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Accidental injuries in patients with generalized tonic–clonic seizures. A multicenter, observational, cross-sectional study (QUIN-GTC study)

Xavier Salas-Puig [a,*], Marc Iniesta [b], Laura Abraira [a], Josep Puig [c], the QUIN-GTC study group

[a] Hospital Universitari Vall d'Hebron, Passeig de la Vall d'Hebron, 119-129, 08035 Barcelona, Spain
[b] Departamento Médico, Esteve Pharmaceuticals, S.A., Pg. Zona Franca, 109, 08038 Barcelona, Spain
[c] Bioclever 2005, S.L., Carrer Balmes, 151, 08008 Barcelona, Spain

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ABSTRACT

Purpose: Patients with epilepsy have a higher risk of accidental injuries. The aim of this study was to determine the incidence of accidental injuries and quality of life in patients with epilepsy and generalized tonic–clonic seizures and their association with patient-related factors.

Methods: This is an observational, cross-sectional, multicenter study of patients with epilepsy and primary generalized tonic–clonic seizures and/or focal to bilateral tonic–clonic seizures in the routine clinical practice of epilepsy clinics. In a single visit, demographic and clinical data and information on the type and severity of injuries were collected, and patients' quality of life was evaluated with the QOLIE-10 questionnaire.

Results: In total, 406 patients with a median age of 41.1 years (range: 13–87) were included; 47.5% were women. Age at onset of tonic–clonic seizures was 25.4 (range: 0–83) years. Epileptic seizures were primary tonic–clonic (67.2%), focal to bilateral tonic–clonic (32.8%), focal with impairment of awareness (23.6%), focal without impairment of awareness (13.5%), absences (14.8%), and myoclonic (9.6%).

Etiology was symptomatic or with unknown etiology focal (42.9%), genetic generalized (36.9%), symptomatic or with unknown etiology generalized (18.0%), and others (2.2%).

The number of generalized tonic–clonic seizures in the last 12 months was as follows: 1 (41.9%), 2–5 (42.4%), and >5 (15.8%). Antiepileptic treatment at the time of the visit was monotherapy in 44.1% of the patients. The most commonly used drugs were levetiracetam (45.1%), valproate (20.7%), lamotrigine (20.0%), and perampanel (18.7%).

In total, 59.6% of the patients had experienced at least one accidental injury associated with tonic–clonic seizures in the last 12 months, the most common being head injuries (35.5%), dental injuries (4.9%), burns (4.9%), and fractures (3.9%). A total of 25.1% had suffered at least one serious injury.

The multiple logistic regression model showed that the factors associated with suffering an injury were the following: etiology (symptomatic or with unknown etiology focal and genetic generalized vs. symptomatic or with unknown etiology generalized, $p = 0.0008$ and $p = 0.0077$, respectively), number of seizures in the last year (2–5 vs. 1, $p = 0.0115$; >5 vs. 1, $p = 0.0004$), and psychiatric comorbidities ($p = 0.0151$).

Patients with injuries had a worse quality of life than patients without injuries, according to the overall QOLIE-10 score ($p = 0.0003$).

Conclusions: More than half of the patients had accidental injuries related with seizures. Symptomatic or with unknown etiology focal epilepsy and genetic generalized epilepsy, >1 seizure in the last year, and concomitant psychiatric disease are the risk factors associated with accidental injuries in patients with tonic–clonic seizures, with the consequent worsening of quality of life.

1. Introduction

Epileptic seizures have important neurocognitive, psychological, and social consequences, and patients have an increased risk of accidental injuries compared with the general population [1–4]. This risk involves personal and social consequences that may result in inactivity, dependence, and social isolation [5,6]. The incidence of injuries in patients with epilepsy is much higher than in the general population and may range from 0.6% to 47.3% [6–8].

There are discrepancies regarding the prevalence of injuries in these patients and varies according to the type of study population (population sample vs. selected population), definition of the disease (genetic, with unknown etiology or symptomatic), accuracy of the injury reports

* Corresponding author at: Neurology Department, Epilepsy Unit, Hospital Universitari Vall d'Hebron, Passeig de la Vall d'Hebron, 119-129, 08035 Barcelona, Spain.
E-mail addresses: javiersalaspuig@gmail.com (X. Salas-Puig), miniesta@esteve.com (M. Iniesta), laura.abraira@vhir.org (L. Abraira), josep.puig@bioclever.com (J. Puig).

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(types, circumstances, and severity), study design (retrospective vs. prospective), and duration of the observation period [4,5].

Risk factors associated with seizure-related injuries include very frequent seizures and generalized onset, atonic, myoclonic, and in particular, tonic–clonic seizures [2,7,9–11].

It should be noted that most accidents occur among patients with uncontrolled active epilepsy while well-controlled epilepsy carries only a moderate risk of accidents, suggesting that patients with poorly controlled seizures should take protective measures [5,12].

The aim of this multicenter, observational, cross-sectional study was to evaluate the incidence in Spain of accidental injuries in patients with epilepsy and primary generalized tonic–clonic seizures and/or focal to bilateral tonic–clonic seizures and their relationship with patient-related factors, such as demographic and clinical characteristics and quality of life, in the routine clinical practice of epilepsy clinics.

2. Methods

We conducted a multicenter, observational, cross-sectional study in the outpatient clinics of 96 neurology specialists in Spain, between September 2016 and October 2017. Each investigator included up to 5 consecutive patients with a diagnosis of epilepsy with primary generalized tonic–clonic seizures and/or focal to bilateral tonic–clonic seizures, aged ≥12 years, who were receiving treatment with at least 1 antiepileptic drug, and who had presented at least 1 generalized tonic–clonic seizure in the 12 months before the inclusion visit. Patients who were unable to cooperate in the completion of the case report form (CRF) were excluded.

The protocol, the informed consent form, and other patient information were reviewed and approved by the Clinical Research Ethics Committee (CREC)/Independent Ethics Committee (IEC) of the Hospital Vall d'Hebron (Barcelona, Spain), and the study was performed according to the principles of the Declaration of Helsinki and its subsequent revisions.

All patients received detailed information about the study and provided written informed consent to participate prior to inclusion.

The aim of this study was to evaluate the incidence of accidental injuries, associated risk factors, and quality of life in patients with epilepsy and generalized tonic–clonic seizures.

Injuries were defined as any dysfunction or pain in a body part resulting from an accidental occurrence and were directly related to seizures. Injuries included those due to falls and other consequences of abnormal motor function or those related to alteration of consciousness (e.g., burns).

Serious injuries were defined as injuries requiring hospitalization or surgical intervention, or causing incapacitation.

Data were collected in a single visit on sociodemographic characteristics and anthropometric measurements [age, height, weight, body mass index (BMI), gender, marital status, educational level, cohabitants, and employment status], clinical characteristics of epilepsy (date of diagnosis, duration of the disease, number of seizures, age at onset of seizures, type of epileptic seizures, syndromic diagnosis, etiology of epilepsy), characteristics of the injuries (type, consequences, incapacitation), comorbidities, previous and current epilepsy treatments, and use of healthcare resources (number of visits to the emergency room, to primary care, and to the neurologist, and number of hospital admissions).

Patients also completed the QOLIE-10 self-administered health-related quality of life (HRQoL) questionnaire, specifically designed for patients with epilepsy and validated in the Spanish population with epilepsy [13]. This tool consists of 10 items and is divided into general and specific domains grouped into three factors: epilepsy effects, mental health, and role functioning. Each item is scored between 1 and 5 so that the total score can range from 10 points (poorest HRQoL) to 50 points (best HRQoL), standardized from 0 to 100.

Sample size was calculated from the estimated proportion of patients with any accidental injury related with their generalized tonic–clonic seizures per interval, using the level of maximum variability (an expected proportion of 50%). Thus, a total of 475 patients were required to estimate the proportion of patients with an accidental injury associated with tonic–clonic seizures with a 95% confidence interval (CI), a maximum amplitude of 9%, and an expected proportion of 50%. Assuming that 5% of the patients might present nonvalid data, we aimed to recruit a total of 500 patients.

Numbers and percentages are presented for categorical variables and mean, standard deviation (SD), and range for quantitative variables. A logistic regression model was adjusted to detect the factors associated with tonic–clonic injury in the last 12 months. The significance level was 5%. All statistical analyses were carried out using SAS© for Windows (version 9.4).

3. Results

A total of 406 patients with a median age of 41.1 ± 17.1 years were included (range: 13–87), 47.5% women, with a mean BMI of 25.34 ± 4.45 (17.3–45.7) (see Table 1).

In total, 51.0% of the patients were single, 40.4% married, 6.9% separated/divorced, and 1.7% were widowed; 90.6% lived with other people and 9.4% lived alone (Table 1).

A total of 32.5% of the patients had completed primary education, 38.9% secondary education, 25.1% university studies, and 3.4% had no studies (Table 1). Thirty-three percent were employees; 10.1% self-employed; 16.0% were students; 15.8% retirees; 10.1% were homemakers; 9.4% were unemployed; and 5.7% were in other situations (Table 1).

In total, 26.8% had a family history of epilepsy. Age at onset of tonic–clonic seizures was 25.4 ± 18.2 (0–83) years, and time since diagnosis of epilepsy was 15.0 ± 14.3 years (0–73.9) (Table 2).

In 67.2% of the patients, seizures were primary tonic–clonic, 32.8% focal to bilateral tonic–clonic seizures, 23.6% focal with impairment of awareness, 13.5% focal without impairment of awareness, 14.8% absences, and 9.6% myoclonic (Table 2).

Etiology was symptomatic or with unknown etiology focal in 42.9%, genetic generalized in 36.9%, symptomatic or with unknown etiology generalized in 18.0%, and other in 2.2% (Table 2).

Before receiving their first treatment, 83.8% of the patients had had fewer than 6 seizures, 13.6% had had between 6 and 12 seizures, 0.5% had had between 13 and 24 seizures, and 2.1% had had more than 24

Table 1
Sociodemographic characteristics of patients (n = 406).

	n	Total (n = 406)
Age (years)	406	
Mean ± SD		41.1 ± 17.1
Min, Max		13, 87
Sex n (%)	406	
Men		213 (52.5)
Women		193 (47.5)
BMI (kg/m^2)	405	
Mean ± SD		25.34 (4.45)
Min, Max		17.3, 45.7
Marital status n (%)	406	
Unmarried		207 (51.0)
Married		164 (40.4)
Separated/divorced		28 (6.9)
Widowed		7 (1.7)
Lives with others n (%)	406	
Lives alone		38 (9.4)
Lives with others		368 (90.6)
Educational level	406	
No education		14 (3.4)
Primary studies		132 (32.5)
Secondary studies		158 (38.9)
University studies		102 (25.1)

Max: maximum; Min: minimum; SD: standard deviation.

Table 2
Characteristics of epilepsy (n = 406).

	n	Total (n = 406)
Family history of epilepsy n (%)	392	
Yes		105 (26.8)
No		287 (73.2)
Age of onset of tonic–clonic seizures (years)	406	
Mean ± SD		25.4 ± 18.2
Min, Max		0, 83
Number of tonic–clonic seizures prior to the initiation of treatment n (%)	382	
<6		320 (83.8)
6–12		52 (13.6)
13–24		2 (0.5)
>24		8 (2.1)
Time since onset of the epilepsy (years)	406	
Mean ± SD		15.03 (14.25)
Min, Max		0, 73.9
Type of epileptic seizures[a] n (%)	406	
Primary tonic–clonic		273 (67.2)
Focal to bilateral tonic–clonic seizures		133 (32.8)
Focal with impairment of awareness		96 (23.6)
Focal without impairment of awareness		55 (13.5)
Absences		60 (14.8)
Myoclonic		39 (9.6)
Other types		1 (0.2)
Etiology n (%)	406	
Symptomatic or with unknown etiology focal		174 (42.9)
Genetic generalized		150 (36.9)
Symptomatic or with unknown etiology generalized		73 (18.0)
Others		9 (2.2)
Number of generalized tonic–clonic seizures during the last 12 months n (%)	406	
1		170 (41.9%)
2–5		172 (42.4)
>5		64 (15.8)

Max: maximum; Min: minimum; SD: standard deviation.
[a] Patients could have more than one type of seizure.

seizures (Table 2). In the last 12 months, 41.9% had presented 1 seizure, 42.4% had 2–5 seizures, and 15.8% had more than 5 (Table 2).

At the time of the visit, 44.1% of the patients were receiving monotherapy, 36.5% bitherapy, and 19.5% polytherapy. The most commonly used drugs were levetiracetam (45.1%), valproate (20.7%), lamotrigine (20.0%), and perampanel (18.7%).

Fifty percent of the patients had comorbidities, primarily vascular (14.0%), and metabolic disorders (13.1%). Psychiatric diseases were present in 26.8% of the patients, and of those, 56.9% had anxiety disorders and 56.9% had a depressive syndrome. In total, 44.6% of the patients were receiving treatment for concomitant diseases.

Regarding the use of healthcare resources for the management of epilepsy, over the past 12 months, 69.0% of the patients had attended the emergency department, with 78.2% attending at least 3 visits; 57.1% had attended a primary care consultation, of which 53.9% reported less than 3 visits. In total, 98.8% had attended a visit with the neurologist, and 53.9% had attended less than 3 visits. Temporary inability to work was reported by 32.8% of the patients, with a mean duration of 53.8 ± 106.5 (1–365) days of sick leave as a result of their seizures. Hospitalization was required in 22.7%, with a mean of 1.5 ± 1.2 (1–10) admissions per patient and a mean stay of 3.8 ± 3.6 (1–25) days. Concussion was the main type of injury resulting in hospitalization and incapacitation.

At total of 59.6% of the patients had experienced some accidental injury related to their tonic–clonic seizures over the past 12 months. The most frequent injuries were head injuries in 35.5% of the patients (25.1% bruising, 15.5% facial or scalp lacerations, 2% concussion, 0.2% skull fracture), dental injuries in 4.9%, burns in 4.9%, and bone fractures in 3.9%; 41.6% of the patients had other injuries (Fig. 1). In 25.1% of cases, the patients had suffered at least 1 serious injury, i.e., requiring hospitalization or surgical intervention, or causing incapacitation. Incapacitation due to some type of injury was reported by 21.7% of the patients, 2.5% due to burns, 11.1% due to head injuries, 2.5% due to fractures, and 1.0% due to dental injuries.

The multivariate logistic regression model showed that the factors associated with a higher probability to suffer injuries were the following: etiology [p = 0.0029; symptomatic or with unknown etiology focal vs. symptomatic or with unknown etiology generalized epilepsy, odds ratio (OR) (95% CI): 2.7 (1.5–4.8); genetic generalized vs. symptomatic or with unknown etiology generalized, OR (95% CI): 2.2 (1.2–4.1)], number of seizures [p = 0.0004; 2–5 vs. 1, OR (95% CI): 1.8 (1.1–2.8); >5 vs. 1, OR (95% CI): 3.5 (1.7–6.9)] and concomitant psychiatric disease [(p = 0.0151; OR (95% CI): 1.8 (1.1–3.0)] (Table 3).

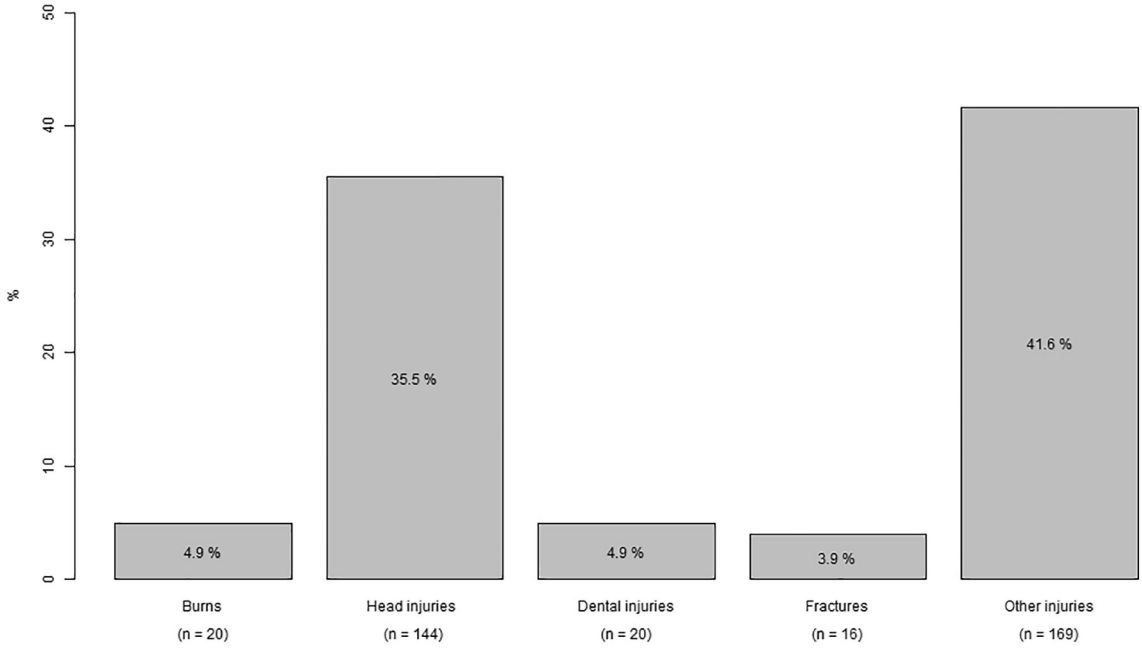

Fig. 1. Incidence of accidental injuries associated with generalized tonic–clonic seizures. Type of accidental injury.

Table 3
Multivariate logistic regression analysis identifying factors associated with a higher probability of injury.

	OR 95% CI	p-Value
Specific diagnosis		0.0029
Symptomatic/unknown focal vs. symptomatic/unknown gen.	2.70 (1.51, 4.84)	0.0008
Focal vs. genetic gen.	1.20 (0.76, 1.92)	0.4347
Genetic gen. vs. symptomatic/unknown gen.	2.24 (1.24, 4.07)	0.0077
Number of generalized tonic–clonic seizures during the last 12 months		0.0004
2–5 vs. 1	1.79 (1.14, 2.80)	0.0115
>5 vs. 1	3.47 (1.74, 6.92)	0.0004
>5 vs. 2–5	1.95 (0.98, 3.87)	0.0580
Psychiatric disease		0.0151
Yes vs. no	1.83 (1.11, 2.99)	

95% CI: 95% confidence interval; gen. generalized; OR, odds ratio.

Patients with injuries had a worse quality of life, according to the total score of the QOLIE-10 questionnaire ($p = 0.0003$) and the questionnaire domains: epilepsy effect ($p = 0.0053$), mental health ($p = 0.0008$), and role functioning ($p = 0.0006$) (Table 4).

4. Discussion

The risk of injury due to epileptic seizures is a significant concern among patients with epilepsy and their families, having limitations when driving and performing certain sports or activities, and also in their work, reducing their independence, social life, and quality of life [8,14].

It has been shown that among the different epileptic seizures, the risk of injury is greater for generalized seizures (including tonic–clonic, atonic, absences, and myoclonic seizures), which are not preceded by an aura [8].

This study evaluated the incidence of accidental injuries in 406 patients with epilepsy and generalized tonic–clonic seizures who attended neurology clinics in a routine clinical practice setting in Spain.

Our study population was limited to patients with tonic–clonic seizures attending specialist neurology clinics. These patients, if not properly treated, present a greater probability of complications and comorbidities [15,16].

In our study, the incidence of accidental injuries associated with tonic–clonic seizures over the last 12 months was 59.6%, a much higher percentage than the estimated incidence of injuries in the general population in Spain, which has an estimated risk of domestic accidents of 2.6% in adults (https://www.msssi.gob.es/estadEstudios) and 7.68% in the population under the age of 15 years [17]. This incidence is somewhat higher than that reported in other studies of patients with epilepsy and different types of seizures, which estimated an incidence of 24%–45% in the past 12 months [8,18]. This can be probably explained by the inclusion of patients with only generalized tonic–clonic seizures in their study.

Table 4
Relationship between injury and quality-of-life questionnaire (QOLIE-10).

	n	Mean (SD)	Min, Max	Missing	p-Value
Overall score					0.0003
With injuries	239	64.3 (20.7)	8, 98	3	
Without injuries	162	71.5 (17.2)	15, 100	2	
Epilepsy effect					0.0053
With injuries	241	67.9 (24.9)	0, 100	1	
Without injuries	164	74.6 (21.4)	8, 100	0	
Mental health					0.0008
With injuries	242	57.2 (22.5)	0, 100	0	
Without injuries	162	64.6 (20.4)	8, 100	2	
Role functioning					0.0006
With injuries	240	66.7 (23.4)	0, 100	2	
Without injuries	164	74.5 (20.8)	6, 100	0	

Max: maximum, Min: minimum; SD: standard deviation.

These results are in line with previous studies, which have shown that most injuries occur in the home after a fall due to a generalized tonic–clonic seizure [10], and that tonic–clonic seizures, both generalized and secondarily generalized, are associated with a high risk of injury [11]. It has also been observed that the presence of aura and a seizure-free interval of 12 months or more reduce the likelihood of injury [2].

In a recent cross-sectional study in 409 patients with epilepsy, the global prevalence of injuries associated with epileptic seizures was 27.9%, the most frequent being abrasions (12.5%), burns (5.9%), dental injuries (4.4%), fractures (2.2%), and head injuries and dislocations (1.5%) [6].

The injuries most frequently described in our study were head injuries, dental injuries, burns, and fractures, and 25% of patients suffered serious injuries. The predominant types of injuries can vary among studies, being head injuries [11,12] and fractures [4,18] the most frequently reported in recent studies. In our study, head injuries, including serious injuries such as bruising or concussions, were the most frequent (35.5% of patients).

The incidence of burns (4.9%) was similar to that described in patients with epilepsy in other series (6.9%) and higher than estimated in the general population (3.9%) [18]. It has been reported that the majority of burns in patients with epilepsy occur during everyday activities in the home, such as cooking, ironing, drying hair, or taking a bath [18,19]. The risk factors for burns in patients with epilepsy have been identified as female sex, advanced age, greater number of seizures, neurological impairment, generalized tonic–clonic seizures, and severity and frequency of seizures [8].

In our study, the factors associated with a higher probability of injury included etiology (focal vs. nonidiopathic generalized; genetic generalized vs. symptomatic or with unknown etiology generalized), number of seizures, and psychiatric comorbidity.

In general, in some studies, the severity of the disease is associated with an increased risk of accidental injuries, in line with the factors described in the literature: polytherapy (as a marker of greater severity), drug-resistant epilepsy, etiology, frequency of seizures and generalized tonic–clonic seizures, disease duration of more than 2–3 years, frequency of pharmacological treatment, type of employment, and cognitive impairment [6,8,12,14].

In the case of the specific diagnosis, in our study, the highest probability of injury was not always correlated with the supposed severity of the disease, perhaps suggesting that patients with more severe disease lead a more sedentary life and are less exposed to the most common injuries.

Psychiatric comorbidities are estimated to affect 32–41% of patients with epilepsy [20], primarily depression, anxiety disorders, and psychosis. As already described, the combination of epilepsy and the psychiatric comorbidity appears to have a supra-additive effect on the risk of injuries, exposing patients to a greater risk of accidental injury [4].

In fact, evidences support an association between mental illnesses and an increased risk of injuries, particularly fractures. The neuropathological changes in the brain of patients with these disorders can influence the balance and gait coordination while low bone mineral density and the use of psychotropic drugs, such as antidepressants, have also a role [21,22].

Finally, this study has also shown that patients who experienced injuries had reduced quality of life, compared with patients without injuries. Similar observations have previously been made in patients with epilepsy and any type of seizure [23].

Given the high prevalence of injuries associated with epileptic seizures and their negative impact on patients, as previously reported by other authors [6], strategies are needed to prevent injuries, especially in those patients whose seizure rate remains uncontrolled over long periods of time. In these patients, it is essential to manage seizures with

the optimal antiepileptic therapy and to implement recommendations from health professionals on how to avoid situations of greater risk of injury [12].

A recent study of 2130 patients with epilepsy and 16,992 controls found that the risk of injury was greater in the 2 years after diagnosis and thus, concluded that it is very important to promptly inform patients with newly diagnosed epilepsy on the prevention of accidental injuries [4]. To this aim, information about the activities that patients were doing at the moment of the injury would be necessary to implement possible prevention strategies. We consider that this issue would deserve further studies.

Moreover, a recent survey of patients with epilepsy and their families and caregivers revealed a considerable discrepancy between the information offered by health professionals and the information that patients would like to receive [3].

Regarding the most commonly used antiepileptic drugs, we should note the high percentage of patients treated with perampanel. This drug was approved in Spain in the previous months of our study as a useful drug in add-on therapy in patients with focal seizures, focal with bilateral tonic–clonic seizures, and primary tonic–clonic seizures. For this reason, there was such a great proportion of patients treated with perampanel.

One of the particular strengths of this study is that we recruited a sizeable sample of patients with well-defined epilepsy, specifically tonic–clonic seizures that carry a greater risk of injury, in a clinical practice setting. We believe that, given the importance of the consequences of accidental injuries in these patients, further studies are needed to assess the impact of a treatment strategy to achieve control of seizures and to analyze the effect of providing appropriate information on avoidable risks.

5. Conclusions

Accidental injuries are frequent in patients with generalized tonic–clonic seizures (reported incidence of 59.6%), being head injuries the most commonly reported (35.5%).

Symptomatic or with unknown etiology focal and genetic generalized epilepsy, occurrence of >1 seizure in the last year, and psychiatric comorbidity are associated with suffering accidental injuries in patients with tonic–clonic seizures, resulting in a significant worse quality of life.

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Competing interest statement

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