# Epilepsy and driving in Belgium : proposals and justification

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On behalf of the "Belgian Working Group on Epilepsy and Driving" (\*), an advisory board, consisting of : the neurologist members of the "Committee for Epilepsy and Risk" of the Belgian League against Epilepsy ; the members of the "Commission on Driving and Neurological Disease" of the "Vlaamse Vereniging voor Zenuwartsen" and of the "Circle of Epilepsy", a panel of Belgian epileptologists

### Abstract

Proposals about the regulations and medical criteria concerning epilepsy and driving, originally drawn up by the Commission on Epilepsy and Risk from the Belgian League against Epilepsy were discussed and amended by a panel of representatives of several scientific societies and of all Belgian universities in order to establish a broad consensus among Belgian epileptologists. The history of driving licencing in Belgium is discussed and some background information given to put the regulations in perspective. A proposal is made for an acceptable level of risk. Subsequently, a quantification of risk for different situations concerning seizures is attempted. The proposals will be discussed and some further practical advice given. Individual assessment of the ability to drive remains indispensable.

*Key words* : Epilepsy ; seizures ; driving regulations ; driving ; consensus ; legal ; licensing ; review.

### Introduction

The prevalence of active epilepsy in the adult population is 4 to 10 in 1000 people (Hauser et al. 1996; Goodridge et al. 1983). In Belgium this figure is not significantly different (Boon et al. 1996). A considerable number of these patients hold a driving licence (Sonnen 1995). In Belgium, driving is one of the top concerns of people with epilepsy, as is noticeable in the daily practice of any neurologist. In surveys, driving is listed as a first or second concern by people with epilepsy, after the wish to be seizure-free (Gilliam et al. 1997; Taylor et al. 2001; Fisher et al. 2000). On the other hand, driving whilst having active epilepsy clearly poses an increased risk (Krauss et al. 1999; Berg et al. 2000). This makes the topic of "epilepsy and driving" of importance to neurologists and the regulators of driving licensing alike, as a way to reduce, as far as that is reasonable, one of the major disabilities associated with epilepsy. In the period that the Belgian law required a 2-year period of seizurefreedom, even after a first epileptic seizure, a group of neurologists estimated that 70% of their epilepsy patients who were not allowed to drive still did

so (Schmedding 1996). There are reasons to think that by making the law more liberal, more people will adhere to it (Sonnen 1997).

More liberal rules may persuade people with seizures to undergo an assessment and stick to the rules for several reasons :

- they may accept the rules as reasonable
- they have the perspective of getting their licence back
- they feel relieved of the responsibility and the uneasiness of doing something that may endanger other people, including their relatives.

A recommendation of the First European Working Group on Epilepsy and Driving states : rules must be as liberal as possible, simple and clear (Sonnen 1997).

They should also be based on calculated risk.

### HISTORICAL BACKGROUND

In the European Union, the regulations about driving licensing used to differ greatly among member states (Fisher et al 1994). At the request of their respective governments, this led to the formation of European workshops on driving licence regulations in May 1995 and March 1996 organised by the International League against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE)

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European Council Directive 91 of 29 July 1991 on driving lice <i>Official Journal L 237</i> , 24/08/2	1/439/EEC onses 1991
Group I	Group II
12.1. A licence may be issued or renewed subject to an	12.2. Driving licences shall not be issued to or renewed
examination by a competent	for applicants or drivers suf-
medical authority and to reg-	fering or liable to suffer from
ular medical check-ups. The	epileptic seizures or other
authority shall decide on the	sudden disturbances of the

state of the epilepsy or other state of consciousness.

disturbances of conscious-

ness, its clinical form and

progress (no seizure in the

last two years, for example), the treatment received and the results thereof. (Sonnen 1995 and 1997). The recommendations of these workshops were not reflected in a European guideline. In these recommendations, as well as in an American consensus statement, control or remission of seizures, measured as the "seizure-

free interval" is the main determinant in the assessment of the ability to drive (Sonnen 1997, Krumholz 1994).

European member states have to stay within a Council directive : they can be more restrictive, but not more liberal (Table 1 : see references).

Following the European workshops, Belgian criteria were revised by a commission of the Belgian League against Epilepsy, leading to an important change in the Belgian law, published on the 30th of April 1998. Some minor changes followed on the 25th of September 2002. Unfortunately, in the regulations for group 2, major changes remained necessary, which, amongst other things, motivate the proposals described here.

It has to be stressed that rigorous scientific proof is absent for many of the decisions that have to be taken with regard to epilepsy and driving. In such cases, the best available evidence and reasonable estimates are used.

### LEGAL ISSUES

The members of the Belgian working group on epilepsy and driving were of the opinion that the final assessment of driving ability should be made by an independent doctor, not by any treating physician. There should be legal protection from liability for the assessing physician. It is preferred that the criteria should appear in guidelines rather than in the law.

The treating physician is not obliged to report the patient to the authorities in Belgium and there was unanimous agreement with this situation. There is however the possibility to report if the physician considers the situation exceptionally dangerous. The European guideline states : "A doctor should only notify the authorities without permission of the patient in case of imminent danger to the public, where the patient refuses to inform the authorities". In those cases there should be legal immunity. These positions are in agreement with a consensus statement of the American Academy of Neurology, the American Epilepsy Society and the Epilepsy Foundation of America (AAN et al. 1994). The working group recognises the obligation to inform the patient about an eventual driving inability and about his legal duties but is of the opinion that this obligation should be part of medical deontology, not of the law.

### THE IMPACT OF EPILEPSY ON GENERAL ROAD SAFETY

What is the impact of epilepsy on road safety? To establish this, several approaches are possible.

One of them is a comparison of accident rates while applying different medical criteria. In a recent study, the rate of seizure-related crashes in one American State did not significantly increase after the necessary seizure-free interval required after having had multiple seizures was reduced from 12 to 3 months. Seizure-related crashes constituted 31% of all motor vehicle crashes due to medical causes in the same period (Drazkowski et al. 2003).

Another approach is to try and calculate the possible impact of epilepsy on road safety.

If one looks at the increase of risk for the population at large, epilepsy-related accidents constitute a small minority :

- Only one in 250 hospital admissions because of an accident has an associated medical factor. Of these, 37% were caused by epilepsy in the study by Taylor (Taylor et al. 1995). This amounts to one in 675 hospital admissions.
- Epilepsy-related accidents constitute an estimated 0.25% of all traffic accidents (Parsonage 1992). This is 1 in 400 accidents.
- Only 11% of all accidents among individuals identified with epilepsy are reported as being due to seizures. (Krumholz A et al. 1991)

# So the numbers are low, but are they increased in people with epilepsy?

The First European Working Group accepted an accident ratio of 1.33% in people with epilepsy compared to the general public, as a mean of 12 studies (median 1.25; range 0.5 to 2.56). If 1 in 200 drivers are epileptic, the chance that 200 people with an accident would have a seizure-related accident is 0.33%. So if all accidents are taken into account 0.17% are seizure-related. This is roughly in accordance with the above-mentioned 0.25%. Not all patients in these studies were driving within the regulations, so the actual rate might be lower (Sonnen 1997).

In a recent UK study, 16 958 drivers with a previous history of epilepsy (but at least one year seizure-free) responded to a self-completion questionnaire and were compared to 8 888 non-epileptic drivers. (Taylor *et al.* 1996). No overall increase in risk of accidents for drivers with epilepsy who drove legally was found in this very large sample.

# Do seizure-related accidents caused by persons with epilepsy more often lead to serious injury ?

There is uncertainty about this. In a Danish study (Lings 2001), the number of epilepsy patients treated at the casualty department was seven times higher compared to a control group (CI 2.18 to 26.13). However, the authors stated about their study : "the numbers are too small for meaningful statistical analysis".

In the UK study, the number of accidents was not increased in people with epilepsy with a valid driving licence, but there were twice the expected number of fatalities. These data were somewhat uncertain because of the methodology used : they could not calculate a relative risk, because there were no fatalities in the control group (Taylor *et al.* 1996). The same UK study found an increase in the chance of a serious accident of 40% (OR : 1.37 CI : 1.02-1.84).

Sonnen (1997) summarises four older studies and concludes that the question of increased severity is unsolved.

Some other statistics put the importance of the regulations about epilepsy and driving into perspective :

- The number of alcohol-related accidents is 30 times higher than that of epilepsy-related accidents (Egli *et al.* 1977).
- First seizures (unavoidable) constitute on average 15% (Sonnen 1995) of seizure-related accidents.

A European internet site gives data about traffic accidents for the year 2000 : 12,956,000 road accidents and 40,812 deaths. The fatalities represent 0,32% of all road traffic accidents and 2.12% of all injured persons. In addition, about 14% of all injuries are considered serious : 9,847 of 69,435 people with an injury caused by an accident in Belgium in 2000 (European internet site ; Assuralia internet site). The contribution of epilepsy to these figures is not known.

If people with epilepsy adhere to the rules, the risk for the general public seems low. Exact numbers are either lacking or unconvincing. It should not be forgotten that the patient himself runs the greatest risk !

# Less quantifiable factors in assessing the ability to drive

The 1995 and 1996 European workshops recommended the period of seizure-freedom as the most important criterion for assessment of the ability to drive and the following is an attempt at quantification thereof. However, it is by no means the only factor to take into consideration. Many of the other factors are not quantifiable, which makes a personal assessment indispensable. However, care should be taken not to use factors that would not be considered in people without epilepsy !

A number of favourable and unfavourable riskmodifiers are described in the literature (Table 2).

Table 2

Unfavourable modifiers		
_ _ _ _	Non-compliance with medication or medical visits and /or lack of credibility Alcohol and/or drug abuse in the past 3 months Structural brain lesion Non-correctable brain functional or metabolic condition Periods of frequent seizures after seizure-free interval	
– Fa	severity of the seizure (e.g. : complex partial seizures) vourable modifiers	
_ _ _	Provoked seizures (if avoidable) Seizures during medically directed medication changes Seizures that do not interfere with consciousness or motor control Established pattern of pure nocturnal seizures.	

For all of the favourable modifiers mentioned in the table, there are already specific articles formulated in the medical criteria for driving licensing in Belgium. Some others, mentioned in the American consensus statement (AAN *et al.* 1994) or by Beaussart (Beaussart 1994), were not considered suitable to be translated into a legal article. Seizures after sleep deprivation are not considered avoidable in most instances. Prolonged and consistent auras have been proven not to be safe enough (Krauss *et al.* 1999).

According to Belgian law, any person who has a "functional disability" (e.g. motor, cognitive) has to be evaluated by a neurologist, but he also has to be tested by the Belgian Institute for Traffic Safety (BIVV-IBSR<sup>1</sup>), which takes the final decision about ability to drive in those cases. These co-morbid conditions are not specific for epilepsy and will not be dealt with in this text.

Similarly there is a general legal obligation of the treating physician to judge the impact of drugs

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on the patient. A study of The Toxicological Society of Belgium and Luxemburg has classified most drugs according to their presumed potential to influence driving ability (The Toxicological Society of Belgium and Luxemburg 1999). Few data exist on the effect of antiepileptic drugs on driving. A U.K. survey did not find an increased rate for any kind of accident (general or severe) in patients taking antiepileptic drugs compared to the general population (Odds ratio : 0.97 CI : 0.87-1.07) (Taylor 1996).

# A quantifiable factor : the period of seizure freedom

"No risk" does not exist. What is : "acceptable risk" ? One percent increase in accident rate seems reasonable for group I

Every driver has a risk of an accident. With the concept of "acceptable risk" one means the additional risk on top of the risk of an accident taken by the general population of drivers.

Data from The Netherlands (Sonnen 1997) show a 10% average risk of an accident per year per person with vehicle insurance (some minor accidents might not come to the attention of the insurance, but they are likely to be of no importance for safety). In the large UK study of Taylor (Taylor *et al.* 1996) it was about 7%. Data from the literature vary between 5.7% and 12% with an average of 10% (Sonnen 1995).

If one looks at the factors, that contribute to this percentage, there are important variations, even for variables that can not be influenced at all according to data from The Netherlands (Sonnen 1995) :

- The accident rate, particularly in the younger age group, is 15% higher in men.
- The maximum deviation from the average value of fatal accidents for days of the week is 36%
- The maximum deviation of the average value of fatal accidents between regions is 60%
- Below the age of 24 years, the accident rate is 525% (own party) and 400% (other party) higher than the accident rate between ages of 50 to 64.

Very similar data can be found for Belgium in 2001 on an internet site of the Traffic Bureau (BIVV internet site)

The suggestion of the European workgroup was to take a 10% increase on top of the average of 10% accidents per year as an acceptable risk, which is an increase of 1%. Clearly this is a very small increase in risk compared to the above-mentioned variables – be it one-sided instead of two-sided.

In the assessment of the ability to drive, different criteria are used for private and professional driving (respectively called group 1 and group 2).

Aproximate deviation of the average of variables in the occurrence of accidents and a proposal for acceptable risk for people with epilepsy



For group 1, a 10% increase of the average risk of an accident for the population was proposed. This population average is 10% per year, so the resulting increase in risk is 1% ( $10\% \times 10\%$ ).

# THE MEASURING STANDARD : THE "COSY" AND THE RELATION WITH THE PROBABILITY OF CAUSING AN ACCIDENT

Whether somebody will experience a seizure in the (near) future is not a yes-no decision, but a weighing of odds. If the law asks a doctor to decide if a patient is able to drive, this question ideally is to be translated into a percentage of chance that the patient will experience a seizure in the defined period (month or year) following that decision. If the chance of a seizure in the next year is known, we can estimate the chance of a seizure behind the wheel and, most importantly, the chance of an accident in the next year. These three factors determine the chance of an accident :

- 1. the time spent behind the wheel
- 2. the percentage of seizures behind the wheel that will lead to an accident.
- the COSY : the Chance of an Occurrence of a Seizure in the next Year relative to a specific moment in time (in general the last seizure)

Assuming that the chance of a seizure is equally spread over 24 hours, the chance of a seizure behind the wheel is a function of the time spent behind the wheel. (Note : according to Janz (1969), 50% of seizures occur during the 8 hours of sleep, which would lower the percentage during the "driving hours" !).

It is estimated that an average person with a driving licence spends 3% of his lifetime behind the wheel (nearly 45 minutes per day : this includes weekends, holidays etc). This means that only 1 in 33 seizures will occur behind the wheel (Sonnen 1997. This number is in accordance with a Dutch figure that states that a driver covers an average

number of 17,000 km per year. When one drives an average of 70 km/h, the daily time at the wheel would be 40 minutes (2.8% of 24 hours). Taylor (Taylor 1995) found a smaller total number of kilometres in Britain : about 10,000 km (6000 miles). For Belgium, this figure was 15.000 km per year in 2001 (BIVV internet site).

If we accept that driving time is 3% and the COSY is 60%, this reduces the chance of a seizure behind the wheel to  $60 \times 3\% = 1.8\%$ .

An average of 5 studies shows that about half the seizures behind the wheel result in an accident (Sonnen 1995). Including the study of Berg (Berg *et al.* 2000) in this calculation, the figure becomes 55.7%. This last study was done in a group of patients with refractory complex partial seizures who drove illegally and almost certainly overestimates the percentage for the epileptic population at large, as most seizure related accidents involve patients with complex partial seizures (Krämer in Sonnen 1995).

If we accept 50% as a reasonable estimate of the percentage of chance that a seizure behind the wheel causes an accident, then for a person with a 60% COSY, the chance of an accident during this year would be further reduced to 0.9% ! This is the risk in addition to the accident-risk in the population at large.

### What about group 2?

There are two sets of criteria for medical assessment. Group 1 refers to non-commercial driving and group 2 to commercial (professional) driving. The medical assessment for group 2 in Belgium is also applicable to the transport of people in a broader sense. Notably : taxi drivers ; rental services with driver ; public transport ; drivers for school transport ; transport of people if this is organised and run by the employer.

For every bus driver who dies in an accident, 4 passengers die. For lorries the rate is inverse : 3 to 1 (Assuralia internet site). The European workgroup recognised the differences in risk for the respective categories of vehicles for which a group 2 assessment is required, but, "for the sake of simplicity", the same rate for all was put forward.

A professional driver typically spends up to 8 hours per working day behind the wheel, which is 20% of his lifetime - six to seven times more than a group 1 driver.

The European workshop of 1996 accepted an arbitrary factor of 5 for the severity of an accident if caused by a heavy-goods vehicle compared to a private car (Sonnen in : Commission on Epilepsy, Risks and Insurance of the IBE 1994).

From these approximations, it was taken that one would have to be 30 times more strict in the assessment for group 2. This results in an acceptable chance of a seizure in the next year of 2% (60% / 30).

This same percentage is used in the American consensus statement and in the official Australian Guidelines (AAN *et al.*1994; Austroads Incorporated 2003).

### What if we take a worse case scenario?

If you would accept an accident rate of 60% per seizure behind the wheel (instead of 50%) and one hour of driving time per day (instead of 45 minutes) the calculation is as follows :

1% (allowed increase) times 1.67 (100/60) times 24 (one hour is 1/24th of the day) = 40%

For Group II, the percentage would become 1.6% (the ratio of driving time compared to group 1 changes, so 30 times more strict becomes 25 times). It has to be remembered though that the thirty-times-more-strict rule proposed by the European Commission was a rough approximation. Also, it was for convenience sake adopted for all drivers in group 2, although the increase in risk for taxis and minivans was calculated as being about 10 times increased, not 30 times !

When does a patient reach this "acceptable risk"-threshold : The influence of the seizurefree interval in different situations.

It is common experience that with an increase in the duration of the seizure-free interval, the chance of recurrence decreases. How this chance changes over time is of critical importance in the determination of the required seizure-free intervals in different situations. In the following, we try to describe two relevant parameters for the different situations :

- 1. The total chance of a recurrence.
- 2. The course of this chance over time.

### First non-provoked epileptic seizure

The first question is to determine what would be the recurrence rate after a first seizure. For this reason, we collected 13 studies which provided data about the recurrence in the first one-to-five years after the event and we arranged them according to the percentage of patients treated in the study (Elwes et al. 1985; Stroink et al. 1998; FIRST 1993; Shinnar et al. 2000; Shinnar et al. 1996; Hopkins et al. 1988 ; Hart et al. 1990 ; Sander et al. 1990; Van Donselaar et al. 1991; Hirtz et al. 1984 ; Camfield et al. 1989 ; Annegers et al. 1986 ; Camfield et al. 1985; Hauser et al. 1990). One study was split into a treated and an untreated group and processed as if they were two different studies (FIRST 1993). This gave an impression of the overall recurrence rate, which was on average 46.2%. Weighing the average made little difference. Many neurologists do not treat patients after a first seizure, so the more important percentage is

the average recurrence of the three studies (Elwes *et al.* R 1985; Stroink *et al.* 1998; FIRST 1993) in which patients were not treated, which was 55,5%. Out of the seven studies in which no more than 15% of the patients were treated, the average recurrence rate was 49%. In contrast, out of the two studies with at least 80% treated patients, recurrence rate was 33,1%. These figures are in keeping with the observation that the recurrence rate in treated patients is roughly 50% lower in accordance with the findings of the FIRST study.

From this, a reasonable estimate of the recurrence rate after a first seizure in untreated patients would be 55%, in treated patients 33%.

In the meta-analysis of Berg (Berg *et al.* 1991), the average percentage recurrence risk in carefully selected studies was 42% (treated and untreated patients). In an overview of the literature, Beghi (Beghi *et al.* 1998) finds a range of 25-52% with an average of 38% (Table 3).

The second question is how the a priori recurrence rate will change over time *in the group where* there were recurrences. We found eight studies with a follow-up of longer than 2 years (in : Berg et al 1991; and : Hart et al. 1990; Sander et al. 1990) and two studies providing data about recurrences in the first 3 months and 6 months after a first seizure (leaving the Hirtz study out, because it provides data about very young children) (FIRST 1993; Annegers et al. 1986). Berg in their meta-analysis calculated the percentage recurrence risk after two years as a percentage of the total risk after 4 years in the studies which provided data over a longer period and found an average of 87% (Berg et al. 1991). We recalculated these data with the addition of later studies (Hart et al. 1990; Shinnar et al. 2000; Hui et al. 2000) and found a very similar number : 86.5% after 2 years. A recurrence risk in the 3rd, 4th and 5th year after a first seizure can be estimated from their data : resp. 8%, 5% and 4%.

### What happens in the first year ?

All studies provided data about the recurrence rate in the first 2 years. For that reason, the calculations of the data from the two studies that provided percentages about 3 and 6 months after the first seizure were recalculated assuming a fixed recur-

	Та	ble 3				
Total	recurrence	after	a	first	seizu	re.

Average of several studies

Author	Percentage
Beghi	38%
Berg	42%
Our compilation	46%
No treatment (3 studies)	55%
Treated (2 studies)	33%

rence-percentage of 87% after 2 years. The percentage recurrence after 3 months was 32%; after 6 months it was 53% and after one year 68%. These percentages are put together to get an approximate curve of recurrence over time (Fig. 3).

# What happens after five years ?

There are few data about the recurrence risk after 5 years These seem to suggest a yearly recurrence of approximately 2% (Boulloche *et al.* 1989; Hauser *et al.* 1990 and Shinnar *et al.* 2000). Confidence intervals for these data are not published but will increase when follow-up is longer, because of decreasing sample size.

Annegers (Annegers *et al.* 1986) states that the recurrence risk fell after 4 years of seizure-freedom to < 5% in the fifth year. He mentions 7 recurrences among 117 subjects who were seizure-free for > 5 years (6%) without stating the time period in which these recurrences occurred.

### The first "idiopathic" seizure

An exceptionally low total recurrence risk was found by Van Donselaar (Van Donselaar et al. 1992) after a first unprovoked idiopathic seizure (10% in the first year C.I. 2-18%; 12% in the first 2 years C.I. 3-21%). Here, "idiopathic" means : without any apparent cause. This is : normal neurological examination ; normal CT scan ; no abnormalities on a standard EEG and an EEG after (partial) sleep deprivation. Similar percentages for the idiopathic group have been published by Berg, Hauser and Annegers (Berg et al. 1991; Hauser et al.1990; Annegers et al. 1986) (after 2 years respectively 24% [C.I. 19-29%], 21% and 22%). For the calculations below (Fig. 4), we used 25% total risk over 4 years (about 22% in the first 2 years).

### Two, three or more seizures

Hauser (Hauser *et al.* 1998) provides data of the total recurrence after 2 or 3 seizures. After 2 seizures, 73% relapsed in an observation period of 4 years; after 3 seizures, 76% in an observation period of 3 years. Out of the patients that have a

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Recurrence risk as a percentage of the total recurrence over the observation period			
	After a n	umber of s	seizures
	1	2	3 or more
After the first 3 months At 6 months At 12 months At 24 months	32 56 68 87	44% 56% 78% 83,5%	41% 63% 80% 88%



FIG. 2. — Five year recurrence rate by percentage of treated patients

Author	Percentage of treated patients in the study
Elwes 1985	0
Stroink 1998	0
FIRST 1993 untreated	0
Shinnar 2000 / 96	14
Hopkins 1998	15
NGPSE 1990	15
Van Donselaar 1991	15
Hirtz 1984 non-provoked	27
Camfield 1989	30
Annegers 1986	61
Camfield 1985	68
Hauser 1990 / 82	80
FIRST 1993 treated	80
Average % recurrence	

Legend of figure 2

relapse, most - about 60% - will do so in the first 6 months (Table 4). In the table recurrence risk is given as a percentage of the total recurrence over the observation period, so the above mentioned



FIG. 3. — When does recurrence take place if it occurs after a first seizure ?

73% and 76% would be expressed as 100% in this table.



FIG. 4. — Remaining percentage recurrence risk for six different situations at 4 seizure-free intervals (S = seizures).

# THE REMAINING RISK OF RECURRENCE AFTER A DEFINED SEIZURE-FREE PERIOD.

The product of these two figures, namely a) the total chance of recurrence in a certain situation and b) the percentage that relapses in a given period, gives an estimate of the remaining risk of a seizure after having attained a certain seizure-free period. In Figure 4, the result of such a calculation is shown for different situations : assuming 95% recurrence risk after several seizures (and applying the recurrence curve that was found after 3 seizures : Table 4); for Hauser's data after 3 seizures; and for four situations after a first seizure : an untreated group, a treated group, the average found by Berg and an "idiopathic" group. For these four first seizure groups, the data from the recurrence curve as shown above (Fig. 3) are used. The recurrence curves for more than one seizure are somewhat steeper than the one after the first seizure. From Figure 4, one could deduce that an acceptable risk level (e.g. the 40% mentioned above as a worse case scenario) after one seizure is reached at 3 months and after more seizures at 6 months. Critics will point to the fact that the data have not been reproduced and that the confidence intervals are unknown. It seems, however, likely that we will have to live with these uncertainties in the forseeable future. Decisions will have to be made on available evidence even if the evidence is not ideally suited.

It might be worth noting that 39 of 51 states of the USA regulations require seizure-free periods of 6 months or less, or have flexible restrictions in the case of epilepsy (Krauss G *et al.* 2001; Krauss G 2002).

### LIMITED LICENCE

If one accepts the concept that the risk is linked to time spent behind the wheel, restricting the time or distance driven will decrease the risk. This can be an important alternative for people who are responsible enough and who cannot reach their work by other means of transport or in similar situations.

Motorcycle drivers are likely to have an accident with every seizure while driving (not just a 50% or 60% risk). Here the risk increases accordingly. Belgian traffic statistics of 2001 support this : the number of serious accidents is 2.6 times higher per owner of a motorcycle compared to owners of cars (BIVV internet site).

The medical criteria as proposed by the Belgian Working Group on Epilepsy and Driving

### First unprovoked seizure

For the above-mentioned reasons, 3-6 months of seizure-freedom is advised and will lower recur-

rence risk under 20%. If there are epileptiform discharges on the EEG, 6 months seems mandatory. The period of 5 years seizure-freedom for group 2 seems acceptable (Fig 2), although confidence intervals are not known.

A note of caution : in using statistics for recurrence after a first seizure it is presumed that it really was the first one. If more than one seizure has occured other statistics apply that are less favourable. More than 50% of patients that first come to a neurologist will have had more than one seizure !

### First provoked seizure

While the above refers to unprovoked seizures, the situation after provoked seizures is much more complex because of the diversity of causes. The cause has to be *explanatory and avoidable* for a seizure to qualify for a different more lenient judgement. Metabolic disturbances, seizures provoked by medication, stroke, trauma and infection can be considered in the latter case. There is doubt about the avoidability of alcohol in many cases.

For group 2, an arbitrary safety period of two years was adopted. The recurrence risk after early post-traumatic seizures is 25-60% according to Jennett (Jennett 1975). Late seizures occur in 50% - 60% in the first year; 85% in the first 2 years (Caveness 1979). After the first late seizure, the recurrence risk is 86% in 2 years (Haltiner et al. 1997). Sasic et al. (2002) found a total recurrence risk after "cerebritis" (meaning viral or bacterial encephalitis) of 57%. Hauser et al.(1990) point out that after early seizures in this situation, the chance of recurrence remains high for 5 to 10 years ! These two causes were excluded as acceptable provoking factors for drivers of group II. We might consider driving under group 2 criteria after serious traumatic cerebral injury only if the following requirements have been fulfilled :

- no early seizures
- after individual assessment of the seriousness of the trauma
- after a seizure-free period of 2 years

Cranial trauma is considered serious if there is a contusion, an intracerebral hematoma or a post-traumatic amnesia of more than 24 hours (Annegers 1980).

These patients should all be tested by the driving authority (BIVV-IBSR). Very often they have psychological or cognitive alterations, which are misjudged by themselves and their physician (Hawley 2001).

Other causes that are not considered sufficiently avoidable in general are : misuse of alcohol and alcohol withdrawal ; drugs ; fever ; sleep deprivation, sleep and arousal ; stress ; reflex causes for seizures.

#### E. SCHMEDDING

Table	5
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Proposed Belgian criteria for group 1

Proposed criteria for group 1 (non-commercial)			
Clinical situation	Advise : able to drive after		
First seizure			
<ul> <li>Provoked seizure because of a recognisable and explanatory and avoidable provoking factor</li> <li>Unprovoked seizure</li> <li>Unprovoked seizure, neurological examination and neuroimaging are normal and there are no epileptiform abnormalities on the EEG</li> </ul>	3 months of seizure- freedom 6 months of seizure- freedom 3 months of seizure- freedom		
Epilepsy			
<ul> <li>Multiple seizures</li> <li>Special situations</li> <li>No seizures after 16th birthday ; no treatment since then ; no cerebral pathology</li> <li>Sporadic seizures : the interval between the last and the penultimate seizure is more than two years.</li> <li>Seizures without influence on consciousness or ability to act and without ever having had any other kind of seizure</li> <li>Seizures exclusively during sleep</li> <li>Year of seizure- free</li> <li>Able to drive ; unlimi</li> <li>As first seizure</li> <li>3 months of this situation</li> </ul>			
Therapy			
<ul> <li>Seizures because of change or reduction of AE therapy</li> <li>After curative epilepsy surgery</li> </ul>	3 months of seizure- freedom 6 months of seizure- freedom		

### Seizures occuring exclusively in sleep

In the law of the 25th of September 2002, the phrase "only driving during the day is permitted" was added. There are to our knowledge no data in the literature to support this nor are there any logical reasons. It was recommended that this phrase should be omitted.

In the literature, few data are available on this specific situation. An older study found 4 patients out of 34 that developed awake seizures but only if the duration of the epilepsy had been less than 2 years (D'Alessandro 1983).

More recently, a difference in recurrence of awake seizures was found : secondary generalised epilepsy has a much higher recurrence risk than primary generalised. For the latter situation, one year without awake seizures could be considered (Park 1998). Differentiation between the two conditions seems difficult. It is important that the diagnosis is firmly established. The commission decided that after a period of 2 years without awake seizures a driving licence can be granted.

### Seizures without influence on driving ability

Some seizures are not considered to be of influence on driving ability, mainly some myoclonias and simple partial seizures. Evidence about the (non-) harmfulness of these is lacking. In the first European Committee, there was no consensus about this. In the experience of the authors this situation is rare. The consensus is that this situation

should exist for at least 3 months and that no other type of seizure should ever have occured.

### **Sporadic seizures : oligo-epilepsy**

Some people only have rare seizures. If this has been the case for some time, the calculated total recurrence risk is low (50% for an interval of 2 years ; 33.3% for 3 years etc.) In accordance with the recommendation of the European workshop (Sonnen 1997) these cases can be assessed as a first seizure.

### Seizure-freedom after curative epilepsy surgery

A 6-month seizure-free period was accepted. This seems a safe period for all subgroups described in a recent review (Spencer 1996).

# Seizures after decrease or change of antiepileptic medication

It was not deemed necessary to prohibit driving when the medication is stopped. Data from the MRC study (Medical Research Council 1991) suggest a 32% COSY on stopping treatment after a seizure-free period of at least 2 years. Berg & Shinnar (Berg & Shinnar 1994) found 25% (C.I. 21-30%) COSY. An American guideline finds a total (!) relapse rate for adults of 39.4% (Practic Parameter 1996) and the MRC study 50% after 4 years : important numbers for counselling. Our advice would be to inform the patient about recur-

#### EPILEPSY AND DRIVING IN BELGIUM

Table (	5
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Proposed Belgian criteria for group 2

	Proposed criteria for group 2 (commercial)
Clinical situation	Advise : able to drive after
First seizure	
<ul> <li>Provoked seizure, because of a- recognisable and avoidable provoking factor</li> <li>First unprovoked epileptic seizure after the fifth birthday</li> </ul>	<ul> <li>2 years of seizure- freedom + general conditions. An EEG should be performed after the acute episode. Excluded are so-called early post-traumatic seizures and early post-cerebritis seizures</li> <li>5 years of seizure- freedom plus general conditions</li> </ul>
Epilepsy	
<ul> <li>One or more seizures, but exclusively before the fifth birthday, and without having taken any anti-epileptic medication during the last five years before its application</li> <li>More than one seizure after the fifth</li> </ul>	Able to drive
birthday	To years of seizure- needoni + general conditions
General conditions :	<ul> <li>and this without anti-epileptic medication; if there has been a appropriate medical follow-up; if on extensive neurological investigation no cerebral pathology has been established; and if there are no epileptiform activities on the EEG during the awake state and a sleep EEG.</li> </ul>

rence risk. A 3 months driving ban on recurrence after medication change seemed reasonable.

### **Benign childhood epilepsy**

There are very few recurrences in Benign Childhood Epilepsy with Centro-Temporal Spikes (BECTS or Benign Rolandic Epilepsy) once the disease has remitted (MA & Chan 2003, Lerman 1992). We thought it would be difficult to make a reliable diagnosis for the non-epileptologist. For this reason, it was not mentioned in the criteria for group 2. It seemed unnecessary to include it as an exception for group 1, as is the case in the current medical criteria.

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### REFERENCES

- AAN, AES, EFA Consensus statements, sample statutory provisions and model regulations regarding driver licencing and epilepsy. *Epilepsia*, 1994, **35** : 696-705.
- ANNEGERS J. F., SHIRTS S. B., HAUSER W. A., KURLAND L. T. Risk of recurrence after an initial unprovoked seizure. *Epilepsia*, 1986, **27** (1): 43-50.
- Assuralia-internet site: "Opsplitsing slachtoffers in 2001 tussen bestuurders en passagiers". http://: www.assuralia.be/.

- AUSTROADS INCORPORATED 2003 : Australian medical criteria. In : "Assessing fitness to drive 3rd ed." ISBN 0 85588 507 6.
- BEAUSSART M. In : Epilepsy and Risk, a first-step evaluation. IBE 1994.
- BEGHI E., BERG A., HAUSER A. Treatment of single seizures. In : Engel J Jr et al : Epilepsy a comprehensive textbook Lippincott-Raven 1998.
- BERG A., SHINNAR S. The risk of seizure recurrence following a first unprovoked seizure : a quantitative review. *Neurology*, 1991, **41** : 965-972.
- BERG A. T., SHINNAR S. Relapse following discontinuation af antiepileptic drugs : A meta-analysis. *Neurology*, 1994, **44** : 601.
- BERG A. T., VICKREY BG, SPERLING MR *et al.* Driving in adults with refractory localisation-related epilepsy: multi-center study of epilepsy surgery. *Neurology* 2000, 54 : 625-630.
- BIVV INTERNET SITE : www.bivv.be/main/Publicatie Materiaal/Statistieken.shtml.
- BOON P., DE DEYN P. P., HAUMAN H., MOL L., SCHMEDDING E., VLIETINCK R., WILLAERT B.: Epidemiologie van epileptische toevallen in Vlaanderen. *Tijdschrift voor Geneeskunde*, 1996, **52**: 47.
- BOULLOCHE I. *et al.* Risk of recurrence after a single unprovoked generalized tonic-clonic seizure. *Dev. Med. Child Neurol.*, 1989, **31** : 626-632.
- CAMFIELD P. R. *et al.* Epilepsy after a first unprovoked seizure in childhood. *Neurology*, 1985, **35** : 1657-1660.
- CAMFIELD P. A. *et al.* A randomized study of carbamazepine versus no medication after a first unprovoked seizure in childhood. *Neurology*, 1989, **39** : 851-852.
- COMMISSION ON EPILEPSY, RISKS AND INSURANCE OF THE IBE Epilepsy and Risks. A first-step evaluation. 1994 : *IBE*, PO box 21, 2100 AA Heemstede The Netherlands.

- COUNCIL DIRECTIVE 91/439/EEC of 29 July 1991 on driving licences. *Official Journal* L 237, 24/08/1991 P. 0001 0024.
- D'ALESSANDRO R. D. et al. Pure sleep epilepsies : prognostic features. In : *Epilepsy, an update on research and therapy.* ALAN R. Liss Inc, New York, 1983, 235-239.
- DRAKOWSKI J. F., FISHER R. S., SIRVEN J. I. *et al.* Seizurerelated motor vehicle crashes in Arizona before and after reducing the driving restrictions from 12 to 3 months. *Mayo Clin Proc* 2003, **78** : 819-825
- EGLI M., HARTMANN H., HESS R. Driving licences in epileptic patients. *Schweiz Med Wochenschr* 1977, **10/12**: 389-397.
- ELWES R. *et al.* Prognosis after first tonic-clonic seizure. *Lancet*, 1985, **2** : 752-753.
- EUROPEAN INTERNET SITE http//: europa.eu.int/comm/ energy\_transport/figures/pocketbook 2003\_en. htm.
- FIRST SEIZURE TRIAL GROUP (FIR.S.T. GROUP) Randomized clinical trial on the efficacy of antiepileptic drugs in reducing the risk of relapse after a first unprovoked tonic-clonic seizure. *Neurology*, 1993, **43** : 478-483.
- FISHER R. S. *et al.* Epilepsy and Driving : An International Perspective. *Epilepsia*, 1994, **35** (3) : 675-684.
- FISHER R. S. *et al.* The impact of epilepsy from the patients perspective I Descriptions and subjective perceptions. *Epilepsy Res.*, 2000, **41** (1) : 39-51.
- GILLIAM F., KUZNIECKY R., BLACK L., CARPENTER G., SCHRODT R. Patient-validated content of epilepsyspecific quality-of-life measurement. *Epilepsia*. 1997, **38** : 233-236.
- GOODRIDGE G. M., SHORVON S. D. Epileptic seizures in a population of 6000. *Br. Med. J.*, 1983, **287** : 645-647.
- HALTINER A. M., TEMKIN N. R., DIKMEN S. S. Risk of seizure recurrence after the first late posttraumatic seizure. *Arch. Phys. Med. Rehabil.*, 1997, **78** (8) : 835-40.
- HART Y. M., SANDER J. W., JOHNSON A. L., SHORVON S. D. National General Practice Study of Epilepsy : recurrence after a first seizure. *Lancet*, 1990, **336** : 1271-74.
- HAUSER W. A., Anderson V. E., Loewenson R. B., McRoberts S. M. Seizure recurrence after a first unprovoked seizure. N. Eng. J. Med., 1982, 307 (9): 522-8.
- HAUSER W. A. *et al.* Seizure recurrence after a first unprovoked seizure : an extended follow-up. *Neurology*, 1990, **40** : 1163-1170.
- HAUSER W. A. et al. Seizures after head trauma. Neurology, 1990, **30**: 683-689.
- HAUSER W. A., ANNEGERS J. F., ROCCA W. A. Descriptive epidemiology of epilepsy : contributions of population-based studies from Rochester, Minnesota. *Mayo Clin. Proc.*, 1996, **71** : 576-586.
- HAUSER W. A. *et al.* Risk of recurrence after two unprovoked seizures. *N Eng J Med* 1998, **338** : 429-432
- HawLey C. A. Return to driving after head injury. J. Neurol. Neurosurg. Psychiatry, 2001, **70** (6): 761-6.
- HIRTZ D. *et al.* The risk of recurrence of non-febrile seizures in children. *Neurology*, 1984, **34**: 637-41.

- HOPKINS A. *et al.* The first seizure in adult life : value of clinical features, electroencephalography and computerized tomography scanning in prediction of seizure recurrence. *Lancet*, 1988, **1** : 721-726.
- HUI A. C., *et al.* Recurrence After a First Untreated Seizure in the Hong Kong Chinese Population. *Epilepsia*, 2001, **42** (1) : 94-97.
- JANZ D. Die Epilepsien G Thieme Verlag, 1969.
- JENNETT B. Epilepsy after non-missile head injury. 2nd ed. Heinemann Medical Books Limited, London 1975.
- JENNETT B. *et al.* Head injuries in three Scottish neurosurgical units : Scottish head injury management study. *Br. Med. J.*, 1979, **2** (6196) : 955-958.
- KRAUSS G. I., KRUMHOLZ A., CARTER R. C., LI G., KAPLAN P. Risk factors for seizure-related motor vehicle crashes in patients with epilepsy. *Neurolo*gy. 1999, **52** : 1324-1329.
- KRAUSS G. K., AMPAW L., KRUMHOLZ A. Individual state driving restrictions for people with epilepsy in the US. *Neurology*, 2001, 57 : 1780-1785.
- KRAUSS G. K. Driving restriction and people with epilepsy : Reply from the authors. *Neurology*, 2002, 58 (12) : 1865.
- KRUMHOLZ A., FISHER R. S., LESSER R. P., HAUSER W. A. Driving and epilepsy : a review and reappraisal. *JAMA*, 1991, **265** : 622-626.
- KRUMHOLZ A. Driving and Epilepsy: A Historical Perspective and Review of Current Regulations. *Epilepsia*, 1994, **35** (3): 668-674
- LERMAN P. Benign partial epilepsy with centro-temporal spikes. In : Roger et al Epileptic syndromes in infancy, childhood and adolescence 2nd ed, John Libbey & Co, 1992, 189-200.
- LINGS S. Increased driving accident frequency in Danish patients with epilepsy. *Neurology*, 2001, **57** : 435-439
- MA C., CHAN K. Benign childhood epilepsy with centrotemporal spikes : a study of 50 Chinese children. *Brain & Development*, **25** (2003) 390-395.
- MEDICAL RESEARCH COUNCIL ANTIEPILEPTIC DRUG WITH-DRAWAL STUDY GROUP. Randomised study of antiepileptic drug withdrawal in patients in remission. *Lancet*, 1991, **337** : 1175-80.
- PARK Clinical courses of pure sleep epilepsy. *Seizure*, 1998, **7** (5) : 369.
- PARSONAGE M. Epilepsy and driving licence regulations. Report by the ILAE / IBE commission on drivers' licensing *IBE*/ *ILAE* 1992 PO Box 21, 210 AA Heemstede, The Netherlands.
- REPORT OF THE QUALITY STANDARDS SUBCOMMITTE OF THE AMERICAN ACADEMY OF NEUROLOGY. Practice Parameter : A guideline for discontinuing antiepileptic drugs in seizure-free patients - Summary Statement. *Neurology*, 1996, **47** : 600-602.
- SANDER J. W., HART Y. M., JOHNSON A. L., SHORVON S. D. National General Practice Study of Epilepsy: newly diagnosed epileptic seizures in a general population. *Lancet*, 1990, **336**: 1267-71.
- SASIC et al. Epilepsia, 2002, 43 (S8), 111.
- SCHMEDDING E. Personal inquiry in a group of 70 Belgian neurologists. Chantilly, 1996.
- SHINNAR S., BERG A. T. *et al.* The risk of recurrence after a first unprovoked afebrile seizure in childhood : an extended follow-up. *Pediatrics*, 1996, **98** : 216-225.

- SHINNAR S., BERG A. T. *et al.* Predictors of Multiple Seizures in a Cohort of Children Prospectively Followed from the Time of Their First Unprovoked Seizure. *Ann Neurol*, 2000, **48** : 140-147.
- SONNEN A. E., THE EUROPEAN WORKING GROUP : Epilepsy and Driving Proceedings First European Workshop epilepsy and Driving Licences Group 1. *IBE*, May 1995.
- SONNEN A. E. Epilepsy and driving : A European View. Driving Commission, IBE, 1997 : 11-32.
- SPENCER S. S. Long-term outcome after epilepsy surgery. *Epilepsia*, 1996, **37** (9) : 807-813.
- STROINK H., BROUWER O. F., ARTS W. F., GEERTS A. T., PETERS A. C., VAN DONSELAAR C. A. The first unprovoked, untreated seizure in childhood : a hospital based study of the accuracy of the diagnosis, rate of recurrence, and long term outcome after recurrence. Dutch study of epilepsy in childhood. J. Neurol. Neurosurg. Psychiatry, 1998, 64 : 595-600.
- TAYLOR J. F. Medical aspects of Fitness to Drive. The Medical Commission on Accident Prevention 1995 35-43 Lincoln Inn Fields London WC2A 3PN.

- TAYLOR J. F., CHADWICK D., JOHNSON "Risk of accidents in drivers with epilepsy". J. Neurol. Neurosurg. Psychiatry, 1996, **60** : 621-27.
- TAYLOR D. C., MCMACKIN D., STAUNTON H. *et al.* Patients' aim for epilepsy surgery : desires beyond seizure freedom. *Epilepsia* 2001, **42** (5) 629.
- THE TOXICOLOGICAL SOCIETY OF BELGIUM AND LUXEMBURG. Invloed van geneesmiddelen op de rijvaardigheid. Ed : BIVV, Haachtsesteenweg 1405, 1130 Brussels. Tel. 02/244.15.11.
- VAN DONSELAAR C. *et al.* Idiopathic first seizure in adult life : who should be treated ? *BMJ*, 1991, **302** : 620-623.
- VAN DONSELAAR C., SCHIMSHEIMER R. J., GEERTS A., DECLERCK A. Value of the Electroencephalogram in Adult Patients With Untreated Idiopathic First Seizures. Arch. Neurol., 1992, 49: 231-237.

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