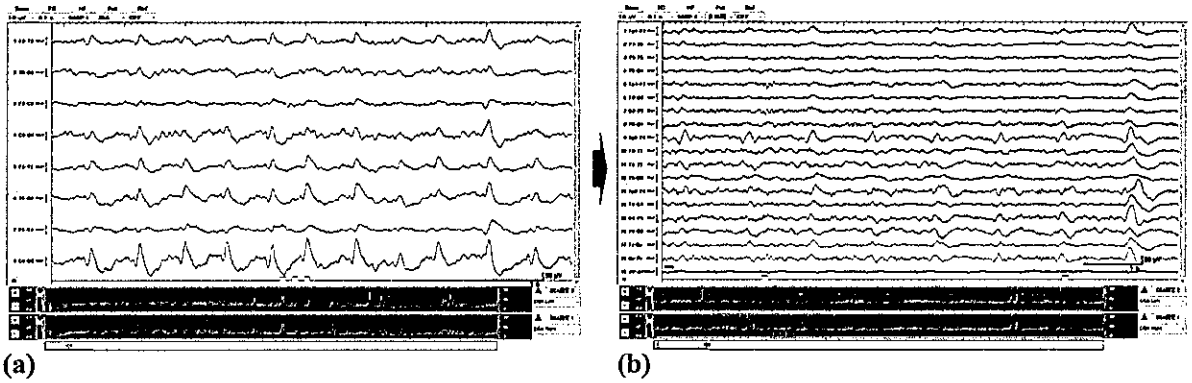

Fig. 4 A 24-year-old woman was admitted with GCSE caused by cerebral arteriovenous malformation. Subsequently, consciousness disturbance continued (GCS score, E4V2M5) with subtle eye movement. We immediately initiated HS-cv EEG monitoring followed by C-cEEG monitoring. The EEG patterns were PDs (Fig. 4a, b). *GCSE* generalized convulsive states epilepticus, *GCS* Glasgow coma scale, *HS-cv EEG* headset-type continuous video EEG monitoring, *C-cEEG* conventional continuous electroencephalogram, *EEG* electroencephalogram, *PDs* periodic discharges

with CDSA and aEEG recorded by eight channels was 83.3% and 81.5%, respectively [16]. However, considering that the modified Salzburg EEG criteria were introduced in the clinical diagnosis of NCSE in 2015 [25], direct comparisons could not be performed because of the heterogeneity of the seizure diagnosis. Thus, we established primary outcomes in the present study as the accuracy for abnormal EEG patterns, PDs, and NCSE. PDs should be essentially recognized because it is observed in up to 29% of patients undergoing cEEG in the ICU [1, 26, 27], and it has the risks of developing seizure and secondary brain injury [28–30]. Considering the moderate accuracy for detecting PDs and NCSE in the present study, the ability to detect seizure by the eight-channel EEG is as high as the results reported previously in the literature.

In the present study, NCSE was detected in 13 (26%) patients using C-cEEG monitoring, and the rate of NCSE in this study was consistent with that in a previous report [31]. However, the 70% sensitivity of NCSE was considered insufficient. From a theoretical perspective, the power of HS-cv EEG monitoring in detecting NCSE is not comparable to C-cEEG monitoring because it occasionally requires more than 24 h to exclude the diagnosis [1]. As shown in Fig. 3, NCSE can be potentially detected later if HS-cv EEG monitoring is performed for a longer period. Considering the examination period of HS-cv EEG monitoring, detection of NCSE merely using HS-cv EEG is impossible. In the present study, the median inspection time of HS-cv EEG was only 134.5 min. Patients strongly suspected of having NCSE required to be examined for longer periods. However, the gel-type electrodes are not durable, and sometimes, they are associated with bedsores on the patient's head if it takes a longer period.

Based on the data obtained in this study, as shown in Fig. 4, HS-cv EEG monitoring could be used to detect abnormal EEG patterns quickly and effectively, especially in emergent clinical settings. Abnormal EEG patterns could be developed into NCSE, particularly if the patient has ictal–interictal continuum [32]. Even if the EEG shows CS, performing cEEG is better because it might indicate an ictal pattern [33]. Moreover, detecting abnormal EEG patterns is clinically important. If a patient exhibits NCSE symptoms, the corresponding treatment could be initiated immediately; if the patient does not exhibit symptoms, further inspection such as C-cEEG monitoring could be conducted. In many facilities, starting C-cEEG is frequently delayed [7]. Conversely, the HS-cv EEG in our Neuro-ICU can save a 303 min (218–908 min) delay, and we can initiate cEEG monitoring within 60 min. HS-cv EEG monitoring could be a helpful device if we locate its position as a connecting tool to C-cEEG.

Limitation

The present study has several limitations. First, it was performed prospectively but retrospectively examined at a single center, which introduced potential selection bias. Uncontrolled confounding factors may have also existed. Second, a relatively small number of patients were included in this study; hence, the results require confirmation in a larger cohort. Beta-error may have also existed. Third, if HS-cv EEG and C-cEEG were conducted simultaneously, a more accurate diagnosing ability could be calculated without differences caused by time interval and clinical interventions. Fourth, if additional RDA and

SW cases could be assessed, we could have performed a more detailed analysis of the abnormal EEG patterns.

Conclusions

HS-cv EEG monitoring demonstrated high reliability for the detection of abnormal EEG patterns, with moderate reliability for PDs and NCSE, and can facilitate rapid initiation of cEEG monitoring in patients with AMS with unknown etiology.

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Author contributions
Satoshi Egawa and Toru Hifumi were responsible for conception of the article and drafted and revised the manuscript. Yuichi Kubota and Yasuhiro Kuroda helped to make a study design and draft the manuscript. Hidetoshi Nakamoto helped to draft the manuscript. All authors have read and approved the final manuscript and take full responsibility for all aspects of the study.

Source of support
None.

Conflict of interest
The authors declare a conflict of interest with Nihon Kohden as a cooperative research.

Ethical approval/informed consent
The protocol and consent procedures were approved by the Institutional Review Board.

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