ORIGINAL ARTICLE

Intervention Time and Adverse Events in a Canadian Epilepsy Monitoring Unit

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ABSTRACT: ***Background:*** Intervention time (IT) in response to seizures and adverse events (AEs) have emerged as key elements in epilepsy monitoring unit (EMU) management. We performed an audit of our EMU, focusing on IT and AEs. ***Methods:*** We performed a retrospective study on all clinical seizures of admissions over a 1-year period at our Canadian academic tertiary care center's EMU. This EMU was divided in two subunits: a daytime three-bed epilepsy department subunit (EDU) supervised by EEG technicians and a three-bed neurology ward subunit (NWU) equipped with video-EEG where patients were transferred to for nights and weekends, under nursing supervision. Among 124 admissions, 58 were analyzed. A total of 1293 seizures were reviewed to determine intervention occurrence, IT, and AE occurrence. Seizures occurring when the staff was present at bedside at seizure onset were analyzed separately. ***Results:*** Median IT was 21.0 (11.0–40.8) s. The EDU, bilateral tonic–clonic seizures (BTCS), and the presence of a warning signal were associated with increased odds of an intervention taking place. The NWU, BTCS, and seizure rank (seizures were chronologically ordered by the patient for each subunit) were associated with longer ITs. Bedside staff presence rate was higher in the EDU than in the NWU ($p < 0.001$). AEs occurred in 19% of admissions, with no difference between subunits. AEs were more frequent in BTCS than in other seizure types ($p = 0.001$). ***Conclusion:*** This study suggests that close monitoring by trained staff members dedicated to EMU patients is key to optimize safety. AE rate was high, warranting corrective measures.

RÉSUMÉ : Temps d'intervention et survenue d'événements indésirables dans une unité de surveillance de l'épilepsie au Canada. ***Contexte*** **:** Le temps d'intervention (TI) en réaction aux crises d'épilepsie et la survenue d'événements indésirables (EI) se sont révélés des éléments très important de la prise en charge des patients dans une unité de monitoring d'épilepsie (UME). Nous avons donc réalisé un audit du suivi des patients à l'UME de notre institution, en portant une attention particulière au TI et aux EI. ***Méthode*** **:** il s'agit d'une étude rétrospective portant sur tous les cas de crise clinique d'épilepsie qui ont nécessité une hospitalisation à l'UME, sur une période d'un an, dans un centre universitaire de soins tertiaires au Canada. L'UME était elle-même divisée en deux sous-unités : la première est une section de l'unité d'explorations en épileptologie, comptant 3 lits, pour une surveillance de jour, sous la supervision de techniciens en EEG ; la seconde, qui est une sous-unité du département de neurologie (UDN), comptant 3 lits et dotée de vidéo-électroencéphalographes, est un secteur où étaient transférés les patients la nuit et les fins de semaine, sous la supervision de personnel infirmier. Les dossiers de 58 patients admis sur 124 ont été analysés, et l'examen des données a révélé la survenue de 1293 crises au total, nombre qui a servi à déterminer la fréquence des interventions, les TI et le nombre d'EI. Les crises survenues au chevet en la présence de personnel ont fait l'objet d'une analyse distincte. ***Résultats*** **:** Le TI médian était de 21,0 secondes (11,0–40,8). L'USE, les crises tonico-cloniques bilatérales (CTCB) et la notion d'alerte en début de crise ont été associées à une augmentation des probabilités d'intervention. L'UDN, les CTCB et le rang des crises (classées par ordre chronologique, par patient, dans chaque sous-unité) ont été associés à des TI plus longs. Le taux de présence du personnel au chevet était plus élevé à l'USE qu'à l'UDN ($p < 0,001$). Des EI sont survenus dans 19 % des cas, indépendamment des sous-unités. Toutefois, les EI étaient plus fréquents dans les cas de BTCS que pour les autres types de crise ($p = 0,001$). ***Conclusion*** **:** Les résultats de l'étude suggèrent qu'une surveillance étroite des patients assurée par du personnel formé, dans une USE est un facteur très important de l'optimisation de la sécurité. Le taux d'EI est élevé, ce qui justifie la prise de mesures correctrices.

Keywords: Epilepsy, Monitoring unit, Safety, Intervention time, Adverse events

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Introduction

A growing number of hospitals now have a specialized epilepsy monitoring unit (EMU) equipped for long-term inpatient video-EEG monitoring (VEM). VEM consists of the continuous, simultaneous recording of video and EEG, generally over the course of several days, to capture and study events of clinical interest. For instance, patients may be admitted to the EMU for VEM to confirm the epileptic nature of paroxysmal events that may seem atypical for seizures or that do not respond to antiepileptic drug treatment, for rapid adjustment of their antiepileptic drug treatment under close monitoring in the context of an exacerbation of seizures, or for a presurgical evaluation in the context of epilepsy surgery. For the lattermost indication, recording the patient's habitual seizures is valuable to localize the

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seizure focus: (a) recorded seizures are reviewed carefully on video since clinical semiology can hint at the localization of the epileptic focus; (b) interictal spikes and seizure discharges are analyzed to infer on side (lateralization) and site (localization) of the epileptic focus. During their 1–2-week stay in the EMU, several (usually three–five) seizures are recorded to ensure that the patient only has one epileptic focus, rather than multiple foci. While this can be easily achieved in patients with frequent attacks, withdrawal of anticonvulsant medication under clinical supervision may be required when seizures do not occur regularly enough.

Over the years, safety has steadily emerged as a key element to consider in EMU management. Regardless of the reason for admission, patients are at risk for adverse events (AEs) in the EMU, especially when measures are taken to purposefully precipitate seizures. AEs most often reported in the literature consist of status epilepticus, falls, injuries, postictal psychoses, seizure clusters, medication-related complications, and cardiorespiratory complications.[1] Unfortunately, evidence regarding safety in the EMU is sparse, heterogeneous, and based primarily on small sample sizes. Current EMU guidelines offer little recommendations with respect to safety, presumably owing to the lack of high-quality evidence on this subject.[2]

On a related note, few studies have reported on intervention time (IT) in the EMU.[3] IT is defined as the time separating seizure onset and the moment staff took action to accommodate the patient. Current literature supports that IT may vary quite a bit between centers, probably due to inter-EMU differences in organization, staff, and protocols. Factors governing IT in the EMU remain poorly understood. Nevertheless, IT can be hypothesized to be a quality indicator in the EMU, and audits investigating IT have been performed in various centers.[3]

This study aims to ensure the overall quality of our epilepsy program by acting as an audit of IT and AEs in the EMU. The results of this audit are used to compare the management of our EMU with that of other centers, in the hopes of bettering our delivery of care. Furthermore, this study provides additional data on safety in EMUs at large, which may prove useful in EMU planning and ultimately be integrated into the formulation of new guidelines.

Methods

Patients

A retrospective study was performed on all clinical seizures of patients admitted to our EMU over the period of 1 year (from January 1, 2014 to December 31, 2014). Purely electrical seizures were excluded. Purely clinical events with no electrical correlation on EEG, such as psychogenic non-epileptic seizures (PNES) and certain auras, were excluded. Clinical seizures with deep foci (e.g. frontal and insular) generating no clear electrical correlation on EEG were, however, included. Auras were included only if they generated characteristic electrical findings on EEG. Patients who did not present any clinical seizures during their EMU stay were excluded since they required no intervention. Patients admitted for intracranial EEG studies had a dedicated nurse and were, therefore, excluded. Seizures occurring while patients underwent tests outside the EMU (e.g. radiology department) could not be analyzed. In total, 58 out of 124 admissions were included in the final analysis. All patients provided informed consent to the use of their data for research and audit purposes.

Work Routines and EMU Setup

Located in an academic tertiary care center, our EMU was comprised of two subunits: the third-floor epilepsy department subunit (EDU) and the fifth-floor neurology ward subunit (NWU). Patients stayed in one of the three private rooms in the EDU during weekdays from 8:00 AM to 8:00 PM. Continuous supervision was ensured by two epilepsy monitoring (EPM) technologists from 8:00 AM to 3:30 PM and by a single EPM technologist from 3:30 PM to 8:00 PM seated at a VEM station located just in front of the rooms. EPM technologists had training in clinical neurophysiology. The distance between the main station and the patients' rooms was around 5m. Patients could contact staff by means of a push-button and a portable bell. Patients could circulate in their room unless impaired mobility or a major risk of fall indicated otherwise. Patients could not circulate outside their room except to go to the common washroom located nearby within the unit. Certain stimuli, such as intermittent photic stimulation, antiepileptic drug tapering/withdrawal, video games, and sleep deprivation, were used to precipitate seizures. The rest of the time, the patients would be in the NWU in one of the three beds (one private room and one semi-private room), i.e. during weeknights from 8:00 PM to 8:00 AM and during weekends. Supervision was ensured by nursing staff via video surveillance at the main desk. The distance between this main desk and the patients' rooms was around 15 m. There was no real-time EEG surveillance, as nurses could not read EEG. Patients were regularly visited by staff and could contact staff using a push-button. One nurse at a time would oversee all three EMU patients, as well as two-to-four non-EMU patients. This nurse-to-patient ratio remained constant throughout the week and during holidays. Nurses attributed to EMU patients were trained for neurologic emergencies but did not have any additional training when compared to other nurses in the neurology ward. EMU nurses would, however, receive specific instructions regarding the patients under their care the moment these patients were transferred to the NWU. Patients would remain connected to monitoring when using the washroom located inside their room. They could circulate in their room but not outside. Complete review of weeknight EEG tracings was performed by EPM technologists the following morning. Weekend EEG tracings were reviewed by an EPM technologist on call the following day. The analyses were made by the attending epileptologist.

Operational Definitions

A seizure was defined as an uncontrolled electrical disturbance in the brain that may generate various physical and cognitive manifestations. AEs were defined as undesirable medical complications that occur during EMU stay. An intervention was defined as staff purposefully interacting with a patient during a seizure or during possible postictal disorders. IT was defined as the time separating electrical onset of a seizure, as determined via visual inspection of EEG recordings, and the moment an intervention took place. This moment corresponded to when a staff member entered a patient's room to interact with the patient or

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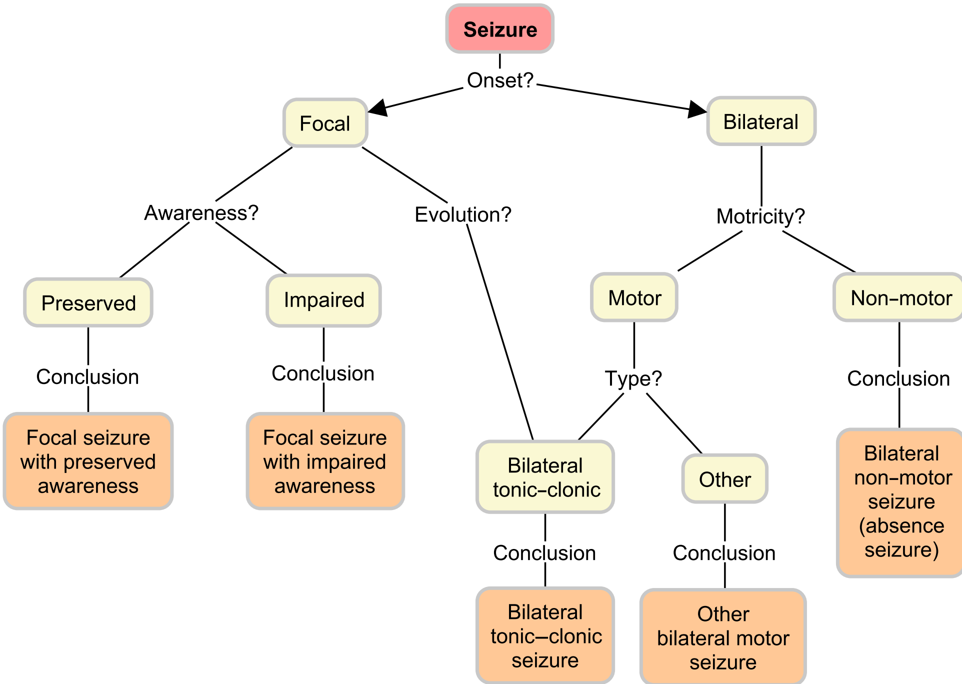

Figure 1: *Seizure classification flowchart, adapted to this study from the 2017 International League Against Epilepsy (ILAE) seizure classification.*[4]

when a staff member purposefully communicated with a patient to ensure their wellbeing without entering their room. For the latter case, staff members could communicate with patients using an intercom system or directly outside their door. For cases in which a staff member would first communicate with a patient to ensure their wellbeing and then enter their room to provide assistance, the moment of intervention corresponded to when the staff member entered the room. A subset of seizures occurred while a staff member was already by the patient's bedside at seizure onset, either by coincidence or because the patient was experiencing repetitive seizures and enhanced supervision was warranted. In these cases, interventions were considered to have occurred, but no IT nor warning issuance could be attributed to them by definition. Warning signals corresponded to visual cues generated at the main desk by a patient using their push-button, audio cues generated at the main desk when a patient would ring their portable bell, vocal notifications from patients or witnesses, and physical interception of a staff member by a witness. Seizure clusters were defined as seizures occurring in repetition at an unexpectedly high frequency for the patient (at least three times the expected frequency) or without full recuperation between each seizure. Seizures were classified as focal seizures with preserved awareness (FSPA), focal seizures with impaired awareness (FSIA), bilateral tonic–clonic seizures (BTCS, either bilateral at onset or secondarily bilateral), other bilateral motor seizures (OBMS), and bilateral non-motor seizures (BNMS, absence of seizures). OBMS included, for instance, tonic seizures, clonic seizures, atonic seizures, and gelastic seizures. This classification was chosen to best separate seizures with potentially different risk profiles (Figure 1).

Data Collection

Video-EEG data were collected using the Harmonie video-EEG recording system (Stellate, Montreal, Canada). All ictal video-EEG recordings and relevant clinical data such as history and psychiatric examination were analyzed by expert epileptologists. Staff intervention was retrospectively evaluated by reviewing the recordings. Recorded patient data included age, sex, hospitalization duration, reason for admission, types of seizure presented by the patient, presence/absence of staff suspicion of PNES, and presence/absence of confirmed PNES. A patient with suspected PNES was defined as presenting either possible or probable psychogenic events, whereas a patient who had confirmed PNES was defined as presenting either clinically established or documented psychogenic events, as outlined in the International League Against Epilepsy's classification of PNES diagnostic certainty.[5] Recorded seizure data included the subunit in which the seizure occurred, seizure type, presence/absence of a warning signal, seizure rank (seizures were ranked in chronological order by the patient for each subunit), intervention occurrence, presence/absence of a staff member by the patient's bedside at seizure onset, IT, and AE occurrence.

Data Analysis

Data are presented as medians (interquartile range) for continuous variables and count (frequency) for proportions. Univariate comparisons between groups were performed using Fisher's exact tests for proportions and using nonparametric Mann–Whitney U tests for continuous variables due to their non-normal distribution. The association between subunit (EDU vs. NWU), seizure type (BTCS vs. non-BTCS), warning issuance, seizure rank, and PNES suspicion on intervention was assessed using a multivariate analysis. We fitted a mixed logistic model for intervention occurrence and a random-intercept mixed linear model for IT. Mixed models were chosen to account for variations between different patients. Subunit, seizure type, warning issuance, seizure rank, and PNES suspicion were chosen as

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predictors since they were initially hypothesized to affect intervention occurrence and IT. IT was log-transformed to correct for its skewed distribution, and normality of the distribution of log-transformed IT was verified both visually and using the Shapiro–Wilk test ($p = 0.14$). Interventions occurring while a staff member was at the patient's bedside at seizure onset were not analyzed in the multivariate models, since no IT nor warning issuance could be attributed to them. The final mixed regression models were obtained after backward elimination of predictors. Significance level was set at 0.05. All statistical analyses were performed using R version 4.02.[6]

Results

Patients and Monitoring Data

In total, 58 admissions were included in the final analysis. Median patient age was 32.5 years (23.3 years–41.5 years). There were 27 males and 31 females. Eight patients were recorded in an ambulatory setting, while the remaining 50 were hospitalized for longer periods of time. To clarify, when patients were recorded in an ambulatory setting, it is meant that these patients were undergoing VEM only for a few hours at the EDU and could not leave the site. Median duration of stay (including patients who were recorded in the ambulatory setting and those who were hospitalized) was 8.0 days (4.3 days–12.0 days). As for reason for admission, 34 patients were admitted for presurgical evaluation, 11 for characterization of seizures, 10 for quantification of seizures and/or medication adjustment, and 3 for postsurgical evaluation. In total, 1293 recorded seizures were included in the final analysis: 541 OBMS, 438 FSIA, 245 FSPA, 44 BTCS, and 24 BNMS. Of the 58 admissions, 19 presented FSIA, 19 presented BTCS, 16 presented FSPA, 15 presented OBMS, and 1 presented BNMS (patients could have more than one type of seizure). The patient who presented BNMS was recorded in an ambulatory setting in the EDU and consequently did not spend any time in the NWU. Of the 58 patients included in this study, PNES were suspected in 9 patients and confirmed as a comorbidity in 4 of those patients. Table 1 compares patients' characteristics between EMU subunits, showing no significant differences in these characteristics between subunits. Table 2 describes seizure count according to seizure type and EMU subunit.

Table 1: Patients' characteristics according to EMU subunit

Patients' characteristics	EDU	NWU	*P*-value (univariate)
Females, n (%)	22 (58)	24 (55)	0.837
Age, years	31 (23.8–40.0)	30.5 (25.8–42.0)	0.783
Duration of stay, days	8.5 (4.0–10.3)	9.0 (1.0–7.5)	0.261
Reason for admission			
Presurgical evaluation, n (%)	33 (70)	30 (61)	0.691
Characterization, n (%)	5 (11)	10 (20)	0.400
Quantification/medication adjustment, n (%)	7 (15)	6 (12)	>0.999
Postsurgical evaluation, n (%)	2 (4)	3 (6)	0.658
Seizure type			
Patients presenting FSPA, n (%)	15 (29)	13 (30)	>0.999
Patients presenting FSIA, n (%)	21 (40)	20 (45)	0.845
Patients presenting OBMS, n (%)	15 (29)	11 (25)	0.818
Patients presenting BTCS, n (%)	14 (27)	15 (34)	0.507
Patients presenting BNMS, n (%)	1 (2)	0 (0)	>0.999
Patients presenting confirmed PNES, n (%)	4 (8)	3 (7)	>0.999
Patients in whom PNES was suspected or confirmed, n (%)	8 (15)	8 (18)	0.787

BNMS = bilateral non-motor seizures (absence of seizures); BTCS = bilateral tonic–clonic seizures; EDU = epilepsy department subunit; FSIA = focal seizures with impaired awareness; FSPA = focal seizures with preserved awareness; NWU = neurology ward subunit; OBMS = other bilateral motor seizures; PNES = psychogenic non-epileptic seizures. *P*-values were calculated using Fisher's exact tests or using Mann–Whitney U tests, when appropriate.

Table 2: Seizure occurrence for different seizure types according to EMU subunit

Seizure type	EDU	NWU
FSPA, n (%)	93 (16.5)	152 (20.9)
FSIA, n (%)	144 (25.5)	274 (37.6)
OBMS, n (%)	284 (50.4)	277 (38.0)
BTCS, n (%)	18 (3.2)	26 (3.6)
BNMS, n (%)	25 (4.4)	0 (0)
Total, n (%)	564 (100)	729 (100)

BNMS = bilateral non-motor seizures (absence of seizures); BTCS = bilateral tonic–clonic seizures; EDU = epilepsy department subunit; FSIA = focal seizures with impaired awareness; FSPA = focal seizures with preserved awareness; NWU = neurology ward subunit; OBMS = other bilateral motor seizures.

Intervention Rate

Interventions took place for 354 seizures. Our EMU's overall intervention rate was 27.4%. Table 3 compares intervention occurrence for each seizure type between the EDU and the NWU. A mixed logistic regression was calculated to predict intervention occurrence based on subunit, seizure type, warning issuance, seizure rank, and PNES suspicion, all while accounting for variations in different patients (Table 4). The final model suggests that the EDU, BTCS, and the presence of a warning signal were associated with increased odds of intervention. Interventions occurring with a staff member at the bedside of the patient at seizure onset were excluded from this regression analysis.

Intervention Time

Out of 354 interventions, 214 ITs were recorded (no IT could be recorded for cases in which a staff member was at the bedside of the patient at seizure onset). In the EDU, 172 ITs were recorded, whereas, in the NWU, 42 ITs were recorded. Our EMU's median IT was 21.0 s (11.0 s–40.8 s). Median IT was 16.0 s (10.0 s–27.0 s) in the EDU and 76.0 s (42.0 s–116.5 s) in the NWU. A mixed linear regression was calculated to predict the natural logarithm of IT based on subunit, seizure type, warning

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Table 3: Intervention occurrence for different seizure types according to EMU subunit

Seizure type	EDU	NWU	*P*-value (univariate)
FSPA interventions, n (IR %)	78 (83.9)	3 (2.0)	<0.001
FSIA interventions, n (IR %)	98 (68.1)	16 (5.9)	<0.001
OBMS interventions, n (IR %)	77 (27.1)	32 (11.5)	<0.001
BTCS interventions, n (IR %)	18 (100.0)	25 (96.2)	>0.999
BNMS interventions, n (IR %)	7 (28.0)	0 (–)	–
Total interventions, n (IR %)	278 (49.3)	76 (10.4)	<0.001

BNMS = bilateral non-motor seizures (absence of seizures); BTCS = bilateral tonic–clonic seizures; EDU = epilepsy department subunit; FSIA= focal seizures with impaired awareness; FSPA = focal seizures with preserved awareness; IR = intervention rate; NWU = neurology ward subunit; OBMS = other bilateral motor seizures. *P*-values were calculated using Fisher's exact tests.

issuance, seizure rank, and PNES suspicion, all while accounting for variations in different patients (Table 4). In the final model, the NWU, BTCS, and seizure rank were associated with longer ITs.

Bedside Staff Presence at Seizure Onset

Out of 354 interventions, 140 were instances in which a staff member was present at the bedside of the patient at seizure onset. Of these instances, 106 took place in the EDU and 34 took place in the NWU. Our EMU's rate of bedside staff presence at seizure onset was 10.8%. This rate was 18.8% in the EDU and 4.7% in the NWU. The rate of bedside staff presence at seizure onset was significantly higher in the EDU than in the NWU ($p < 0.001$).

Adverse Events

All 58 admissions were analyzed for AE occurrence. In total, 15 AEs occurred in 11 admissions: 6 injuries (4 postictal backaches, 1 minor foot trauma, and 1 forehead bruise), 4 seizure clusters, 3 falls, and 2 postictal aggressive behaviors (Table 5). Ten AEs occurred in the EDU, while 5 occurred in the NWU. Four AEs occurred in BTCS, while 11 occurred in other seizure types. Total AE rate corresponded to 1.2% of seizures and to 19.0% of admissions. There was no significant difference in AE rate between the EDU and the NWU ($p = 0.113$). AE rate was significantly higher in BTCS than in other seizure types ($p = 0.001$).

Discussion

In summary, the EDU, BTCS, and the presence of a warning signal were associated with increased odds of intervention when accounting for variations in patients and excluding interventions occurring with a staff member at the patient's bedside at seizure onset. The NWU, BTCS, and seizure rank (seizures were ranked in chronological order by the patient for each subunit) were associated with longer ITs when accounting for variations in patients and excluding interventions occurring with a staff member at the patient's bedside at seizure onset. The rate of bedside staff presence at seizure onset was higher in the EDU than in the NWU. AE rate was higher in BTCS than in other seizure types but did not vary between subunits.

Before tackling IT and AEs, our EMU's intervention rate must be addressed. Literature on EMU intervention rate is sparse and limited. Previously reported EMU seizure intervention rates consisted of 40.6%, 67.0%, and 88.6%.[7–9] Our EMU's overall intervention rate of 27.8% was lower than what has been reported. However, our EDU's intervention rate was 49.3%, a number that seems grossly appropriate in comparison with the limited literature. Indeed, the odds of an intervention taking place were higher in the EDU than in the NWU. This difference between subunits was expected, since the level of supervision was much more optimized in the EDU. Consequently, the results of this study must be interpreted while keeping in mind that a substantial portion of seizures had no intervention, and that this portion differed between subunits and among seizure types.

In our EMU, the overall median IT was 21.0 s (11.0 s–40.8 s). Few EMUs have published their IT in the literature. When ITs are reported, they can be somewhat heterogeneous, owing probably to differences in EMU practices and study designs. A Detroit EMU had an overall average IT of 142.3 s, though it remains unknown if IT was defined in regard to electrical or clinical onset of seizure.[10] Shin et al. investigated response time to safety signals at a Boston EMU, with 23.5 s for FSIA, 20.3 s for BTCS, and 30.2 s for PNES.[11] Witek et al. conducted a 4-week study at an unspecified EMU in 2014, yielding a median diurnal IT of 22 s and a median nocturnal IT of 49 s, with IT defined in regard to clinical seizure onset.[12] Malloy et al. reported an average IT of 22 s for BTCS after analyzing a combined dataset from 12 American EMUs, with IT defined in regard to EEG generalization.[3] Rommens et al. reported an overall median IT of 31 s at a Netherlands epilepsy center, with IT defined in regard to electrical seizure onset.[7] By gross approximation, our overall median IT remains seemingly satisfactory. Nevertheless, it appears clear that more institutions will need to publish their overall IT for a more precise comparison to be possible.

The design of our EMU offered an opportunity to compare IT between two different setups. To our knowledge, this study is the first to evaluate safety data pertaining to such an EMU. As can be expected, IT was longer in the NWU than in the EDU. Many explanations may be given for this finding, the most obvious being differing levels of supervision. In the EDU, staff provided continuous VEM and was, therefore, able to quickly detect events, even nonsignificant ones, and react accordingly. In the NWU, given that the nurses could not provide real-time EEG surveillance and also tended to other non-EMU patients, reaction to seizures was less optimized. Another explanation would be the physical organization of each subunit. For example, in the EDU, the staff was usually around 5m away from the patients' rooms, whereas, in the NWU, the staff was more around 15m away from the patients' rooms. The final potential explanation lies within differences in scheduling. Patients were assigned to the EDU on weekdays and to the NWU on weeknights and weekends. MORTEMUS, a multicenter study on sudden unexpected deaths in epilepsy (SUDEP) in EMUs, sounded the alarm on the suboptimal nocturnal supervision that many EMUs engaged in. According to MORTEMUS, SUDEPs mostly occurred at night, with supervision levels like that of traditional neurological wards.[13] Witek et al. backpacked on these ideas, demonstrating

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Table 4: Regression results for intervention occurrence and for intervention time

	Intervention occurrence $n = 1153$		Log-transformed intervention time $n = 214$	
Model	**Model 1**	**Model 2**	**Model 1**	**Model 2**
NWU	0.76***[0.74, 0.78]	0.76***[0.74, 0.79]	1.38***[1.05, 89]	1.31***[1.02, 1.60]
BTCS	1.67***[1.50, 1.86]	1.65***[1.48. 1.83]	0.49*[0.10, 0.87]	0.50*[0.12, 0.87]
Warning	1.95***[1.83, 2.07]	1.94***[1.82, 2.06]	−0.14[−0.45, 0.18]	–
Rank by subunit	1.00[1.00, 1.00]	–	0.05**[0.02, 0.08]	0.05**[0.02, 0.08]
PNES suspicion	0.85[0.71, 1.02]	–	−0.23[−0.77, 0.31]	–
(Intercept)	1.58***[1.47, 1.69]	1.55***[1.44, 1.66]	2.65***[2.41, 2.89]	2.59***[2.36, 2.81]
Marginal R^2/Conditional R^2	0.437/0.705	0.411/0.700	0.336/0.591	0.330/0.599

BTCS = bilateral tonic–clonic seizures; NWU = neurology ward subunit; PNES = psychogenic non-epileptic seizures. Estimates are shown as odds ratio for intervention occurrence and as coefficient B for log-transformed intervention time with 95% confidence intervals. Odds ratio for intervention occurrence was calculated using a mixed logistic model. Coefficient B for log-transformed intervention time was calculated using a random-intercept mixed linear model. Model 1: model with all candidate variables. Model 2: final model after backward elimination of variables.
*p-value < 0.05; **p-value < 0.01; ***p-value < 0.001

Table 5: Adverse event characterization according to subunit and seizure type

ID	AE	Subunit	Seizure type
1	Seizure cluster	NWU	FSPA
3	Injury (forehead bruise)	EDU	BTCS
4	Seizure cluster	EDU	OBMS
5	Injury (postictal backache)	EDU	FSIA
11	Injury (minor foot trauma)	EDU	FSIA
15	Injury (postictal backache)	EDU	BTCS
15	Injury (postictal backache)	NWU	BTCS
26	Fall	NWU	FSIA
39	Fall	EDU	OBMS
39	Fall	EDU	OBMS
45	Postictal aggressive behavior	EDU	BTCS
45	Postictal aggressive behavior	EDU	FSPA
49	Seizure cluster	NWU	FSIA
49	Seizure cluster	NWU	FSIA
52	Injury (postictal backache)	EDU	OBMS

AE = adverse event; BTCS = bilateral tonic–clonic seizures; EDU = epilepsy department subunit; FSIA = focal seizures with impaired awareness; FSPA = focal seizures with preserved awareness; ID = identification; NWU = neurology ward subunit; OBMS = other bilateral motor seizures.

a longer EMU IT during the night than during the day.[12] Whether or not schedule-related IT differences are purely secondary to differing levels of supervision remains unclear. Nevertheless, scheduling may count for part of the reason as to why IT was longer in the NWU.

BTCS was analyzed apart from other seizure types. This stratification was chosen to take into count BTCS' particular risk profile.[14] BTCS was associated with increased odds of intervention, a finding that is probably testament to the greater sense of urgency that BTCS instill in staff members in comparison with other seizure types. BTCS was, however, associated with longer ITs. This finding can be explained by the discrepancy in intervention rate between BTCS and other seizure types. Staff almost always intervened for BTCS, including when they were not carefully monitoring for seizures. In contrast, staff needed to be very vigilant to detect non-BTCS, especially in the NWU, where interventions often occurred because a staff member was by the patient's bedside at seizure onset or because a staff member was coincidentally near the patient's room at seizure onset. An alternative explanation lies within the time required to prepare interventions for BTCS. Intervening for a BTCS can often be more complicated than for other seizure types. An additional preparatory time may therefore contribute to longer BTCS ITs.

Warning issuance was associated with increased odds of intervention but had no significant effect on IT. One might hypothesize that warning issuance would shorten IT by providing early guidance to an ongoing seizure. Nevertheless, some warnings were issued a substantial amount of time after seizure onset, notably when seizures had gone unnoticed by staff members. Furthermore, some warning signals may have been less effective at garnering staff members' attention, which could have resulted in long ITs regardless of there being a warning. Our finding that warning issuance had no effect on IT may reflect the occurrence of these scenarios.

Seizure rank was associated with longer ITs. This result indicates that, in each subunit, IT lengthened as more seizures occurred in a given patient, suggesting the existence of a "staff desensitization" phenomenon. This phenomenon may be explained by the diminishing sense of urgency a staff member might feel after a patient was known to present numerous

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innocuous seizures. Nevertheless, seizure rank was not associated with intervention occurrence, which suggests that even though staff would intervene slower the more seizures a patient had, staff would still at least intervene.

One could hypothesize that IT would be longer in a patient with suspected PNES. This might be the case if PNES elicited a lesser sense of urgency and staff tended to misinterpret seizures as PNES. Though PNES were not recorded in this study, patients in whom PNES were suspected were noted. PNES suspicion was not associated with intervention occurrence or IT. Hence, staff did not respond differently to patients in whom PNES were suspected. This finding is concordant with the literature, which currently supports that PNES has a similar AE and IT profile as other seizures. Atkinson et al. demonstrated no difference in AEs between electrical seizures and PNES.[9] Shin et al. showed that there was no difference in response time to safety signals between FSIA, BTCS, and PNES.[11]

A subset of interventions occurring with a staff member at the bedside of the patient at seizure onset was analyzed apart from other interventions. These interventions had by definition no attributable IT or warning issuance. Univariate analyses indicated a higher rate of bedside staff presence at seizure onset in the EDU than in the NWU. This finding once again reflects the enhanced level of supervision in the EDU.

Our AE rate corresponded to 19.0% of admissions or 1.2% of seizures. Sauro et al. conducted a systematic review on EMU safety data, concluding with a pooled proportion of AEs of 7% despite considerable inter-study variability.[1] Sauro et al. then sought to improve EMU comparability by developing consensus-driven quality indicators. One of these EMU quality indicators was AEs. Sauro et al. created a non-exhaustive list of AEs that should be recorded in EMU safety studies.[15] Of these AEs, our EMU reports six injuries and four seizure clusters, along with three falls and two postictal aggressive behaviors. Our EMU AE rate of 19.0% is higher than the pooled AE proportion of 7% reported by Sauro et al. A factor that contributed to our EMU's higher AE rate was these study's exclusion criteria. Since this study was also aimed to evaluate IT, all admissions that did not present clinical seizures were excluded. Purely electrical seizures were also excluded. This constitutes an important omission bias. Excluding these admissions probably elevated our AE rate. In comparison, recent EMU safety studies by Craciun et al. and by Cox et al. generated AE rates of 7.9% and 2%, respectively. These AE rates were calculated from the total number of patients admitted in each center over a span of time, without excluding patients who, for instance, had no clinically significant seizures during their hospitalization.[16,17] By this logic, it appears justified that our EMU AE rate is higher than the rates observed in these two centers. Nonetheless, if it is presumed that omission bias played a limited role in this study, our EMU AE rate would indeed be quite high, and measures should be taken to lower it.

There was no difference in AE rate between the EDU and the NWU. This result does not entail that IT and AE occurrence are unrelated. Our small number of AEs and the various discrepancies between the EDU and the NWU preclude us from making any strong conclusion. On a separate note, AE rate was higher for BTCS than for other seizure types, a finding that is consistent with the literature.[14]

This study presents some limitations. First, a considerable amount of seizures had no interventions, and this amount varied between subunits. Second, due to the study's design being centered on IT, the chosen exclusion criteria may have injected some omission bias with respect to AE reporting. Third, PNES were excluded, which may affect the generalizability of this study's results to other EMUs. Fourth, this study did not measure the delay separating the moment a staff member would first realize a seizure was taking place and the moment of intervention. Such a "knowledge-action" delay would be interesting to investigate in future studies. Measuring IT based on clinical onset would have also been a meaningful alternative to measuring IT based on electrical onset. Still, basing IT on electrical onset has its own share of advantages, as clinical onset is a more challenging variable to measure with precision. Basing IT on electrical onset also seemed more harmonious with this study's design when considering that purely clinical auras were excluded. Finally, we could not determine with precision the impact of the nurse-to-patient ratio and of the training/experience of staff members on interventions and AEs, beyond the fact that these factors contributed to the differences found between the EDU and the NWU.

Conclusion

To our knowledge, this study is the first to investigate safety data pertaining to an EMU that splits patients among two distinct setups. EMUs that function in two subunits may particularly derive much use from this study's findings. This study may prove interesting for single-unit EMUs that seek to optimize their functioning and that share similarity to one of our EMU's two setups. Hospitals interested in investing in an EMU may use this study's findings to fine-tune their EMU design according to their budget.

It seems evident that, in order to optimize IT, supervision and physical organization of the EMU should be carefully evaluated. In the best scenario, continuous VEM would be provided by dedicated, trained EPM technologists at all times of the day. If other staff members such as nurses, nursing aides, or care attendants are tasked to monitor EMU patients, we would recommend they receive additional training in epilepsy intervention and remain dedicated to EMU patients. Attempts should be made to physically adapt the EMU set up to be as favorable as possible for quick seizure detection and interventions. Considerations may include minimizing the distance between staff and patients as well as improving patients' visibility to staff by various means.

Since the beginning of this study, our EMU has been relocated to a new building. Our EMU is no longer divided into two subunits, and many changes have been implemented in its practices. An audit of our new EMU will be performed to evaluate its AE and IT data, in comparison with our previous EMU.

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Disclosure

The authors report no disclosures.

Data Statement

All relevant data for this study are available upon request addressed to the corresponding author.

Statement of Authorship

JL: major role in data analysis, drafting, and manuscript revision.

DHT: design of the study, major role in data revision, data analysis, study coordination, and manuscript revision.

EBA: design of the study, major role in study coordination, and manuscript revision.

SM: major role in data analysis and drafting.

JF: major role in data collection and data analysis.

MK: minor role in data analysis.

MR: design of the study and data management.

AF: major role in data analysis and manuscript revision.

DKN: design of the study, manuscript revision, leading author.

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